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Agriculture**

Animal and Plant  
Health Inspection  
Service

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# **Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program**

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## **Introduction**

Title 9, *Code of Federal Regulations* (9 CFR), part 71, contains general provisions for the interstate transportation of animals, poultry, and animal products, while part 80 pertains specifically to the interstate movement of domestic animals that are positive to an official test for Johne's disease (JD).

These regulations provide that cattle, sheep, goats, and other domestic animals that are positive to an official test for JD may generally be moved interstate only to a recognized slaughtering establishment or to an approved livestock facility for sale to such an establishment. The animals must bear an official eartag and be shipped with an owner-shipper statement.

Supplementing the regulations is the Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program (VBJDCP) that outlines the national standards of the program and provides specific information on administration of the program, program elements and procedures, and laboratory procedures. This document describes the cooperative VBJDCP to be administered by the State and supported by industry and the Federal Government. This publication is intended as a working document that will change as the program develops.

The objective of this program is to provide national standards for the control of JD. The program consists of three basic elements: 1) education to inform producers about the cost of JD and to provide information about management strategies to prevent, control, and eliminate the disease; 2) management to work with producers to establish good management strategies on their farms; and 3) herd testing and classification to demonstrate the level of risk of JD on the farm.

The program has been developed in cooperation with the National Johne's Disease Working Group and the Johne's disease committee of the United States Animal Health Association, State Veterinarians, and industry representatives. The program has been approved by the USDA's Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS).

The national standards described in this document do not preclude the adoption of more stringent methods and rules by any geographical or political subdivision of the United States with regard to activities within its boundaries; however, regulations dealing with interstate movement must conform to Federal regulations.

## **I. Definitions and Abbreviations**

### *Accredited veterinarian*

A veterinarian approved by the APHIS Administrator in accordance with the provisions of 9 CFR, part 161, to perform functions required by State-Federal-Industry cooperative programs.

### *Administrator*

The Administrator of APHIS or any person authorized to act for the Administrator.

### *Animal and Plant Health Inspection Service (APHIS)*

The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

### *Animal health official*

An employee of the State animal health department or of APHIS who has authority from the State Veterinarian or the Area Veterinarian in Charge to carry out program activities.

### *Anniversary date*

The date on which the designated Johne's disease coordinator gave final approval for initial program participation for a herd.

### *Approved laboratory*

A private, State, Federal, or university laboratory that has passed the annual check test for JD administered by the National Veterinary Services Laboratories (NVSL). The Administrator approves a laboratory to conduct an official or screening JD test only after determining that the laboratory meets the check test proficiency requirements prescribed by NVSL. Approval continues as long as such check test proficiency requirements are met annually. All program testing must be done in a laboratory approved by NVSL for the specific test being used in a State's testing program.

### *Area Veterinarian in Charge (AVIC)*

An APHIS veterinarian authorized by the Administrator to supervise and manage the animal health work of APHIS in a specified area of the United States.

### *Authorized agent*

A qualified individual authorized by the State animal health official to perform sample collections for the VBJDCP. This person shall have completed training specified by the *designated JD coordinator* for JD epidemiology. The State animal health official will also specify the types of samples that may be collected by the authorized agent.

### *CFR*

*Code of Federal Regulations*

### *Check test*

A panel of samples developed and released annually by NVSL to determine if participating laboratories are proficient at detecting positive samples (antibody or organism detection) within an expected range of accuracy.

### *Classification*

Categorization of a herd based upon the results and years of Johne's disease testing performed on eligible animals within the herd.

### *Clinical disease in cattle*

Generally characterized by one or more of the following clinical signs: severe weight loss, profuse diarrhea, edema, or a significant drop in milk production.

### *Commingling*

Animals grouped together having direct contact with the same facilities, equipment, individuals, or environment under circumstances where unprotected contact may spread disease. For example, all cattle in the same pen, corral, or vehicle or all cattle grazed together on the same area of a property or farm will be considered commingled.

### *Designated JD coordinator (DJC)*

An individual who has demonstrated the knowledge and ability to perform the functions required under these program standards and who has been selected for this position by the State animal health official and the AVIC. The VS regional JD epidemiologist and the VS JD headquarters' staff must concur in the selection and appointment of the DJC.

### *ELISA*

Enzyme-linked immunosorbent assay.

### *Exposure*

Contact with known infected animals, contact with the manure or raw milk of infected or exposed animals of susceptible species, or contact with infected herds via contaminated water or feed sources including runoff from neighboring premises.

### *Herd*

A group of animals managed as a separate and discrete unit. This may include two or more geographically separated groups of animals under common ownership or supervision but have an interchange or movement of animals without regard to health status. The DJC will make the final determination of the herd status of a group of animals.

### *Herd Classification Test*

The testing of a statistically appropriate group or subset of test-eligible animals from a herd. Depending on the herd size this may include all test-eligible animals.

(See Appendix 1: Sampling Sizes and Random Selection for Statistical Subset Testing.)

*Herd management plan*

See *management plan* below.

*Herd member*

An animal of any susceptible species that is commingled with the herd.

*Infected animal*

An animal that has been found by an official JD test to be infected with *Mycobacterium avium* subsp. *Paratuberculosis*.

*Infected herd*

A herd that has one or more individual animals, pooled fecal samples or environmental samples found positive on an official JD test.

*Johne's disease (JD)*

An infectious, communicable, and incurable disease, also known as paratuberculosis, that primarily affects cattle, sheep, goats, and other domestic, exotic, and wild ruminants and is caused by *Mycobacterium avium* subsp. *paratuberculosis* (MAP).

*Johne's disease Certified Veterinarian (JCV)*

An accredited veterinarian who has completed training approved by the DJC for JD epidemiology and development of herd management plans.

*Johne's disease test*

Diagnostic test used to aid in determining if an animal has been exposed to or is infected with *Mycobacterium avium* subspecies *paratuberculosis*. Test terminology used by the VBJDCP:

- Environmental fecal sampling  
A manure sample that is collected from areas where fecal material from which a large proportion of the herd is commingled. The sample is tested using a MAP detection test.
- Official Johne's disease test (OJT)  
An individual organism detection test approved by the Administrator and conducted in a laboratory approved by the Administrator. A list of currently approved laboratories and the requirements for obtaining approval are available from the Diagnostic Bacteriology Laboratory, NVSL, P.O. Box 844, Ames, IA 50010. A laboratory will be approved only after demonstrating that it meets the check test proficiency requirements prescribed by the NVSL on an annual basis.

- **MAP detection test (MAPDT)**  
An organism detection test approved by the Administrator and specific for MAP. This includes either screening (multiple animals or environmental) or official (individual) tests conducted in a laboratory approved by the Administrator. A list of currently approved laboratories and the requirements for obtaining approval are available from the Diagnostic Bacteriology Laboratory, NVSL, P.O. Box 844, Ames, IA 50010. A laboratory will be approved only after demonstrating that it meets the check test proficiency requirements prescribed by the NVSL on an annual basis.
- **Screening test**  
A test approved by the Administrator for use in the VBJDCP and conducted in an approved laboratory to diagnose MAP to aid in determining the presence or absence of MAP within a herd. A screening test cannot be used to classify an individual animal for the purposes of the program. An animal found positive by a screening test should be considered a JD suspect and may be further tested using an official JD test. However, if the animal is showing clinical signs of JD or is from a herd previously diagnosed with MAP, it should be considered positive based on a screening test.

*Level achievement year*

The year a herd obtained its current classification in the herd testing and classification element of the program.

*Management herd*

A herd that is enrolled in the program and meets the management component requirements described in this document.

*Management plan*

A written plan produced by the JD certified veterinarian or animal health official in conjunction with the producer that includes animal husbandry and hygiene practices specific to that herd and is designed to limit opportunities for exposure to MAP. The plan is developed following the completion of a risk assessment for the operation.

*Mycobacterium avium subsp. paratuberculosis*

The causative agent of Johne's disease, sometimes referred to as MAP or *Mycobacterium paratuberculosis*.

*NCAHP*

National Center for Animal Health Programs.

*National Johne's Disease Coordinator*

The lead staff veterinarian responsible for the coordination of the National Johne's Disease Control Program for Veterinary Services, National Center for Animal Health Programs.



### *National Veterinary Services Laboratories*

The APHIS laboratory that supports the Johne's program is the Diagnostic Bacteriology Laboratory, USDA, APHIS, VS, NVSL 1800 Dayton Road, P.O. Box 844, Ames, IA 50010. The Internet site for this laboratory can be found at [http://www.aphis.usda.gov/animal\\_health/lab\\_info\\_services/about\\_dbl.shtml](http://www.aphis.usda.gov/animal_health/lab_info_services/about_dbl.shtml).

### *Official eartag*

An eartag that provides a unique, nontransferable identification for an individual animal. An official eartag must bear the U.S. shield. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users. The tag must be tamper-resistant and must have been shown to have a high retention rate in the animal. These tags must adhere to one of the following numbering systems:

1. National Uniform Eartagging System.
2. Animal identification number (AIN).
3. Premises-based number system. The premises-based number system combines an official premises identification number (PIN), as defined in this section, with a producer's livestock production numbering system to provide a unique identification number. The PIN and the production number must both appear on the official tag.
4. Any other numbering system approved by the Administrator for the identification of animals in commerce.

### *Premises identification number (PIN)*

A unique number assigned by a State or Federal animal health authority to a premises that is, in the judgment of the State or Federal animal health authority, a geographically distinct location from other livestock production units. The PIN is associated with an address or legal land description and may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. The PIN may consist of:

1. The State's two-letter postal abbreviation followed by the premises' assigned number.
2. A seven-character alphanumeric code, with the right-most character being a check digit. The check digit number is based upon the ISO 7064 Mod 36/37 check digit algorithm.

### *Program*

Voluntary Bovine Johne's Disease Control Program (VBJDCP).

### *RAMP*

The combination of the risk assessment (RA) and the development of a herd management plan (MP). This can be accomplished during separate visits or in a single visit of the Johne's disease certified veterinarian or animal health official.

*Risk assessment*

An evaluation of the facilities and management practices performed by a JCV or animal health official in conjunction with the producer that includes an evaluation of the animal husbandry and hygiene practices specific to that herd that may provide opportunities for exposure to MAP. The risk assessment is performed prior to developing a herd management plan and periodically afterward to assess the current risk status of the herd.

*State*

Any of the 50 States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the District of Columbia, and any Territories and possessions of the United States.

*State animal health official*

The State official responsible for livestock and poultry disease control and eradication programs.

*State JD Group*

A group of individuals organized by the State animal health official to assist in the oversight and coordination of the State's Johne's disease program.

*Susceptible species*

Domestic and exotic ruminants, such as cattle, bison, sheep, goats, cervids, and camelids that are capable of being infected through natural exposure with MAP.

*Test-eligible animals*

Female bovine animals 36 months of age or greater and male bovine animals 24 months of age or greater.

*USDA*

United States Department of Agriculture.

*VBIDCP*

Voluntary Bovine Johne's Disease Control Program.

*Veterinary Services (VS)*

The division of APHIS in charge of Federal animal health activities within the United States.

## II. Administration of the Program

### A. Designated Johne's Disease Coordinator

#### 1. General

Each State must designate at least one individual to act as its DJC. This person should be selected jointly by the State animal health official and the AVIC, and approved by the VS regional JD epidemiologist or Regional Director and the National Johne's Disease Coordinator of VS' NCAHP.

#### 2. Qualifications

Each DJC candidate must:

- a. Be a State, Federal, or university-employed veterinarian
- b. Successfully complete a JD education course approved by the National Johne's Disease Coordinator. Course instructions include on-farm Risk RAMP training
- c. Have at least 80 hours experience in assessing risk, developing herd plans, and classifying JD tested animals and herds
- d. Attend continuing education provided by APHIS when necessary

After being selected and approved, a DJC may be given a 1-year grace period to allow the candidate to meet the education and training requirements

#### 3. Responsibilities

The DJC has the responsibility to:

- a. Interpret laboratory test results and classify animals and herds based on the use of official and screening tests
- b. Provide training for personnel performing program work
- c. Provide training for JCV and develop a mechanism to evaluate and monitor the involvement of the JCV
- d. Review and approve the RAMPs for participating/program herds
- e. Periodically audit the program, and herds within the program, to determine if it is adequately achieving its goals and objectives

- f. Assist JCV, animal health officials, and herd owners with the development of herd management plans as requested or needed
- g. Participate in the program activities as a member of the State JD group
- h. Provide required reports to the Area Office, VS regional JD epidemiologist, and the JD staff of VS' NCAHP on the progress of the program

## B. State JD Group

### 1. General

The State JD group will assist the State in program development, implementation, and review. The group must meet at least once a year.

### 2. Recommended members

This group should include pertinent stakeholders, such as:

- a. Dairy producers—purebred, commercial, and/or commodity groups
- b. Beef producers—purebred, commercial, and/or commodity groups
- c. University and extension faculty
- d. Animal health diagnostic laboratory personnel
- e. Regulatory veterinary medical officers (State or Federal)
- f. Veterinary practitioners—beef and dairy

It is recommended that a beef or dairy producer serve as the chairperson for the group. The DJC must be a member.

## C. Johne's Disease Certified Veterinarians

### 1. General

States may elect to use the services of private practitioners in addition to State or Federal personnel to assist herd owners in conducting RAMPs. States using these veterinarians must determine that they meet the qualifications listed below. The DJC needs to develop a process to closely monitor the herd management plans developed by new JCVs. For example, the DJC may require the new JCV to develop the first one-to-five herd management plans in conjunction with an experienced animal health official.

## 2. Qualifications

JCVs must be accredited veterinarians, must have received additional education on JD, and must be able to demonstrate to the DJC that they have the knowledge needed to:

- a. Perform appropriate JD risk assessments
- b. Develop approved herd management plans
- c. Understand JD epidemiology, testing, and test interpretation
- d. Understand State and Federal program requirements
- e. Collect and submit appropriate samples for JD testing

## 3. Training

In order to maintain consistent competency levels of JCVs between States, a curriculum has been outlined in Appendix 3: Johne's Disease Certified Veterinarian Training Guidelines. At least once every 5 years, JCVs must complete a JD refresher course approved by the DJC and outlined in Appendix 3.

## 4. Responsibilities

JCVs have the responsibility to:

- a. Develop RAMPs at the request of herd owners that will meet the approval of the DJC
- b. Collect and submit samples according to the requirements set by the DJC

## D. Premises Biosecurity

Individuals working on the VBJDCP must use sanitary procedures to minimize the risk of transmitting infectious diseases to other premises.

## E. Exceptions to Deadlines

Animal health officials must follow deadlines for the herd management plan and testing except when a DJC determines that there are extenuating circumstances. The extenuating circumstances must make it impossible to meet the deadline established for a particular herd. The animal health official will set a new deadline in consultation with the herd owner, or his or her representative, to accomplish the required activities at the earliest opportunity.

The new deadline must be consistent with the principles of JD control and eradication.

F. Administrative Review of a State's VBJDCP Activities and Progress

An administrative review of a State's VBJDCP may involve any or all of the following:

1. VS personnel will conduct ongoing reviews at local and national levels by receiving and examining routine monthly, quarterly, annual, and other statistical and narrative reports that have been prepared and submitted by the State or Federal animal health officials in each of the States.
2. The National Johne's Disease Coordinator will monitor the results of existing State policies and procedures for controlling and eradicating JD by examining factors such as the test/activity and herd management plans.
3. The National Johne's Disease Coordinator will evaluate the information provided by the various States in special reports regarding the authorities and policies for implementing the various minimum standards of the State's VBJDCP.
4. Regional Directors, a regional epidemiologist, and VS staff personnel will visit various States to observe program procedures and to make general or specific evaluations.
5. Special evaluation teams comprised of several individuals representing State, Federal, industry, and academic interests will make visits to designated States to make limited or comprehensive reviews of the State's VBJDCP.

### III. Program Elements and Procedures

#### A. Education

##### 1. General

The education element in a State serves as the entry level for producers to participate in the State's voluntary JD control program. This element should provide producers with basic JD information, effective management strategies for controlling and eliminating the disease, and information on the various aspects of the State's program. Education can take place through group workshops, one-on-one sessions, or through online training. A record of participation should be kept. In the education element of the program, producers should receive information on the topics indicated below.

##### 2. Required topics for education

- a. Basic JD information: cause, clinical stages, transmission, etc.
- b. Management strategies for:
  - 1) Manure and waste
  - 2) Colostrum and milk
  - 3) Calves and young stock
  - 4) Additions and high-risk animals
  - 5) Biosecurity
  - 6) Infected animals
- c. Control and testing strategies, including:
  - 1) Testing options
  - 2) Test interpretation
  - 3) Using test results
- d. State program components
  - 1) Options for program participation

## B. Management Level

### 1. General

Producers informed about JD may wish to participate in the management level of the program, which recognizes producers for implementing meaningful management practices to control the introduction or spread of MAP. At this level, any individual animal or herd testing is optional but strongly encouraged. JD testing should be based on a plan with clear action determined prior to testing. JD testing protocols can be developed using the guidelines provided in the “Consensus recommendations on diagnostic testing for the detection of paratuberculosis in cattle in the United States” published in the December 12, 2006, Journal of American Veterinary Medical Association. Reporting test results is not required; while not required, testing should be done in an approved laboratory to ensure the validity of the test results.

### 2. Requirements

The following components must be completed to the satisfaction of the DJC:

#### a. Risk assessment

Before developing a herd management plan, a JCV must conduct a risk assessment to identify management practices and facility issues likely to introduce and spread MAP throughout the herd. A copy of the risk assessment must be submitted to the DJC for review.

#### b. Herd management plan

The JCV, in conjunction with the herd owner, will develop a herd management plan to minimize the introduction and spread of MAP in the herd. A copy of the management plan must be submitted to the DJC for review and approval.

Guidelines for developing a herd management plan are reviewed in the “Handbook for Veterinarians and Dairy Producers” third edition, 2003; the “Handbook for Veterinarians and Beef Producers” third edition, 2003; and the “How to Do Risk Assessments and Management Plans for Johne’s Disease” 2003. Copies of these documents are available through the Ruminant Health Programs, NCAHP, VS. The herd management plan should review applicable topics outlined below under “3. Johne’s Disease Best Management Practices” that prevent the calves and young stock from becoming infected with MAP.

### 3. Johne’s Disease Best Management Practices - General



- a. Animal identification—All cattle should be individually identified using an identification method approved by the State animal health official. It is recommended that all animals in participating herds be individually identified using official eartags. Any regulations issued in 9 CFR regarding animal identification with other animal health programs still apply.
- b. Minimum biosecurity measures—These measures are recommended to reduce exposure to manure or milk from cattle of unknown JD status. The herd management plan should emphasize the following biosecurity measures:
  - 1) Keep maternity and calving areas clean, dry, and free of manure. Wherever possible, use individual calving pens, or minimize cow density. The maternity and calving area should not house non-calving or sick animals, nor should it be immediately adjacent to mature animal housing areas.
  - 2) Ensure animals added to the herd come only from status-level or documented low-risk sources. Record the source and manage additions as higher risk animals unless you have evidence to the contrary.
  - 3) Minimize the exposure of young stock to manure from adult animals.
  - 4) Minimize exposure of livestock to other cattle and other susceptible animal species that may be infectious.
  - 5) Feed calves colostrum from an individual, identified, low-risk, test-negative cow, or a suitable quality colostrum replacer.
  - 6) Minimize contamination of feed, water, equipment, and vehicles with manure.
  - 7) Segregate, test, and remove clinical suspects from the herd as soon as possible. Make recommendations to reduce the risks from official test-positive cattle by humanely euthanizing the animals or sending them to slaughter.
- c. Best management practices—Dairy herd specific:
  - 1) Immediately separate from adult animals any heifer calves and bull calves that will be retained in the herd or sold for dairy purposes.
  - 2) After receiving colostrum, only give calves pasteurized milk or a quality milk replacer.
  - 3) Keep young stock free from exposure to the manure of mature cattle, house by age, and separate from older animals.
- d. Best management practices—Beef herd specific:
  - 1) Minimize the density of cow and calf pairs as much as possible.

- 2) Use feeding practices that reduce manure contamination of water, feed, and feeding areas as much as possible.
- 3) Raise weaned replacement animals physically separate from older animals.

#### 4. Renewal

To continue in the program, a herd owner and JCV must review and update the RAMP at least every 3 years after enrollment and make appropriate changes to the herd management plan. The updated RAMP must be submitted to the DJC between 60 days before and 60 days after the anniversary date.

### C. Herd Testing and Classification

#### 1. General

Herd testing and classification constitutes the third level of participation in the program. The purpose of this component is to identify herds with a low prevalence of JD.

#### 2. Requirements for entry

Herd owners enrolling in the herd testing and classification level must have a current approved RAMP in place, following the guidelines outlined in the management element (III.B.2).

#### 3. Testing

Initial testing is required to determine the herd's test status, using an appropriate testing strategy as listed in Appendix 2 under Level 1. Statistical subsets or greater numbers of cattle must be tested to establish a herd classification (see Appendix 1).

All samples must be collected by, or under the supervision of, an accredited veterinarian, an animal health official, or authorized agent. All samples from herds whose owners are applying for herd classification must be submitted to an approved laboratory.

- a. Animals positive to a screening test should be classified as a suspect for MAP infection. It is recommended that the status of suspects is confirmed using an official JD test unless MAP has already been confirmed on the premises. Any animal classified as a suspect or infected should be officially identified.
- b. It is recommended that animals with positive results on an official JD test be identified as infected and restricted to the premises. When

infected cattle leave the herd, it is recommended that they be humanely euthanized or go directly to slaughter.

Animals crossing State lines must do so in accordance with 9 CFR, part 80, which requires an owner-shipper statement (a signed statement made by the owner or shipper) that declares the animal as infected; provides the official eartag number(s), origin, destination, consignor and consignee; and directs that the animal go directly to slaughter.

- c. The process for appealing the status of an official JD test-positive animal is described in Appendix 4.

#### 4. Herd classification

- a. Animal identification—All cattle must be individually identified using an official identification method approved by the State animal health official. Any regulations issued in 9 CFR regarding animal identification with other animal health programs still apply.
- b. Appealing a positive test—A test-positive animal's status may be appealed using the appeal process described in Appendix 4. If an animal is removed from the herd while screening test results are pending, a fecal sample should be collected, submitted, and held at the laboratory. The DJC will make the final classification of the animal and herd.
- c. Herds enrolled in this component must use testing protocols approved by the DJC. Herd additions—At initial levels of the program, all purchased animals should be from herds with approved herd management plans. Heifers raised off the premises should be raised with at least the minimum biosecurity and control measures in place. At higher levels of the program, purchasing restrictions apply (see section III.C.5.c).

#### 5. Classification Testing

- a. The herd owners (with the JCV) should develop a testing protocol as follows:
  - 1) All animals specified in the testing protocol must be tested within 10 to 14 months of the anniversary date. Multiple test dates are allowed including split-herd testing or rolling-herd testing provided that all animals are tested within the specific timeframe.
  - 2) Herds not adhering to the prescribed testing requirements will be placed in the management element.
- b. Testing

- 1) The classification system consists of levels 1 to 6 and is described in Appendix 2. Classification levels 1 to 3 identify herds with low test positive prevalence or an initial year of test negative results, and levels 4 to 6 identify herds with 2 or more years of test negative results. Levels 1 to 4 require annual testing.
- 2) Vaccinated herds will be eligible for levels 4 to 6 after vaccination has been discontinued. Testing of vaccinated animals must be done using an official JD test; however, non-vaccinated herd mates may be tested using ELISA testing or a combination thereof.
- 3) Herd removal provisions—If an animal in a classified herd tests positive to an official JD test in levels 4 to 6, or if the testing requirements are not followed, the herd must be downgraded to the appropriate classification level or removed from the classification element as determined by the DJC.

c. Herd additions

- 1) Purchased animals may be added to the herd, provided that:

- (a) For levels 1 to 3:

There are no purchasing restrictions at these levels of the program. However, it is strongly recommended that animals are purchased from sources with a classification level (or testing equivalent) that meets or exceeds that of the herd it is entering.

- (b) For levels 4 to 6:

- i. If purchasing animals from unclassified or levels 1 to 3 herds, the herd will be demoted to level 3 (highest level of program without animal movement restrictions).
- ii. If purchasing animals from levels 4 to 6 herds:
  1. If the purchase is from the same or higher level than the herd's classification, the herd retains its classification and no additional testing is required.
  2. If the purchase is from a lower level than the herd's current classification, then:
    - a. The herd will be dropped to the lowest level of the purchased animals.

OR

- b. The herd may maintain its current classification if all purchased animals from the lower status herd are tested three times with an OJT at 6-month intervals, starting at not less than 12 months of age, and all tests are found to be negative. Purchased animals must then be included in the next herd classification test.
  - (c) Once all herd additions have been granted status equal to the herd's current classification, the herd may advance in the classification program by following the testing protocol.
  - (d) Heifers raised off the premises must be raised with the proper biosecurity measures in place and with animals at an equal or greater classification level.
  - (e) Classified herds may use embryos from other cattle herds if the embryos are processed according to International Embryo Transfer Society protocols. Embryo transfer recipient cows must meet herd addition requirements.
  - (f) Purchasing a classified herd
    - (i) If a classified herd is purchased, testing is not required if the purchased cattle remain on the premises. A new certificate will be issued in the new owner's name. The anniversary date will remain the same.
    - (ii) If part or all of a classified herd is purchased and the cattle move directly to a premises without cattle, they may retain their current classification level without testing; however, it is recommended that the risk of exposure to MAP from the environment is evaluated. A new certificate should be issued in the new owner's name. The anniversary date of the new herd is established by the original classification date, unless a new herd classification test of the purchased cattle is requested.
- d. Herd level maintenance
- 1) Herds at levels 1 to 3 must undergo a herd classification test annually to establish their classification level for the year.

2) Herds at levels 4 to 6 can maintain their classification by following any MAPDT strategy in Table 2 of Appendix 2. Testing for maintenance of herd classification must be repeated annually in level 4 herds; however, levels 5 and 6 herds are only required to test every 2 years from the classification date to maintain their herd classification. The level achievement year should be noted because continued monitoring increases confidence the herd is not infected. If a positive test is found during maintenance level testing in a level 4 to 6 herd, the herd will be reclassified to level 1 of the program. Alternatively, the herd can elect to complete additional testing to attain a higher classification following the requirements for herd classification in Appendix 2.

e. Renewal and advancement

A herd will remain at any level for up to 14 months (up to 26 months for levels 5 and 6 herds). For continuation of this classification, the herd owner must reapply with a copy of test results. An updated herd management plan (biosecurity plan) and an agreement to follow the classification component requirements must be submitted every 3 years.

The herd owner can send the DJC a letter of intent to renew or advance if confirmation of screening test results will be received after the 14-month (or 26 month for levels 5 and 6 herds) deadline. If the letter of intent is received by 30 days after the deadline, the DJC may allow the herd to retain its status for up to 5 months. Herds for which the necessary test results have not been supplied by the extended 5-month deadline must be removed from the classification program. Herds removed from the classification program may retest and may be classified based on the results of testing used.

## IV. Laboratory Procedures

### A. Approved Laboratories

Official JD tests and screening tests used for the VBJDCP may be conducted in a private, university, State, or Federal laboratory. The State animal health official has the authority to decide if any laboratory passing the NVSL check test may participate in the State program. States should have the authority to periodically audit the JD diagnostic laboratories participating in the program. If a laboratory is outside of the State, the State may rely on audits conducted by the animal health officials from the State in which the laboratory is located.

### B. Laboratory Approval Process

Check test proficiency panels must be passed annually in order for laboratories to be approved to participate in the VBJDCP for each testing format they plan to use. The check test procedures for participating in the annual proficiency tests are outlined below for MAPDT and ELISA tests. For further information, please contact NVSL's Diagnostic Bacteriology Laboratory.

1. Approval process for laboratories performing organism detection tests
  - a. A laboratory seeking approval to perform MAPDT must contact NVSL for a proficiency test kit of 25 samples. A valid proficiency panel sample from NVSL will be determined by a consensus of at least 70 percent of the laboratories participating in the fecal culture check testing process.
  - b. Laboratories must request a proficiency panel for each procedure or a standard operating procedure (SOP) that they wish to use for approved testing. Criteria for panel composition and grading may be obtained from NVSL and is also referenced in NVSL's SOP-MB-4011: Proficiency Panels for External Laboratory Assessment for Johne's Disease Organism Based Tests.
  - c. Laboratories requesting a pooled proficiency panel must also successfully complete and pass the corresponding individual panel using the same method. For example, laboratories requesting a pooled Herrold's Egg Yolk (HEY) proficiency panel must also request and pass an individual proficiency test for HEY.
  - d. The laboratory must not identify any of the negative test samples as positive samples.
  - e. The laboratory must not identify any of the test samples classified as high levels of MAP (Too Numerous to Count or TNTC) as negative samples.

- f. The laboratory must correctly identify at least 70 percent of the test samples that were not classified as negative or TNTC as positive samples.
  - g. Laboratories performing culture may report a sample as “contaminated” and will be allowed sufficient time to reculture and report results without penalty. Contamination must be reported to NVSL first. Proficiency panel samples will contain at least 4 g of material to cover this possibility.
  - h. The laboratory must use the same procedure and materials during the check test that are used during routine testing. If laboratory protocols are changed after certification is granted for the current year, a recertification test must be successfully completed, and a copy of the new protocols must be provided to NVSL.
  - i. One retest per year is available if a laboratory fails the first time. Any laboratory that fails to pass the retake of the check test will become a nonapproved laboratory until the check test is administered again and passed the following year.
2. Approval process for laboratories performing ELISA tests
- a. A laboratory seeking approval to perform ELISA testing must contact NVSL for a test kit of 25 samples. (A valid check sample will be determined by NVSL using available licensed ELISA kits.)
  - b. Laboratories will report the ELISA score (sample to positive [S/P] ratio, ELISA score, and optical density values) of test samples and kit controls.
  - c. Samples will be divided into extreme and intermediate samples based on consensus median values from all participating laboratories.
  - d. Extreme samples (strong negative and strong positive) will be graded qualitatively.
  - e. Laboratories that incorrectly identify any extreme test samples (graded qualitatively) will fail the proficiency test.
    - 1) Intermediate samples will be graded quantitatively using Z scores. Z scores indicate how many standard deviations away from the mean the score resides. A positive Z score indicates that the value is above the mean while a negative Z score indicates that the value is below the mean.



- 2) Laboratories must score within three Z scores of the mean value to correctly identify a serology proficiency test sample.
- 3) Laboratories with more than two quantitative (Z scored) test results outside the acceptable range will not pass the proficiency test.
- 4) A Z score calculation will be used to determine variation of quantitative results. A major advantage of the Z score grading system is that it allows laboratory feedback on whether laboratories are consistently above or below the consensus median value. Calculating absolute values allows a visual representation of consistency, since a laboratory that is not consistently above or below the median will still have a large absolute value Z.
- 5) Laboratories with an absolute average Z score of greater than two will be notified that quality control practices should be evaluated. Specific actions could include requiring internal quality control review using NVSL's low positive sera, contacting the kit manufacturer, and evaluating other equipment and procedures.
- 6) The laboratory must use the same procedure and materials during the proficiency test that are used during routine testing.
- 7) One retest per year is available if a laboratory fails the first time. Any laboratory that fails to pass the retake of the check test will become a nonapproved laboratory until the check test is administered again and passed the following year.

### 3. Continuing quality assurance

Producers and veterinarians must have confidence in the quality of serology results they receive. To ensure the credibility of the infection status assigned as a result of testing under the guidelines of the national control program, each approved laboratory should run low positive quality control sera purchased from NVSL to monitor variations in testing results. NVSL will provide the current protocol for running and submitting the data from the quality controls.

### 4. Reporting

To monitor VBJDCP activity, testing conducted at approved laboratories must be reported to the State animal health official. Data from the laboratory must be reported monthly or as required by the State animal health official. Data should be reported and sorted by the State in which the herd resides. The minimum required data for national reporting includes:

- a. Number of herds tested by screening tests, sorted by method of detection and species
  - b. Number of screening test positive results, sorted by method of detection and species
  - c. Number of herds with test-positive results by screening tests, sorted by method detection and species
  - d. Number of official JD tests submitted and run, sorted by method of detection and species
  - e. Number of herds tested by official JD tests, sorted by method of detection and species
  - f. Number of official JD test results that are positive for MAP, sorted by method of detection and species
  - g. Number of herds with positive results by official JD test, sorted by method of detection and species
5. If the required data are not reported on a timely basis, the State animal health official may refuse to allow a laboratory to do State program testing. It is recommended that the State animal health official require that all JD test results be reported to the State.

#### C. Approved Program Tests

1. Official Johne's disease test (OJT)—An organism detection test done on an individual sample from a single animal approved by the Administrator and conducted in a laboratory approved by the Administrator.
  - a. Fecal and tissue culture—Culture is the standard for organism-based tests. Methods include both solid and liquid culture preparations. Protocols for recommended methods can be obtained from NVSL upon request. Fecal and tissue cultures are considered an MAPDT.
  - b. Direct fecal polymerase chain reaction (PCR)—Direct PCR tests can detect the presence of MAP without having to grow it. An advantage of the PCR test is that it takes less than 3 days to conduct. However, the disadvantages are higher cost and the potential of missing low shedders. Direct fecal PCR tests are considered an MAPDT.
  - c. Histology of tissue—A check test is not available at this time. Microscopic identification of the characteristic pathological changes and of MAP organisms in tissue is a definitive test for JD. Tissue changes and bacteria can be observed in the intestinal lining and in nearby ileal, mesenteric, and ileocecal lymph nodes in infected

animals. Sensitivity depends on the stage of disease, the number and type of specimens collected, and the experience and time spent examining tissues by the pathologist.

2. Screening test—Tests that do not meet the 9 CFR 80 definition of an official JD test but are used for herd classification. Screening tests are tools that have been developed to aid in determining the presence or absence of MAP within a herd. Depending on the method, screening tests may include individual animals or multiple animals in a diagnostic sample.
  - a. USDA approved ELISA—Animals found positive by ELISA tests should be considered suspect until confirmed using an OJT for low-level risk herds. ELISA tests are to be used as screening tools or to help make management decisions.
  - b. Environmental fecal sampling—Fecal material samples collected in areas where a large proportion of the herd is commingled. Samples are tested using organism detection methods in approved laboratories. The sampling protocol is available in Appendix 2.
  - c. Pooled fecal cultures or PCR—Fecal samples collected from individual animals that are pooled together in groups of five. Individual samples should be submitted to laboratories approved for fecal pooling and tested by an organism detection test. The pooling protocol is available in Appendix 2. Pooled fecal cultures or pooled fecal PCR tests are considered an MAPDT.

## Appendix 1: Sampling Sizes and Random Selection for Statistical Subset Testing

### Sample Sizes

**Table 1. Sampling sizes for statistical subset testing**

Number of cattle in herd (36 months or older)	Minimum Number of Cattle to Sample (36 months or older)	
	ELISA Testing	MAP Detection Test
≤ 300	Test all	Test all
301 – 400	Test all	Test all (up to 313)
401 – 500	Test all	324
501 – 600	Test all (up to 531)	332
601 – 700	540	338
701 – 800	547	342
801 – 900	552	345
> 901	580	360

In smaller herds, all cattle 36 months of age and older must be tested. In herds with fewer than 30 animals that are 36 months of age or older, animals 24 months of age or older must also be tested.

The sample numbers above are based on the following assumptions:

- The cattle to be tested are 36 months of age or older.
- ELISA tests are assumed to have 25 percent sensitivity, and fecal cultures are assumed to have 40 percent sensitivity. These were consensus estimates of the Herd Status Committee of the National Johne's Working Group of the United States Animal Health Association Committee on Johne's Disease in 1998 for cows 24 months of age or older with subclinical infections. No changes were made for older populations sampled.
- ELISA and fecal culture are assumed to have 100 percent test specificity (given followup of all ELISA positives with fecal culture).
- The calculations are based on sampling without replacement.

### Random Selection Procedures or Statistical Subsets

The authorized agent should randomly select and sample the appropriate number of eligible cows. This works in small herds or in herds where the animals can be easily caught. For a more scientific method, select animals using a random number generator or random number tables.

If the list is made in random order, a systematic sampling can be used on the list (i.e., selecting every  $n$ th individual from a list [or coming through a chute] after choosing a random number from 1 to  $n$  as a starting point). Determine  $n$  by dividing the number in the herd by the required sample size needed in the statistical subsets).

Large herds should use a stratified randomization approach to collect a more representative sample. The number of animals in each group should be determined (e.g., high producers, low producers, and dry cows) and the percentage of each type of animal computed. The percentage of samples collected from each group should equal the percentage of each group of animals in the herd (i.e., if 10 percent of the animals in the herd are low producers, then 10 percent of the samples should be collected from low producers). Sampling in each group would be done by simple or systematic sampling.

These will not be perfect randomized sample collections, but they are better than convenience sampling. Unless the producer is suspicious of infection in the herd, targeting 'high-risk' animals is not the method to use. Testing high-risk groups or target testing should be reserved for herds in the management or control programs. All testing for herd classification should be as close to random as possible.

## Appendix 2: Approved Testing Strategies for the Classification Component

The program levels are established to provide herds with a lower risk of transmitting MAP, a way to demonstrate years of participation and progress in the program. An alternate testing strategy may be approved for any level as long as it meets or exceeds the testing sensitivity for the given testing level as approved by the DJC.

The classification system was developed based on review of scientific literature, data analysis, and discussions by a team of experts in the fields of epidemiology, diagnostics, and cattle management systems.

### I. Concepts applied in development of JD Herd Test Strategies

- A. *Unknown status.* Untested herds or herds not desiring classification will not be given a JD classification level.
- B. *Eligible cattle.* Test-eligible cattle for testing will include all cattle 36 months of age and older and male bovine animals 24 months of age or older. Subset sampling will be based on Appendix 1, with a maximum of 580 cattle randomly sampled for ELISA and 360 for MAPDT. Herds will be categorized by herd size based on the number of eligible adult cattle 3 years of age or older.
- C. *Eligible tests.* All ELISAs that have passed the NVSL check test will be considered as equivalent for herd categorization. All official Johne's disease tests (OJT) (individual MAPDT) that have passed the NVSL check test will be considered as equivalent for herd categorization. The option is available for followup testing of ELISA positive cattle with an OJT. For pooled fecal testing using MAPDT, the required cattle sample will be collected individually and tested in groups of five cattle per pool by the laboratory. Herd classification categories are based on statistical probabilities (the upper 95 percent confidence limit for within-herd prevalence is below the specified values for classification levels 1 to 6) with minor adjustments made for practicality of on-farm sampling and internal consistency.
- D. *Herd classification based on test results.* Cattle herds in the initial year of testing will be placed in classification levels 1 to 3 with whole-herd test of test-eligible animals or subset testing for large herds as described in Appendix 1, Table 1, or in level 1 with a minimum sampling herd test (Appendix 2, Table 2). After the second year of testing with no positive test results, cattle herds can be upgraded into level 4; after the third year, into level 5; and after the fourth year, into level 6. Categorization of herds should be made using critical threshold levels (Appendix 2, Table 1) without rounding. Herds can be placed in levels 1 to 3 with positive test results after herd testing. Herds with positive test results are not allowed in levels 4 to 6. For herds using pooled MAPDT, the option exists to test individual cows from positive pools and calculate the percentage of MAPDT-positive cows to assign an appropriate classification level using the individual MAPDT line from Table 1 (Appendix 2). Any positive pool

that subsequently yields all negative individual MAPDT results will be considered as one positive individual MAPDT.

- E. *Adjustment to Classification Levels.* The designated Johnes' coordinator can make adjustments to the herd classification level based on available data and best judgment.

## II. Example Situations

- A. A dairy herd with 150 cows (n=100 cows 36 months of age or older) without previous status in the existing Test Negative Program could choose to test all eligible cattle (n=100) using ELISA (and could choose ELISA/MAPDT option if desired), individual MAPDT, or pooled MAPDT. If ELISA is chosen as a test option, one positive ELISA would result in classification level 2 ( $\leq 1.5$  percent in the 100-199 cattle category). If individual MAPDT is chosen, three positive OJT would result in classification level 2. The herd owner could choose to test a minimum number of randomly selected cattle (60 for ELISA or 30 for individual MAPDT) tested using ELISA or MAPDT, or use environment fecal MAPDT to achieve level 1, assuming no positive results are obtained.
- B. A beef herd with 80 cattle 36 months or older and already at level 2 of the current Test Negative Program desires to advance within the program. The herd will be placed at classification level 3 with a pooled MAPDT or could move to level 4 by testing all eligible cattle with individual MAPDT, if all tests are negative.
- C. If the herd size is between 1 and 99, individual MAPDT must be used to advance to level 4. The following year pooled MAPDT may be used to advance. In the case where the herd size is between 100 and 199, individual ELISA samples or individual MAPDT must be used to advance to level 4. The following year pooled MAPDT may be used to advance.

**Table 1. Herd Testing Strategies to Achieve JD Herd Classification Levels**

Herd Size <sup>■</sup>	Testing Strategy	Herd Classification level					
		1	2	3	4	5	6
		Maximum proportion positive to achieve level (no rounding)					
1 - 99	ELISA	≤1.5%	0%				
	ELISA/Ind MAPDT*		0%				
	Individual MAPDT	≤6%	≤2%	0%	0%	0%	0%
	Pooled MAPDT	≤15%	0%	0%		0%	0%
	Environment MAPDT <sup>▲</sup>	0%					
100 - 199	ELISA	≤2.5%	≤1.5%	≤0.5%	0%	0%	0%
	ELISA/Ind MAPDT	≤1.0%	0%				
	Individual MAPDT	≤6.5%	≤3.5%	≤1.5%	0%	0%	0%
	Pooled MAPDT	≤15%	≤10%	0%		0%	0%
	Environment MAPDT	0%					
200 - 299	ELISA	≤3.5%	≤2%	≤1%	0%	0%	0%
	ELISA/Ind MAPDT	≤1.5%	≤0.5%	0%			
	Individual MAPDT	≤7%	≤4%	≤1.5%	0%	0%	0%
	Pooled MAPDT	≤13%	≤10%	≤6%	0%	0%	0%
	Environment MAPDT	0%					
≥ 300	ELISA	≤4.0%	≤2.5%	≤1%	0%	0%	0%
	ELISA/Ind MAPDT	≤2.0%	≤1%	≤0.5%	0%	0%	0%
	Individual MAPDT	≤7.5%	≤5.0%	≤2%	0%	0%	0%
	Pooled MAPDT	≤11%	≤7%	≤5%	0%	0%	0%
	Environment MAPDT	0%					

\*ELISA/Ind MAPDT—ELISA with followup individual MAPDT

▲Environment MAPDT—This testing strategy is only available for dairy herds (not beef herds)

■Herd size—Number of the test-eligible animals in the herd



**Table 2. Minimum herd testing options for entry into program at classification level 1 or maintenance of classification levels 4 through 6, if no positive test results are obtained**

<b>Test</b>	<b>Minimum number cattle to test*</b>
ELISA	60
ELISA/Ind MAPDT	60
Individual MAPDT	30
Pooled MAPDT	6 pools (30 cattle)
Environment MAPDT	6 environmental fecal samples

\* If the test-eligible herd has fewer animals than the minimum number to test, refer to Appendix 2, Table 1, for testing options based upon test-eligible herd size. If there are any positive test results from the minimum herd test, producers may elect to test the remainder of animals needed to classify the herd according to Table 1.

### **III. Collection and Processing Protocols**

#### **A. Environmental Fecal Sampling (For dairy herds only)**

From each dairy farm, collect two composite environmental fecal samples tested by an MAPDT from each of the following locations on the farm: manure concentration areas (cow housing alleyways or gutters), manure storage areas (lagoons, piles, pits, or manure spreader), and another manure concentration area (sick cow pens or other cow alleyways and travel-ways). A total of six samples should be collected for submission to the diagnostic laboratory.

Each composite environmental fecal sample should contain approximately 20 g of fecal material with bedding or soil from a minimum of four different sites within each sampling location. Collect each sample with a separate disposable latex glove, place in a 95-mL plastic-covered specimen container labeled with the sampling location and herd identifier, and store in a cooler with ice during transport to the laboratory. Be sure to include sufficient manure in the sample when sampling from well-bedded areas such as sick cow pens or loose-housing lots.

In free stall barns, obtain each cow alleyway sample from a minimum of four sites across cow alleyways, collected to represent most of the mature cows (24–36 months of age and older) within the farm. Crossovers (areas around waterers, corners, and ends of scrape lanes) are excellent places to collect well-mingled manure subsamples.

In tie stall barns, obtain samples from all gutters containing manure from mature cows (24 months of age and older). Other suitable locations for subsampling are places where the gutter cleaner exits the barn, along the ramp, and in corners.

Sample manure storage lagoons (using personal precautions for safety) from four locations at the perimeter of the lagoon by submerging the sampling container up to 10 cm beneath the water's surface.

Each composite sample from manure piles should be obtained from four different sites up to 10 cm beneath the surface.

Each composite sample from manure pits can be collected using two to three sterile 4 × 4 gauze pads tied to fishing line with fishing weight and soaked at least 10 cm below the manure's surface.

(Modified from Raizman, et al., 2004)

## B. Random Pooled MAPDT

Submit individual fecal samples of 30 randomly selected test-eligible animals to be tested by an MAPDT in 6 pools of 5 animals each. Submit individual samples to laboratories approved for fecal pooling.

Herds with fewer than 30 test-eligible animals can still use fecal pooling. All animals 24 months or older are to be included until a total of 30 animals has been reached or all 24-month-old animals have been tested. At least 3 pools of 5 (15 animals) should be available to use pooling. If 15 animals are not available, individual samples should be used.

### Fecal Pooling Procedure

1. Fecal pooling procedure – to be done in the laboratory – five samples per pool

- a. Homogenization by stirring

Weigh out 2 g of each sample to be pooled and place into a sterile 50 ml conical centrifuge tube. Mix samples by stirring with a sterile wooden stick. Vortex samples vigorously for 10 to 15 seconds until the mixture appears homogeneous. Remove 2 g of the resulting mixture for processing and testing by routine method used in laboratory.

- b. Homogenization by stomaching

Weigh out 2 g of each sample to be pooled and place into a stomacher bag. Be sure to add the samples to the same corner of the bag to ensure even mixing. Stomach the samples on the highest setting for 2 minutes. Inspect the mixture to determine if it appears homogeneous. Additional stomaching may be required to

homogenize the mixture. Remove 2 g of the resulting mixture for processing and testing by routine method used in laboratory.

#### IV. References

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5. Wells, S.J. et al. 2003. Evaluation of bacteriologic culture of individual and pooled fecal samples for detection of *Mycobacterium paratuberculosis* in dairy cattle herds. *JAVMA* 223:1022-1025.
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## **Appendix 3: Johne's Disease Certified Veterinarian Training Guidelines**

### **I. Initial Certification Training**

#### **A. Johne's Disease Overview**

1. Description (strains and survival)
2. Pathogenesis (host susceptibility, stages of disease, differential diagnosis)
3. Transmission pathways (fecal/oral, colostrum/milk, prepartum, saliva, artificial insemination, embryo transfer [E.T.])
4. Pass-through events

#### **B. Disease Prevention Management**

1. Directed at enhancing biosecurity
2. Include general principles and point out differences between dairy and beef herd management practices
3. Prevent entrance of MAP
4. Risk from herd additions and replacements (include E.T. recipients and herd bulls)
5. Risk from environment (vehicles, water, feed, etc.)

#### **C. Disease Control Management**

1. Directed at reducing risk for pathogens
2. Include general principles and point out differences between dairy and beef herd management practices to break the infection cycle, prevent ingestion, prevent spread, and decrease pathogen load in the environment
3. Cover manure management in specific animal environments such as newborns, suckling and weaned calves, yearling and bred heifers, and mature animals
4. Provide information on colostrum and milk management with emphasis on pooled versus individual feeding, effect of feeding unpasteurized hospital or waste milk, and methods of onsite pasteurization

5. Include strategies for managing infected animals through animal identification, removal/separation management, and provide information on the importance of protecting susceptible young stock and reducing the environmental pathogen load
6. Provide ideas for the management of replacements and/or additions including biosecurity of heifers raised off-site, knowing the risk of the source herd of additions and strategies to buy from low-risk sources
7. Develop a risk management plan based on assessment

#### D. Overview of Diagnostic Tests

1. Types of tests being used
  - a. ELISA
  - b. Fecal culture
  - c. Agar gel immunodiffusion
  - d. PCR
  - e. Biopsy
  - f. Gamma interferon
2. Interpretation of test results
  - a. Sensitivity and specificity
  - b. Likelihood ratio
  - c. Predictive values
  - d. Interpretation at the herd level
  - e. Interpretation at the individual animal level
3. Discuss differences in strategies for testing to determine herd prevalence, enhancing control, measure herd progress, purchasing herd additions, and participating in the VBJDCP

#### E. Overview of RAMPs

1. The information in the handbooks is the cornerstone for conducting risk assessments and developing management plans (“Handbook for Veterinarians and Dairy Producers” and “Handbook for Veterinarians and Beef Producers”).
2. Each book should be covered in enough detail to ensure that veterinarians are able to collect required data, perform risk assessments, and complete management plans with their clients.
3. The instructional handbook, “How to Do Risk Assessments and Management Plans for Johne’s Disease” is recommended as a guide for specific information details.

- F. Overview of Uniform Program Standards for the Voluntary Bovine Johne's Disease Program
  - 1. Responsibilities of the JCV in the JD program
  - 2. Explanation of the requirements for the management element and herd testing and classification element on the VBJDCP
- G. Overview of Specific State Regulations and Program Standards
- H. Model Time Allotments for the Actual Training Sessions (6 to 8 hours)
  - 1. Topics to be included:
    - a. Overview of JD pathology and epidemiology in cattle (1 hour)
    - b. Management strategies for preventing JD in dairy and beef herds (30 minutes)
    - c. Management strategies for controlling JD in dairy and beef herds (30 minutes to 1 hour)
    - d. Overview of diagnostic tests (1 to 2 hours)
      - (1) Types and interpretation of results including predictive values
    - e. Strategies for use (30 minutes)
  - 2. How to use handbooks (2 hours)
    - a. Information collection
    - b. Risk assessment
    - c. History, prevalence, and management practices
    - d. Testing strategy
    - e. Management plan development – Link back JD management to existing management and owner goals
  - 3. Uniform Program Standards for the Voluntary Bovine Johne's Disease Program (30 minutes to 1 hour)
  - 4. State specific regulations and program standards (30 minutes)

## **II. Recertification Training**

- A. Required Topics
  - 1. Review of JD basics
  - 2. Epidemiology update
  - 3. Testing and interpretation
    - a. New and emerging tests
    - b. Best tests for different scenarios
  - 4. National and State program review, highlighting any changes

5. JD economics and marketing tips

B. Additional Suggested Special Challenges and Topics

1. Correcting common misconceptions (identified by DJC) – Case scenarios
2. Update on research regarding the zoonotic issue
3. Vaccine usage
4. Potential use of JD “control” products

#### **Appendix 4: Appealing the Status of a Test-positive Animal**

- I. For animals found positive to a screening test, a herd owner may elect to confirm the test results as follows:
  - A. An official JD test must be submitted by an accredited veterinarian within 45 days of notification of the screening test results.
  - B. The herd will be classified based upon the initial test results. If the status of a positive animal is appealed, the herd classification may be changed based upon the discretion of the DJC and the guidelines in Table 1 of Appendix 2. The animal must be included in the next round of program testing if it remains in the herd.
  - C. If the animal that was test positive to a screening test has left the herd so that no confirmation of the results can be obtained, the herd maintains its classification based upon the original herd test.
- II. To appeal positive results to an official JD test, a herd owner must submit a written statement to the DJC within 30 days of the positive results to request an appeal, and then, at his or her own expense, arrange for an accredited veterinarian to:
  - A. Conduct a necropsy of the animal with an official JD test on tissue and histopathology of the ileum and of the mesenteric and ileocecal lymph nodes; or
  - B. Conduct a full-thickness biopsy of the ileum and biopsy of the mesenteric or ileocecal lymph nodes with histopathology and an official JD test on tissues and fecal samples taken at the time of biopsy; or
  - C. Submit six separate, serial fecal samples from the animal, with samples collected between 30 and 45 days apart for an official JD test. All six samples must be negative for the animal to be considered a test-negative animal.
  - D. The herd JD status will be suspended until all testing is completed. The herd will be classified at the DJCs discretion, based upon the test results and the appropriate classification in Table 1 of Appendix 2.