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Milk and Egg Report
For The Board of Livestock
December 6th, 2017

- The dairy license renewal applications 2018 have been sent out for all categories of licensees.
- So far there have been no notifications of producers not continuing operations for 2018.
- Our annual milk sampling for Pesticide residues has been completed and sent to the MSU Chemistry Lab. Analysis turnaround is usually 30 days on pesticide samples.
- The FDA Regional Milk Seminar has been set for Reno, NV April 30-May 3, 2018. The two State Rating Officers and one Lab Evaluation Officer are required to attend the seminar. I have applied for grant money from FDA to cover travel to the Seminar.

- The operation at Montana Egg is continuing to improve and the truck shortage for shipping out processed eggs appears to have been corrected.
- The USDA Shell Inspection program is still operating with the Avian Influenza biosecurity restrictions of one producer visit per day with a day in between inspections.
**Consent Agenda Item: Milk Control Update**

Update on milk market regulation study, Nov. 8, 2017 Board of Milk Control meeting, upcoming Board of Milk Control meeting, upcoming rulemaking (milk equivalent conversion factors for milk control assessment, FY2019 milk control assessment rates)

Recommendation: none

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Update on Milk Control Study

- The proposal evaluation committee met on November 8 in Helena and awarded the highest score to Dairy Technomics, LLC to carry out the study. The firm is based in New Jersey and had a very solid proposal.
- On November 8th, the Board of Milk Control accepted the evaluation committee’s recommendation contingent upon completion of the reference check process not receiving negative feedback on Dairy Technomics. The reference check process was completed November 13th; and feedback provided by references was favorable.
- The study’s contract was reviewed the week of Nov. 20 – 24 and will be signed by the end of November.
- Dairy Technomics will meet with Montana stakeholders and tour Montana pool plants from December 11 – 14. The bureau is arranging for meetings and will travel with the consultants. Time will be reserved for additional meetings with stakeholders in the afternoon following the December 14 Board of Milk Control meeting in Helena.
- The project is on schedule. The target time for a draft report of the study is mid to late March 2018.

Board of Milk Control Upcoming Activity

A board meeting will be scheduled for the morning of December 14th in Helena. Besides formal discussion between the board and Dairy Technomics LLC pertaining to the milk control study, the board:

- will appoint producers to the Producer Committee for the Jan. 1, 2018 – Dec. 31, 2019 term and
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Annual Self-assessment

Since the last Board meeting the bureau has been working to complete the annual self-evaluation for the Federal State Audit Branch of FSIS. The self-assessment is a written document that describes in detail how Montana carries out its meat inspection program in an “at least equal to” manner. Proof that the program is doing what it says it is doing is sent in along with the written assessment.

After FSIS receives the documents, they analyze them in detail. Once the analysis is completed, FSIS sends states a detailed list of topic areas upon which they would like to have further clarification. States then send in additional proof along with any clarification that might be necessary. This process may happen two or three times until the Federal State Audit Branch is satisfied that a state is carrying out its regulatory responsibilities in an at least equal to manner. The self-assessment has been completed and was submitted on November 16, 2017.

FSIS Training

October 30 through November 1, FSIS brought inspection training to Montana that was designed to give inspectors a solid foundation in how to carry out inspection duties. This training covered all aspects of inspection including HACCP, establishment relations, how to properly write noncompliance records and sanitation. It was well received by the students. In fact, the bureau chief received several phone calls and held conversations with inspectors who commented that this was the most thorough training they had received since they started with the Department of Livestock.

Students noted that this was the first time in the history of the program that all inspectors were together under one roof for any purpose. In the future, this type of training will be developed and delivered in-house. However, due to logistics and the need for inspection services, the in-house training will be delivered to small groups of inspectors.

Compliance Meeting

On November 29, 2017, staff will travel to Great Falls to attend a joint meeting between the federal compliance investigator and our state compliance investigators. During these meetings, compliance investigators discuss multiple topics such as open cases, compliance issues that have arisen since the last meeting, and areas of focus.

For example, compliance investigators conducted a joint surveillance activity (investigation) involving an entity that had been reportedly selling exempt poultry out of state. Since this is not allowed, both state and federal compliance investigators met and jointly visited the facility. During this visit investigators reviewed records, examined the facility and looked at frozen birds for proper labeling. The investigators determined that there was nothing out of place and will
continue to monitor the entity’s activities in an effort to determine if violations occur in the future.

**Processing Class**

Our in-house trainer is conducting a processing class for inspectors that have not yet received this training. During the processing class, students will be exposed to topics such as performing a net weight analysis and how to determine proper concentrations in solutions such as brine or lactic acid. Training will be conducted November 27, 28, and 29, 2017.
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<tr>
<th>From: Tahnee Szymanski</th>
<th>Division/Program: Animal Health Bureau</th>
<th>Meeting Date: December 6, 2017</th>
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**Consent Agenda Item:** Animal Health Bureau Report from the Recent USAHA Annual Meeting

Background Info: Four individuals from the Animal Health Bureau recently attended the United State Animal Health Association (USAHA) Annual Meeting in San Diego, California. Attached is a summary of our attendance at the meeting.

Recommendation: NA

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**Consent Agenda Item:** Request to hire Bison Program Specialist

Background Info: The Animal Health and Food Safety Division is requesting permission to fill the Bison Program Specialist position recently vacated by Bridger Cunningham. This position is currently based out of West Yellowstone, MT and is responsible for disease control activities associated with Yellowstone National Park bison. This position is funded through the USDA Umbrella Cooperative Agreement.

Recommendation: Board Approval to hire a new Bison Program Specialist Assistant

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Zaluski, Szymanski, Liska, and Kaleczyc attended the United States Animal Health Association annual meeting in San Diego, CA. The following sessions/meetings were attended:

- National Assembly of State Animal Health Officials
- Western State Livestock Health Association, Szymanski-president
- Executive Committee, Zaluski-second vice president
- USAHA Board of Directors, Zaluski-second vice president
- Meeting With Kevin Shea, USDA Administrator
- Subcommittee on Tuberculosis
- Subcommittee on Livestock Identification
- Subcommittee on Trichomoniasis
- Committee on Sheep, Goats, and Camelids
- Committee on One Health
- Committee on Parasitic and Vector Borne Diseases
- Committee on Captive Cervids
- Committee on Wildlife and Captive Wildlife
- Subcommittee on Johne’s Disease
- Committee on Animal Emergency Management
- USDA APHIS VS Updates
- Joint Plenary Session on FMD
- Committee on Foreign and Emerging Diseases
- Committee on Biologics & Biotechnology
- Subcommittee on Brucellosis, Liska-Chair
- Committee on Cattle and Bison
- Committee on Program
- Subcommittee on Global Animal Health and Trade
- Committee on Animal Welfare
- Subcommittee on Salmonella
National Assembly of State Animal Health Officials (NASAHO) (10/13-14/17):

Foot and Mouth Disease (FMD) Bank – The US currently spends 4.2 million per year which accounts for approximately 70% of the associated costs of the bank. The vaccine bank currently holds 1.2 million doses of each strain. For a large-scale outbreak, this number of doses is not sufficient to employ any vaccination strategy.

The request for funding for the upcoming Farm Bill includes a request for 90 million dollars for preparedness activities, 30 million for diagnostic testing, and 150 million for the vaccine bank. This level of funding would provide enough doses for a Level 2 or 3 FMD outbreak.

Tuberculosis/Brucellosis Rule – The proposed rule moved to the inactive list. Currently USDA is maintaining operations under the Federal Order issued in 2010. USDA is considering whether additional guidance documents are necessary to provide clarification to the Federal Order. There are three options for how to proceed regarding the rule.

1. Rework existing proposed rule and go through a second comment period.
2. Start the rule writing over (this is supported by half of National Assembly members).
3. Rescind federal order and default back to the CFR.

Elephant tuberculosis – No more STAT PAK testing, DPP only ($12 at NVSL). The 2017 guidance document is available at aazv.org.
Western States Livestock Health Association (WSLHA) (10/15/17):
Dr. Szymanski is the current president of WSLHA and presided over the meeting. Topics covered during the 2018 USAHA Western District meeting included the following topics:

- Harmful Algal Blooms
- Secure Food Supplies
- GYA Brucellosis updates
- Expansion of the Equine Passport program
- South Dakota TB investigation
- Interface between domestic livestock and wildlife

Meeting with Kevin Shea, Administrator of USDA Plant and Animal Health Inspection Service (10/14/2017):

- Discussed three main issues
  - Yellowstone bison and requested quarantine at Fort Peck
  - Delisting of B. Abortus (removing the agent from the Select Agent list to allow more research).
  - Traceability: Discussed some recommendations from the ADT working group.

Subcommittee on Tuberculosis (10/15/17):

In development – new TB tests with novel seroreactive antigens (up to 95% diagnostic accuracy).

- Phage assay
- Qiagen QFT

Dr. Schoenbaum presented on TB test performance: Variability of test results

In the SD herd beef herd with a 5.6% infection rate 37 of 40 CFT positive on skin test detected (92.5% sensitivity), CCT only 78.4% sensitivity. 72.5% sensitivity when used together. All animals negative on the Idexx ELISA.

In the TX dairy herd (2% infection rate) 114 of 147 positive on CFT for 78% sensitivity, CCT 43% sensitivity. 33% sensitivity when used together.

Why so much variability?

- Repeat testing on dairy – desensitization
- Dairy – removal of strongest reactors in first test
- Management/breed differences
- Bacterial strain differences

SD TB update:
CEAH modeled index herd – cost and time to test out in model supported depopulation.


Some of the SD animal coinfect with more than one strain of TB. In herd long enough to mutate.

All people with significant exposure tested. No international visitors. All 15 people tested were negative. Still suspect that introduction was from humans.

One million dollars indemnity. Additional cost of $287,000 to state for investigation.

TB Outbreak Models: With slaughter as sole source of surveillance, 5 yr. delay between infection and detection. Beef herds even slower b/c fewer animals to slaughter. Cost of whole herd surveillance is cost prohibitive. Consider targeted surveillance.

**Subcommittee on Livestock Identification (10/16/17):**

Meat processors provided a perspective on tag collection at slaughter. The issues highlighted include:

- Backtag placement in integral to successful collection at slaughter line speeds
- Retention of backtags is poor
- Cattle shipped to slaughter with no backtag per ADT exemption are not receiving backtags preslaughter.
- USDA won’t utilize numbers collected if the state code is unreadable. There is likely value in even incomplete backtag numbers.
- Backtags with extra numbers on them? Recognition? Acceptable?

A representative from the Canadian Food Inspection Agency (CFIA) spoke on Canada’s national traceability system:

- Private not for profit organizations manage regulated traceability data on behalf of CFIA.
- Animals are required to be ID’d prior to departure of farm of origin.
- Movements are required to be reported within 30 days of occurrence for all bovine, bison, sheep, and pigs.
- Current proposed changes to the system include:
  - Inclusion of goats/farmed cervids
  - Report receipt of animals, including individual ID and origin
  - Decrease reporting requirements to <7 days
  - Require movement documents for all movements of livestock and carcasses

**Subcommittee on Trichomoniasis (10/17/17):**

Following a previous interlaboratory comparison panel in which participating laboratories were shipped known positive samples with variable numbers of trich organisms in order to evaluate a labs ability to detect positive samples; discussion centered on whether there is value in completing a second panel
comparison. The general consensus of the group is that greater value would be derived from ensuring that communication between laboratories and state animal health officials is well established and in ensuring that veterinarians have adequate information on proper sample submission.

**Committee on Sheep, Goats, and Camelids (10/17/17):**

Blue Tongue – Evaluation of historical cases of blue tongue in Oregon and Washington state show a cyclical nature to the disease. With a larger scale outbreak occurring on an approximate three-year cycle. This is cyclicity of the disease is believed to be due to genetic drift of the virus resulting in the virus continuing to evolve beyond developed immunity.

Temperature capable RFID microchips for sheep – Research is being done on the practical application of temperature capable RFID tags for use in sheep and goats. The RFID tags can be implanted at the base of the ear or in the caudal tail fold. Studies include the accuracy of the detected temperature vs. rectal temperatures. The possible application of this technology includes early disease detection, assistance with reproductive programs, and potential detection of new/emerging disease. It has not yet been determined if the additional cost of the technology is worthwhile for these purposes.

Additionally, the current FSIS guidance document does not include base of the tail as an approved location for microchip application, but does accept the scrapie guidance document which lists the base of the ear, the base of the tail, and the dewclaw for heifers (dairy). Microchips must be declared at slaughter.

Parasites – Increased resistance to deworming products by the barber pole worm. Producers who purchase replacement animals are potential purchasing resistant genetics in replacement animals. Increase risk factors for presence of the barber pole worm are irrigated ground, frequent rotation of deworming products, and lack of parasite testing (fecal egg counts).

Gains shown:

30 irrigated acres; 36 paddocks; animals moved daily; 200 ewes/300 lambs =>

- Average daily gain increased from .55 to .65 pounds
- Dewormers nearly eliminated over 5 years
- Net profit: 200 ewes
- 330 lambs on grass: 16 lambs treated in 2014 ($8.64)
- Increased gross income: 100 ADG @1.80/lb = $5940
- Decreased dewormer cost = ($1070)
- Net Profit - $7010 or $35 per ewe.

Small ruminant producers should be employing FAMACHA scoring to determine deworming frequency and for which animals.

A second tool available to producers is grazing management. Forty days of pasture rest, leaving 6-8 residual inches of forage on a field, and intensive rotation practices greatly decrease the amount of required deworming.
Third tool is culling. If animals consistently show > 500 eggs per gram on fecal testing and/or a FAMACHA score of 4 or 5, animals should be culled.

The fourth tool to manage parasite resistance is in the selection of replacement dams. Damns of replacement animals and replacement animals themselves should have FAMACHA scores of 1 or 2.

(web.uri.edu/sheepngoat/famacha)

VFD/FARAD/AMDUCA – Utilize www.farad.org for the following resources:

- Withdrawal information
- Information on VFD’s
- Small ruminant information
- Scientific research papers
- FDA approved drug listings
- Prohibited ELDU.

Animal Medicinal Drug Use Clarification (AMDUCA) does not apply to medications in feed!

Extra label USE in Minor Species is addressed in CPC 615.115 – If no treatment option exists, FDA will not pursue action against extra label use in minor species.

**Committee on One Health (10/18/17):**

Minnesota One Health Antibiotic Stewardship is a program focused on improving antibiotic use. Their approach includes the following talking points:

- Human, animal, and environmental health are inseparable.
- Lack of “proof” if harm is not an argument for irresponsible use.
- Greater abuse in other disciplines is not an argument for injudicious use in yours
- Acknowledgement that there are unreasonable critics
- Behavior change is key

63% of infectious disease doctors have treated patients with infections that did not respond to antibiotics. 2 million Americans acquire serious infections caused by antibiotic resistant bacteria each year and 23,000 people die each year as a directed result of these infections.

The goals of antibiotic stewardship are to maintain drug efficacy and to maintain health and well-being across all disciplines.

Antibiotic residues have been found in ground water. What is the effect of this? What are the pathways that result in this contamination? (Both urban and rural.)

Antibiotics are a shared resource, we need to work to optimize the use benefits for all. All parties contribute. All antibiotic use contributes to resistance.

5 D’s:
Committee on Captive Cervids (10/17/17):
Resolution to eliminate interstate brucellosis testing requirements for captive elk that are not from the GYA passes unanimously

Resolution to increase the testing interval for TB accredited cervid herds from 3 for 5 years for herds that are accredited for >6 years, assuming all additions are from accredited herds and that the herd is not in a TB zone – passes unanimously

Live testing for CWD:
- Not good for calling an individual animal negative, but do enough of them and you get pretty good herd information
- 4 live animal tests – 3rd eyelid, tonsil, rectal mucosa, medial retropharyngeal lymph node
- Texas uses tonsils and rectal biopsy in white tailed deer
  - Tonsil biopsy requires general anesthesia, good for detecting early infection (has found mule deer 42 days post-infection) in younger animals, 97% sensitivity and 100% specificity, can be collected more than once, takes some skill to perform, instruments are expensive and when you get a positive you must throw them away
  - Rectal mucosal biopsy – can do with the animal awake in a chute, is cheaper and less technically challenging, best in young animals (lymph follicle numbers decrease in older animals), must discard instruments after getting a positive
- In Texas to be movement qualified (state program) have to test 80% of eligible animals (>16 mos of age), but also have to test 3.6% of the herd, can make up post-mortem results at 3:1 with a live animal test

Cervid health update:
- Voluntary HCP program started in 2012, just now to the point where we have 5 full years with consistent rules
- HCP programs in 28 states with 2,103 certified herds
- USGS maintains up-to-date map of CWD
- No new states with CWD in FY17, 8 new positive herds
  - IA – wasn’t certified yet, depopulated and found two additional positive animals that were both G/G genotype, was combined with a herd that had been under quarantine as part of trace-out from a different affected herd
  - MN 1 – not a certified herd, 1 animal that had left this herd died and was tested positive – this herd still has animals
o MN 2 – this herd purchased animals from the MN 1 herd, this was a certified herd, this herd has been depopulated, the additional 4 positive animals were G/G and G/S genotype
o MI – 2 white tailed does were positive, shooter facility, not certified but the state requires 25% mortality testing in all herds, the wild deer tested nearby have all been negative
o PA 1 – one buck from a shooter facility, was only positive in the RPMLN, was not a certified herd, the buck was born in a certified herd
o PA 2 – one white tailed doe, is a certified herd, has been depopulated, found 27 additional positive animals, most of the positives were G/G, nearest positive wild deer was found 2.5 miles away
o PA 3 – one white tailed doe, born in a breeding facility and then moved to a hunter preserve where she was positive, related to the PA 1 herd, very close to positive wild deer detections
o TX – white tail buck, transferred from a breeding herd and found when tested for state transfer status, adjacent to a previously positive herd, herd has been depopulated

Revised CWD program standards:
- Revisions are currently with USDA administrators for review, then they will go out for public comment
- Revisions cover interstate movement of wild-caught cervids that are intended for release and how much CWD testing is required, options for antemortem testing
- Pilot of live animal WTD testing in OH is ongoing
- Canada may be able to provide more data for elk rectal biopsy testing
- DPP testing at NVSL is now all caught up, more tests are currently available, but only one manufacturer, so there may be problems in the future
- USDA does not currently have any funding to conduct review of state HCP programs – this is a concern because three of the positive herds in FY17 were certified herds

Mycoplasma bovis:
- Presented by Newport Labs
- Lots of different mycoplasma species and lots of strain variation
- Animals that are infected, treated, and seem to recover never go back to 100%
- Spread in respiratory secretions, can survive 6 months in water, 2 months on solid surfaces under cool conditions – so very hard to clear from a herd
- In cervids have only found *M. bovis* in respiratory disease (not in arthritis, otitis, or mastitis)
- Usually use a PCR test because hard to culture
- Mycoplasma vaccines only work for the specific strains included in the vaccine, no cross protection – Newport Labs will develop vaccines for individual herds based on strains cultured from that herds
- Seems to kill fawns and adults equally (like in bison)

Colorado elk research:
• Goal was to look at management strategies for reducing CWD on a positive ranch, but ranch isn’t cooperating
• Genotype of the animal is related to the sensitivity of the live animal tests
• Best case scenario a rectal biopsy has sensitivity of 75-80%, misses very early infections
• Genetic resistance – resistant animals are not immune, similar to scrapie in sheep, but using resistant genetics has allowed the prevalence of scrapie to decrease significantly over 15 years
• Resistant deer and elk have lower prevalence and prolonged incubation
• Gene in elk is 132LL (resistant) and 132MM (susceptible), in the wild 132LL animals are only 5% of the population, anecdotally people say that resistant animals “don’t look right”
• In the infected herd in the study the prevalence of resistant animals increases over time
• Resistant genotype doesn’t seem to affect pregnancy rates

Committee on Wildlife and Captive Wildlife (10/17/17):
HPAI Surveillance:
• Interagency wild bird surveillance, goal is to be an early warning system for HPAI (either new trains, homegrown, or re-emergence), passive surveillance of sick and dead birds year-round, the bulk of surveillance is from hunter harvest in the fall and in the spring and summer when researchers band birds, conduct environmental fecal sampling if other types of surveillance aren’t available
• Designed to detect HPAI at a prevalence of 1%, target sampling by watershed, statistically there are 500,000 infected birds before the surveillance picks one up
• Based on the detections in the last two years, suspect that about 1% of wild birds are infected, no detections yet this year
• Generally, influenza A viruses circulate at the highest levels in the summer when young birds move out of the nest and are exposed to lots of new viruses
• Typically, when a new virus is detected in wild birds it shows up in poultry 2-4 months later
• Based on surveillance data the introductions to commercial poultry are from viruses circulating in dabbling ducks and geese/swans – introductions to poultry in the live bird markets are from all sorts of wild bird sources – potential vectors from wild birds to domestic include house sparrows and cottontails and shared water sources

Feral swine:
• CSF surveillance has been conducted since 2006, also conducting surveillance for ASF and FMD
• 3-4 million feral swine in 38 states
• B. suis and pseudorabies are also becoming more problematic, can also carry influenza, seem to have a generally low prevalence of PRRS, lepto is an emerging pathogen
• Concerns that they could be a reservoir for TB (in Spain feral swine are the main reservoir for M. bovis), haven’t found TB in US feral swine yet
• FSIS has expressed concerns about zoonotic disease when slaughtering feral swine – can sometimes culture B. suis from sero negative animals

Wild/domestic sheep diseases:
• More commonly isolating P. multocida from chronic respiratory infections
• Wild sheep are good at hiding signs of respiratory disease when people are around, catch the signs of video when no people are around
• Nasal swab versus oropharyngeal swabs get different pathogens
• Some herds with chronic respiratory disease die off, some seem to thrive despite respiratory disease, not sure what the difference in those herds is
• Outbreak of BVD in big horn sheep in a Fort Collins research facility after being given a bluetongue virus vaccine

TB in Indiana Deer:
• Started surveillance in 2009 after initial positive cattle and elk herds, continued when cattle herd was positive in 2011, now surveillance is ongoing because the 2016 positive herd is refusing indemnity and has not been depopulated
• Have found one positive WTD and a positive raccoon on the 2016 infected herd property
• Have given an incentive of an extra buck tag to hunters who agree to have their deer tested for TB, have also culled wildlife from infected property and allowed the owner to shoot deer on the property
• Strain found in the wild deer and raccoon likely a spillover from livestock, related to the strain in the elk herd that was depopulated, suspect it had been circulating in wild deer since about 2008(?)
• Has cost $650,000 to do deer surveillance so far

Subcommittee on Johne’s Disease (10/16/17):
NCBA – policy is to advocate for ARS to conduct research on Johne’s disease, Johne’s is a priority production disease, would like to sequence the genome of the bacteria, study host immune response and what triggers that change from subclinical to clinical disease, look for a vaccine – herd security, general herd biosecurity, best practices checklist from beef quality assurance, goal to keep out of low-risk herds and controlling the spread in infected herds

Early MAP detection research:
• We don’t know much about what triggers an animal to go from infected but not shedding to shedding but subclinical to clinical for Johne’s disease
• Hard to detect animals in the early phases of shedding, no way to detect animals that are infected but not shedding
• Which antigens are detected by the immune system varies over the course of infection and disease – research to figure out which antigens are detected when, look for antigens that are elevated in cows that are PCR/culture/ELISA negative but are from highly infected herds

Committee on Animal Emergency Management (10/14/17):

APHIS Summary:
- New World Screw Worm outbreak in Florida – APHIS alone spent >3 million dollars, other agencies spent additional money on top of that, the largest number of responders were law enforcement
- Avian Influenza in Tennessee – had two HPAI and several LPAI, HPAI was detected first and then LPAI was detected as part of the investigation, some cases never got sequenced because birds were already in the recovery phase (had positive titers but no virus left)
- EMRS Update – in the last year had 1600 FAD investigations, 1300 of them were for swine, mobile EMRS-to-go that would be accessible offline should be available soon
- NVS Update – changed the way PPE is packaged, now just send in bulk, also carry more sizes, fixed up some of the foaming units to be usable in the winter, also now have whole house CO₂ units for caged layers, new catalog should be available in December, equipment is also now all equipped with GPS tracking

CEAH Model for FMD Vaccination:
- CEAH has created a new, comprehensive model for FMD spread and control strategies – it includes bison, cattle, sheep, goats, and swine with multiple production system types for each species, includes 1.8 million farms and more than 900 livestock markets in the model, use data from NASS, also includes movements of animals and others (i.e. farrier, vet, feed truck, etc.) on and off farms
- Goal is to use the model to evaluate control strategies – i.e. What impact does surveillance have? How do movement changes, depopulation, or vaccination affect the spread of disease?
- Right now, running scenarios to find the most efficient use of the limited doses of vaccine available, varies based on where the outbreak starts, what species/production type is affected first, how many vaccine doses are available and how fast they can be administered, assume a 14-week lag between starting vaccination and getting enough vaccine to do continuous vaccination
- Aggressive vaccination works best in homogenous beef herd outbreak where herds are not too close together
- However, aggressive vaccination uses up all your resources in personnel and vaccine, and it doesn’t stop long distance jumps
- Don’t vaccinate sheep and goats because it won’t stop them from getting infected, but it could mask their already subtle signs of infection – swine take 2 doses of vaccine

Carcass Management:
- Emergency Carcass Disposal Desk Reference – published September 2017
- New guidance/publication forthcoming that says it is okay to landfill HPAI carcasses
- New livestock composting protocols
- Incinerating deer (test on 68 deer with CWD) works okay
- For 10,000 carcasses infected with FMD, need to be 2,000 meters away from any animals to stop spread of FMD
Secure Food Supply Plans:
- New websites for the secure food supply plans
- NPIP site biosecurity auditing to qualify for indemnity
- Focus on site specific biosecurity plans, enhanced biosecurity checklists, template biosecurity plans for producers
- Questions for permits – how to document evidence of no infection
- Need better tests for FMD

LPAI
- No clear definition for “backyard” versus “commercial” flocks
- VS did that work in EMRS during the KY outbreak
- Leverage social media – for those attending live bird markets
- USDA had to do testing in KY because state employee respirator fit testing had expired
- Need to do better engaging local emergency planners, public health, and wildlife agencies
- Issues when control zones cross state lines
- Suspect that severe weather disrupted migratory birds and caused them to hand around longer, also caused damage to poultry houses that might have allowed entry – one house only sign was slight drop in egg production, no mortality and no respiratory disease
- Industry often wants to kill birds before finding out if they are eligible for indemnity or even if the birds could be control marketed – states and industry wanted to depopulate for H5 and H7, but USDA didn’t want to
- Highway patrol was used to stop movement in GA
- Trade restrictions limited to the affected counties

Wildfires:
- CO has a system to permit veterinarians, veterinary technicians, and ranchers that take a short training – allows those people to integrate into ICS/IMT managing fires – allowed ranchers to get into affected areas to move animals and provide crews with detailed local knowledge

USDA VS Updates (10/15/17):

Glanders Import Testing:
- Issues have arisen when serology is non-negative – old protocols say that the horse must be euthanized or refused entry – recent cases with several valuable horses where owners requested re-testing of low positive or suspect horses
- All imported horses are tested for Glanders (except Canada, Australia, New Zealand, and Iceland because those countries are glanders free)
- 30,000 horses are imported to the US each year, 15,000 come across the Canadian border, 8,000 come through USDA import centers, and 4,000 come across the Mexican border
- Currently use the CF test, which is based on OIE manual, considered a “suitable” test, CF is used world-wide
• Considering using a Western Blot as a confirmatory test, developed at an OIE reference lab in Germany, issue getting test validated because glanders is on the select agent list, so there is limited access to infected horses to get known positive sera

TB/Brucellosis Rule:
• TB prevalence is 0.001%, brucellosis prevalence is 0.002% – programs have been a success, but now need to define a finish line
• TB incidence is now so low that most cases are found through epi tracing, high risk area testing (MI), and slaughter trace backs – is there a better way to do surveillance? Finding infected herds sooner would allow more test and remove rather than depopulation
• Challenges are wildlife sources of infection, non-uniform detection at slaughter, poor collection of ID at slaughter, and larger cattle herds (means that when a herd is infected depopulation is very expensive)
• Options for proposed rule (currently it is inactive):
  o Write guidance documents for the federal order that is in effect now – lawyers don’t want to leave federal order in effect because it’s been around longer than orders are meant to be, and would likely be overturned if challenged in court
  o Re-work the proposed rule – could likely be modified extensively
  o Restart the rule making process – administration is emphasizing limited rule making, waiting for a new under-secretary before doing anything new
  o Rescind the order and go back to current CFR
• Indemnity is going to go away – depopulation is often the best choice for disease management, but if we require depopulation how do we pay for it?
• Biggest source of risk is now wildlife/livestock interface, and APHIS and NASAHO don’t have authority over wildlife, wildlife agencies don’t care about these diseases the way livestock agencies do
• Research priorities are to improve testing for TB, come up with better surveillance strategies, develop a vaccine for TB in white tailed deer and brucellosis in elk, develop biosecurity assessments
• APHIS funding priorities – proposing to cut brucellosis slaughter surveillance, suggest that legacy programs like brucellosis and TB should be cut – VS wants input from industry and NASAHO

ADT:
• Traceability of Mexican cattle imports – destination listed on import paperwork is often the broker’s pens, but from there animals often get moved interstate without a CVI, trying to get better records for those interstate movements
• USDA is going to send the 17-30 to the state listed as the destination and to the states to which animals are commonly diverted
• Research projects about how to get ID entered into VSPS so that states can have individual ID
• Canadian cattle all have RFID, right now those numbers come to USDA on a piece of paper – working on getting that data electronically

LPAI:
• VS is considering changes because funding for LPAI program is no longer available
- Issues with controlled marketing are humane issues (can take too long for birds to clear the virus)
- Goal to preserve edible protein, lots of edible protein lost when a flock is depopulated
- Looking for comments from states and industry

**Committee on Foreign and Emerging Animal Diseases (10/16/17):**
- New pig coronavirus that is similar to PEDV detected in China – 95% nucleotide match to a bat coronavirus in the area
- Secure Pork Supply – pork industry (NPB) wants to be a player in FAD response, industry recognizes that in the initially outbreak all movement will have to stop, the faster everyone shares information the faster animals will get moving again, to make this easier the pork industry is supportive of premises registration, producers want to be prepared so that everything is in place for them to be on the top of the list for a movement permit
- Economic model for FMD outbreak scenarios – new economic models include wildlife, model the downstream effects (i.e. job loss, price of food, etc.) from different on-farm strategies – when done well (i.e. thoroughly and quickly) vaccination seems to always make economic sense, the more animals that make it through an outbreak live, the better the economic outcome, over 10 years a vaccinate to live strategy saves $12-36 billion

**Subcommittee on Brucellosis (10/16/17):**
Revisiting brucellosis in the GYA by the National Academies of Sciences 16-month review developed 7 recommendations:
- Prioritize prevention of transmission by elk
- Make data-based decisions to reduce risk from elk
- Phase out feedgrounds
- Continue to implement the IBMP
- USDA-APHIS should take measures to address the spread of brucellosis beyond the GYA
- All agencies involved should coordinate efforts
- Research community should address the knowledge and data gaps that slow progress

**GYA-Update: Idaho**
- Caviness/Simplot (C/S) opened a cull cow slaughter plant in June of 2017 and collect blood samples on 100%.
- C/S has collected over 66,000 samples as of Oct 11, 2017. All are tested at the Idaho laboratory.
- Idaho fish and game continues to conduct wild elk surveillance along the edge of the DSA.
- Idaho continues movement testing out of their DSA
- Currently no affected herds in Idaho

**GYA Update: Wyoming**
- Last affected herd found in 2015 was released in June of 2017
- Bighorn Mountains: 11 seropositive elk since 2012 (hunter kill)
- 18,000 head of cattle have been tested in Big Horn and Sheridan Counties
- September 1, 2016-September 7, 2017: 35,886 DSA tests (Cattle and bison)
Now require a test on sexually intact down to 12 months of age (was 18 months)

National Surveillance FY 2017
- 1.85 million slaughter tests
  o No affected herds found through slaughter traces
- 275,720 from GYA States
- 2017 U.S brucellosis prevalence: .0002% or 2.2 per 1 million

GYA Update and USDA/WY brucellosis Management Review
- Strengths:
  o Solid regulations
  o Both live and slaughter surveillance leaving the DSA
  o Good cooperation with markets
  o Wyoming Lab provides a strong diagnostic system with rapid reporting
  o Recent herds have been detected early with low prevalence
  o Effective and capable game and fish department.
- Weaknesses:
  o Surveillance ins based on individual animal testing
  o No written rule or policy for criteria to change DSA boundary
  o Lack measurable metrics to monitor compliance
  o Herd plans are voluntary with less than 30 % participating
  o Lack information on risk in the Bighorn Mountains
- Recommendations:
  o Develop written guidelines or policy based on specific criteria for defining the boundary of Wyoming’s DSA.
  o Establish criteria that would trigger a change in the DSA based on these risk factors
  o Develop a method to report the testing of animals leaving the DSA to ensure compliance with rules and regulations and report annually.
    ▪ Establish a minimum annual target for percentage of animals tested from each DSA herd. This target can be based on expected cull and replacement rates within the average herd
  o Classify DSA-herds into high-, medium-, or low-risk categories
  o Continue reimbursement for pre-movement testing for all test-eligible animals moving out of the DSA as well as supporting the laboratory testing
  o Work with WGFD to maintain or increase elk surveillance, especially in the Bighorn Mountains
  o Implement wildlife management strategies to decrease prevalence when necessary
  o Require testing at change of ownership for eligible animals in Big Horn County and continue voluntary testing in Sheridan County
  o Maintain funding for Wyoming’s brucellosis management program. A decrease in funding may put any portion of activities at risk and therefore the effectiveness of this program at risk

Brucellosis PCR, *B. suis/B. abortus* differentiation
- A novel real-time qPCR assay was developed: 100% specificity and sensitivity
• Significance: This will likely be the standard for diagnosis of brucellosis affected herds with or without culture.
  o Without culture, we would not have the ability to genotype.
• Utilized to show apparent prevalence in YBP bison 66% (calves 70%)
• Next step is to field validate for the detection of B. suis.

Select agent status of Brucella abortus/suis:
• Criteria considered for select agent list include:
  o Effect of exposure to the agent or toxin
  o Pathogenicity or toxicity
  o Availability and effectiveness of pharmacotherapies and prophylaxis
  o Other criteria that the Secretary considers appropriate
• January of 2016 USDA proposed removal of Pasteur Strain B. anthracis, B. abortus and B. suis
• Rationale for proposing to delist Brucella
  o Endemic in some wildlife populations
  o Benefits R and for countermeasures (vaccines, therapies, etc.)
  o Antibiotics are available
  o Low mortality
  o Support of public

RB51 Exposure through consumption of raw milk from a Texas dairy (July 2017)
• Permitted (must be sold from farm of origin) raw milk jersey dairy of 43-47 head
• Bi-annual ring testing was negative (last in May)
• CDC press release said approx. 800 households had POTENTIAL exposure (June 1-Aug 7)
• Two negative whole herd tests (July and August)
• Two negative bulk milk tank samples (July 30/Aug 18)
• Individual cow culture sampling revealed 2 cows with strain RB51 at NVSL
  o Whole genome sequencing conducted at NVSL demonstrated correlation between the case patient’s blood culture and the 2 positive cows’ milk cultures.
• Both cows were removed and the dairy resumed sale 30 days later
  o Both cows were born on the farm in 2014
  o 2nd freshening for both
• At slaughter, one cow had no gross lesions but did culture in multiple lymph nodes.
• At slaughter, one had gross lesions of diffuse micropustular lesions throughout the udder and culture from multiple lymph nodes
• Immunocompromising conditions including genetic predisposition are being investigated
• First case of human infection with strain RB51 in the U.S.
• “Risk factors that may have contributed to this perfect storm include the breed of cow, an unidentified immunocompromised condition of the cows, human consumption of raw milk, and the immunocompromised condition of the patient.”

Evaluation of the Brucellosis Milk Enzyme Linked Immunosorbent Assay (ELISA) Validation as an Additional Test for Brucellosis in Bulk Milk
• Based on data generated from a study in 2015, the top 3 performing ELISA kits of that study were compared using milk from 10 brucellosis positive cows.
• All three commercial ELISA kits evaluated in this study appeared to have similar sensitivity.
In general, the stronger the FPA response of the animal used in the study, the higher the milk dilutions were detected by both the BRT and ELISA.

- The ELISA could detect 50% of the positive cows with a dilution of 1250 or lower.
- In contrast, the BRT was only able to detect 50% of the animals at a dilution of 400 or lower.
- Further work is needed to evaluate the specificity of these ELISA kits within the North American dairy population.

Dr. Zaluski sponsored a resolution for “Permitted Research on Brucella Abortus As a Select Agent”

- This resolution strongly urges that within the Select Agent regulations, the USDA and the Department of Health and Human Services permit brucellosis research studies on pathogenesis under field conditions in endemic areas based on natural transmission of disease.
- Passed subcommittee unanimously

Mr. Travis Lowe (Executive Director, North American Elk Breeders Association) brought a resolution “Brucellosis Testing in Farmed Cervidae” to the subcommittee.

- Urges the elimination of brucellosis testing requirements for farmed Cervidae outside of the GYA states.
- Passed subcommittee and Committee on Captive Cervids unanimously

Committee on Cattle and Bison (10/17/17):

Bovine Leukemia Virus (BLV) in the U.S: Impact and Options for Control

- Retrovirus/ RNA virus invades blood lymphocytes
- ELISA + within a few weeks
- Old cattle are more likely to be +
- Prevalence in U.S. dairy herds<10% in the 70s but now>40%
- Most countries begin a control program when prevalence is still <5%
- Cattle infected with BLV have an altered immune system-likely accounts for their reduced milk production, lifespan and lymphoma
- Lymphoma (due to B cell increase) is the most easily measured impact
- Economic Impact- tumors, lost milk production, shortened cow longevity, regulatory restrictions, loss of breeding stock and cost of prevention.
- Animal welfare issues and health concerns are also gaining attention and could impact the industry
- Malignant lymphoma accounts for 13.5% of beef cattle condemnations and 26.9% of dairy
- Most common reason for condemnation (2009)
- Estimated that 209 # of milk/cow/year lost for each 10% increase in BLV infected cows within a herd
- Positives are 25-40% more likely to be culled over a 19-month period
- No known human health impacts.
- Antibodies are common in humans and can be grown in human tissue culture cells
- 2009 and 2015 study showed $380 loss per milking cow per year.
- 21 nations have eradicated BLV through culling cows with BLV antibodies
- In a herd with <5% prevalence was eradicated using milk ELISA after 2 whole herd tests
- No good vaccine
- Control of BLV through identification of super shedders
- Super-shedders often account for 1/3 of ELISA positives with a high lymphocyte count and high proviral load (PVL)
- Multiple routes of infection direct and indirect
- Needles OB sleeves
- One herd reported no reduced BLV when changing needles and sleeves.
- Must be other important routes or transmission
- In many cases, culling of all antibody positive cattle would not be economically feasible
- Beef cattle 39 herd study found that 45% of the bulls were ELISA positive

USDA-National Animal Health Monitoring System (NAHMS)
- Beef cow/calf study started in early October 17
- Will be the 4th time this has been done
- 4,000 beef cow/calf producers from 24 States will be asked to participate
- Describe trends in beef cow/calf health and management practices
  - Cow health, longevity, calf health reproductive efficiency, selection methods for herd improvement and biosecurity practices
  - Management as related to animal welfare emergency preparedness, environmental stewardship, record-keeping and animal ID
  - AB practices, determine prevalence of resistance patterns of pathogens such as Sal.
- Is voluntary
- NASS will administer in-person Oct-Nov
- Samples will be collected by USDA veterinarians and AHTs

Bovine viral diarrhea virus
- Pestivirus taxonomy
  May rename the Pestivirus genus to reflect Pestivirus A, B, etc. rather than using the nomenclature Bovine Viral Diarrhea Virus (BVDV), Classical Swine Fever Virus, etc.
- Serosurvey for ruminant pestiviruses using cattle sera
  Approximately 2,000 samples collected from 2014 to 2015 US Brucellosis Testing Program were evaluated. Type 1 BVDV is the predominant titer and data would suggest 1 in 10 animals reach breeding age with no protection against BVDV.
- Serosurvey for ruminant pestiviruses using sheep sera
  Approximately 500 samples from domestic sheep were evaluated and similar to the samples collected as part of the Brucellosis Testing program and found BVDV type 1 titers predominated.
- Protection needed to prevent fetal infections
  Titers greater than 1:256 are generally thought to be protective titers to protect against fetal protection. Recent data from Auburn University reported geometric mean titers greater than 1000 in the modified-live treatment group and BVDV virus was detected, suggesting titers may not be the best or only indicator of protection. Further data reported from suggests that fetal protection was not achieved against HoBi-like virus in cows that previously gave birth to BVDV PIs and had greater than 1000 titers to BVDV and half of the animals had titers greater than 256.
• Is vaccination enough? Vaccination in the presence of PIs.
  Two case reports from dairy operations reported well-vaccinated herds in the absence of BVDV testing to observe ill-thrift calves and upon testing for BVDV found BVDV 1b persistently infected (PI) calves. Further, in one of the dairies vaccine virus was detected in multiple affected animals as well as in PI animals when vaccination occurred in the presence of PI animals.

• Diagnostic submissions
  Approximately 10 years of diagnostic submission data from Kansas State University has reported 22% BVDV in tissues and 6% in nasal swabs. While a greater percent of BVDV PI’s are 1b, a greater number of positive samples are 2a in diagnostic samples. 65-75% of clinical cases that are 1a positive are 1a vaccine virus and of those samples positive for 1a vaccine virus greater than 75% are Singer strain.

• How effective are our current BVDV vaccines?
  Due to the diversity of BVDV and continued prevalence of BVDV 1b PIs, it is being further investigated if more contemporary isolates should be included in BVDV vaccines to help provide cattle producers with the best tools to control BVDV.

Subcommittee on Global Animal Health and Trade (10/15/17):
Summary of OIE general Session
  • Primary topics: the continued work of the OIE helping guide countries on reducing biological threats, eradicating diseases of significant economic impact, and managing antimicrobial resistance (AMR)
  • During the OIE general Session, Dr. Margaret Chan, outgoing Director General of the World Health Organization (WHO) discussed the challenges of AMR, also stressed the importance of furthering the Tripartite Group (WHO, OIE and FAO) collaboration on activities related to One-Health.
  • The U.S. delegation included 21 representatives from Federal agencies, USAHA, and industry
  • Activities of the OIE during the previous calendar year (2016)
  • OIE’s organizational structure was modified to make it consistent with the strategic mission of the organization.
  • Two technical items were presented at this year’s General Session.
    o Global action to alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the ‘One-Health’ initiative
    o Public-private partnerships: expectations of private sector partners for international animal health and livestock development programs
      ▪ Noted was the critical importance of forging partnerships to better address the complexities of agricultural, environmental and human health. The increased demand for animal protein, the expected doubling of the human population during the next several decades, the emergence of new diseases affecting human and animal health, and environmental pressures, are all exerting demands on the veterinary profession.
  • Reported on the most significant animal health events of 2016
    o Avian influenza
Rabies: 95% of human rabies cases are associated with dog bites. Dog rabies vaccination campaigns are critical in reducing human cases.

Peste de petits ruminants (PPR): this is a priority disease under the Global Framework for the Eradication of Transboundary Animal Diseases (GF-TAD)

- FMD
- Lumpy Skin Disease

OIE code chapters were discussed, including:

- Chapter on the prevention and control of *Salmonella* in pigs
- Animal welfare and dairy cattle production systems
- Welfare of working horses

Transboundary Risk of disease spread by feed ingredients- A Proposed Model

- Results demonstrate survival of certain viruses in specific feed ingredients (“high-risk combinations”) under conditions simulating transport between countries. This work supports previously published data on the survival of Porcine Epidemic Diarrhea Virus in feed and provides further evidence indicating that contaminated feed ingredients may serve as risk factors for foreign animal and endemic diseases.

APHIS- Evaluation of regionalization services and its impact on import and export of animals and animal products:

- presented the process in assessing the regionalization and its impact on imports and exports of animals and animal products.
- the foreign region must provide the eight-factor information to support an animal health evaluation.
  - Scope of the evaluation requested
  - Veterinary control and oversight
  - Disease history and vaccination practices
  - Livestock demographics and traceability
  - Epidemiological separation from potential sources of infection
  - Diagnostic laboratory capabilities
  - Surveillance practices
  - Emergency preparedness and response.

Committee on Animal Welfare (10/18/17):

- Several representatives from the swine industry discussed pressure on reducing antibiotic use in animals.
  - Reduced options for antibiotics based on increased FDA regulations
  - Competitors using labels (non GMO, Antibiotic Free)
- Non antibiotic marketing requirements hurt small producers b/c they have fewer channels for marketing swine (typically, large producers will have non-antibiotic line, and line where antibiotics had to be used because of health.
- Swine Veterinarians Association affirmed that antibiotics should not be withheld from animals that have a medical need for them.
**Subcommittee on Salmonella (10/15/2017):**

Whole Genome Sequencing:
- Whole genome sequencing (WGS) is being used to identify bacterial strains that are causing human illness. WGS is more accurate than previous method (PFGE).
- CDC and public health agencies are using (WGS) to link human outbreaks that otherwise would be considered as separate.

Reports of salmonella caused human outbreaks:
- S. Heidelberg has been associated with humans handling young dairy calves in the Midwest. This strain has shown high antibiotic resistance.
- S. Agbeni has been associated with contact with turtles. The speaker reported that of 37 cases, 16 persons had to be hospitalized. 45% of the cases reported contact with turtles.
- Cases of salmonellosis from contact with poultry have been rising. Especially in last 5 years due to more prominent role of chicken as a pet.

Control and intervention of Salmonella infections:
- Human salmonella was declared as reportable disease in early 1940s.
- National surveillance for salmonellosis started in the 1960s.
- Various interventions have been attempted to reduce human illness. While legislative solutions were initially sought, these have now been combined with a focus on owner education.
- There is a comprehensive program of pre-harvest salmonella control on poultry farms.
STATE OF MONTANA
DEPARTMENT OF ADMINISTRATION
STATE PERSONNEL DIVISION

POSITION
DESCRIPTION

*** PART I: Identification ***

AGENCY: Agency Code: 5603 Position No: 00876
(Asst. Manager: FT, Law Enf., & Admin.)

Department
Livestock
Division
Animal Health

ADDRESS:
City
West Yellowstone

FUNCTIONAL DESCRIPTION OF THE WORK UNIT:
The Animal Health Division is responsible for the prevention, control and eradication of animal diseases. This involves safeguarding the health and food production capacity of the State's livestock and poultry and preventing the transmission of animal diseases to man. The prevention and control of domestic animal diseases are achieved through four major areas of activity: Import/Export, Disease Control, Game Farm, and Field Operations. Cooperation with USDA/APHIS on eradication programs is conducted through the local Federal Area Veterinarian in Charge in Helena. The programs receive laboratory support from the Diagnostic Laboratory Division. The Import/Export Section supervises the livestock and animal import permit system as provided for in Montana Statutes. The Disease Control Program functions to protect the Montana livestock industry from disease loss by providing for the diagnosis, prevention, control, and eradication of animal diseases. The Game Farm Program regulates game farms with elk, deer, and other cervidae for disease control and inspection for ownership, in cooperation with the Department of Fish, Wildlife & Parks. Field operations include investigation of disease occurrence, import compliance and enforcement of Montana Codes and Administrative Rules. Recognition of veterinary practitioners to perform official work gives each program a necessary pool of professional service in field operations.

*** Part II: Job Description ***
**Position overview:**
This position is a Brucellosis Control Assistant Program Manager responsible for assisting in the coordination of the Yellowstone National Park (YNP) bison/disease control activities. Duties include assisting in managing YNP bison brucellosis disease control and YNP bison herd management operations; coordinating program operations and resources; performing law enforcement and investigations; and supervising project staff. The position reports to the Brucellosis/Bison Control Program Manager (position #75), and is responsible for assisting with supervision of project staff (specific FTE and position vary).

1. **ASSIGNED DUTIES:**
   Note: All duties listed are considered essential functions of the position unless otherwise noted.

   A. **Operations**  
      Assist in managing YNP bison brucellosis disease control and YNP bison herd management operations to protect the citizens and livestock of the state from disease. This involves some supervision of project staff, assisting with coordination, and assisting with overseeing operational activities (i.e., testing, capture, removal, site and facility maintenance, etc.), attaining necessary permits and permission documentation, coordinating interagency efforts, preparing reports, and performing operational work as required. This involves extensive contact with staff, industry, landowners, and other agencies and groups to ensure operations are coordinated effectively, and to promote and maintain effective relationships.

      1. Implement approved operating procedures and methods to capture, test, remove, or haze bison to ensure that disease control requirements are met, that animals are treated in a humane manner, and that project staff are performing work safely. This involves performing, and directing staff involved in hazing animals back into park boundaries, capturing animals, removing animals, and conducting testing. Adjust work plans as control needs dictate, seeking approval on issues that are a significant departure from established operating plans. Ensure compliance of all operational activities with relevant state and federal rules and regulations, Board directives, the Joint Bison Management Plan, and subsequent management plan(s). Notify department management of all planned operations activities prior to commencement.

      2. Coordinate or perform operations support activities such as snow removal, offal removal, transportation, snowmobiles, housing, feed purchase, power, slaughter, auction, sale, etc. by providing oversight and direction to individuals involved in the project, negotiating the use of resources, reviewing work for attainment of objectives, and resolving problems as they arise in coordination with the supervisor.

      3. Notify and direct other involved parties and agencies involved in YNP bison brucellosis disease control activities of planned operations and their role. This involves coordinating field dressing and removal activities with Native American groups, ensuring adequate law enforcement support for operations activities, coordinating the slaughter and sale of removed animals in compliance with state and federal laws and regulations, and resolving problems between landowners and the department. This is
done through establishing and monitoring operational procedures, direct supervision and observation, and personal involvement in operations activities.

4. Prepare incident reports for the Department of Livestock and Animal Health Division, Helena offices to ensure accurate and timely reporting of operations activities. Ensure proper report formatting, and the accuracy and conciseness of all information.

5. Attain all necessary permission slips from landowners to conduct removal or hazing on their property. This involves explaining operations, negotiating use agreements, and ensuring appropriate documentation of all agreements.

6. Communicate with the supervisor and department management to attain additional staff and other resources as needed for operations activities.

7. Assist in supervising project staff including department employees, contracted employees, staff of other state and federal agencies, and other involved groups and individuals. This involves participating in selection of employees for project work, assigning and reviewing work, training, resolving performance or disciplinary problems, and providing input on formal performance evaluations (for department staff).

8. Monitor bison movements and report bison location(s), to ensure qualified, competent individuals are assigned to monitor bison movements. Monitor and organize the activities of assigned staff as needed.

9. Coordinate and/or perform the transportation, assembly, and disassembly of bison handling facilities to provide appropriately located facilities in a timely manner and to ensure the safety of staff, animals, and the public. This involves moving equipment to designated locations, determining the best location and setup based on the site and bison handling requirements, and overseeing and performing the assembly, disassembly, transportation, and storage of facilities and associated supplies and equipment.

10. Maintain capture and operation facilities. This involves activities such as performing or providing oversight for trap repair and maintenance, fence repair, etc. Ensure the proper security of facilities by personally guarding the area and property, or ensuring qualified competent individuals are assigned, and monitoring their work periodically.

11. Respond to complaints from landowners and others regarding wandering YNP bison or YNP bison control activities. This involves determining the nature of the complaint, assessing jurisdiction, and taking steps to ensure the appropriate response (e.g., hazing or removal of the problem, or referral to the appropriate agency).

12. Maintain a contemporary knowledge and understanding of NEPA, MEPA, ESA, Montana Bald Eagle Management, and Joint Bison Management plans to ensure YNP bison brucellosis disease control activities do not conflict with these requirements. This includes conducting research and maintaining liaison with legal and environmental specialists and authorities as appropriate.
B. **Program organization and administration**  
15%

Coordinate program operations to implement YNP bison brucellosis disease control operations within existing resource constraints. This involves monitoring bison status, coordinating intra- and interagency staff and resources, and coordinating operations.

1. Participate in the coordination of activities, and exchange information with other agencies such as the NPS, USFS, FWP, local and state law enforcement, and Native American groups to assist the supervisor in planning and implementing program operations. This includes assessing needs and availability of resources for operations activities (e.g., site and facility preparation, transportation, removal, testing, slaughter, etc.).

2. Develop contacts and establish and maintain effective relationships with key personnel in a variety of agencies and organizations to facilitate communications, increase cooperation, and negotiate strategies and approaches for YNP brucellosis disease control activities. This will involve contacts with agencies such as FWP, MDT, USFS, NFS, MHP, Federal Law Enforcement Agencies, etc.

3. Monitor weather conditions, head counts, ground conditions, amount of grass, etc., to project YNP bison control needs and concerns. Develop recommendations to the supervisor on operational plans to ensure department responsibilities for protecting the state from disease are met, while minimizing the need for removal of animals.

4. Coordinate site preparation activities, and resolve problems in consultation with supervisor on issues such as proposed trap sites (e.g., endangered species impacts, environmental issues) or operational plans by identifying issues, communicating with other agencies, researching laws, administrative rules, and scientific information, and developing recommendations.

5. Develop, negotiate, and monitor contracts with various private agencies and individuals for provision of services and goods necessary for program operations. This involves establishing contract specifications, ensuring bidding and contracting requirements are met, negotiating terms, and ensuring contractor/vendor compliance with the contract. Recommend termination of contracts if services or goods are not being delivered as specified.

C. **Law enforcement**  
15%

Perform law enforcement and investigations related to YNP brucellosis disease control and Yellowstone bison herd management, and other department enforcement and investigation activities as needed. Ensure the safety of operations personnel, ensure that animals are treated humanely and in compliance with state and federal animal health laws, investigate crimes, and assist in the prosecution of criminals. This work requires knowledge of state and federal laws and regulations related to animal health and bison herd management, the interim operating plan, interviewing methods and techniques, laws of search and seizure, conflict management
practices, criminal behavior, state and federal court and criminal justice systems, and departmental policies and procedures.

1. Receive complaints and information regarding a variety of violations. Gather information regarding the nature of complaint, and identifies factors such as location of violation, individuals involved, the nature of the violation, and potential contacts. Travel to the location of the violation to begin determining the scope of the violation, laws broken, and to begin interviewing and collecting evidence.

2. Conduct crime scene investigation including interviewing witnesses/complainants, gathering physical evidence, and photographing and diagramming crime scenes to gather and preserve physical evidence and ensure compliance with search and seizure laws. This may involve sending parts of dead or butchered animals to the diagnostic lab to retrieve evidence or perform necropsy procedures to determine the cause of death in questionable circumstances.

3. Determine the nature of violation, and laws violated to determine how to proceed with cases. Criminal cases investigated range from misdemeanor violations to felonies, and often involve federal as well as state violations. The position will be required to independently develop a case plan to determine how to conduct the investigation. This case plan will require continual modification based on individual circumstances as the case proceeds. Collect additional evidence which is not in immediate site by drafting (independently & in conjunction with prosecuting attorneys) and executing search warrants following legal requirements and investigative procedures to ensure evidence is obtained in a legal manner.

4. Detain suspects and make arrests based on violations and investigations, knowledge of rules of evidence and search and seizure, and proper police procedures. This requires carrying a firearm, and knowledge of techniques for subduing and securing individuals. Interview suspects after arrests by using effective interview techniques to obtain written and tape recorded interviews, admissions, and confessions.

5. Prepare comprehensive reports explaining the chronology and results of the investigation in accordance with division and department format and policies and law enforcement standards to assist prosecuting attorneys. Assist the prosecution in preparation and presentation of the case.

6. Conduct surveillance activities and patrols operations activities to ensure enforcement of herd management, transportation, and health rules and regulations, etc., using knowledge of patrol and surveillance methods and techniques, state and federal laws, and related law enforcement laws and procedures (arrest, search and seizure, etc.).

E. Other duties as assigned

Perform other related duties as assigned. These duties include but are not limited to cooperative interagency activities, representing the department at special events and conferences, coordinating information dissemination, disease control, etc.
2. **WORKING CONDITIONS AND PHYSICAL DEMANDS:**

The position requires that the incumbent live within 15 miles of the west side of Yellowstone Park (e.g., West Yellowstone) to ensure appropriate response time for emergencies and other situations and to minimize travel costs.

The position will involve extensive travel in excess of 1,000 miles per month by truck. The position will also involve hazards and conditions associated with working with bison (exposure to extreme weather conditions, working with unpredictable bison, exposure to a pathogen [brucella abortus], unpleasant sights, sounds, odors, and other risks associated with bison control work). The position involves significant physical demands associated with working bison, repairing and maintaining facilities, hazing, removal, cleaning carcasses, etc. (heavy lifting, driving ATVs, snowmobiles, and riding horseback over rough terrain, continued standing, running, etc.).

Law enforcement functions of the position require the ability to subdue and arrest individuals. The position is required to stop vehicles, serve search warrants and collect evidence from the field, make arrests, issue citations, seize vehicles and other property, and independently conduct felony investigations. Due to the law enforcement responsibilities and the potential threat encountered while performing the work, the incumbent is required to be P.O.S.T certified, and qualify with firearms as prescribed by department firearms policy by attending MLEA firearms training and qualifying twice annually. The position will carry a firearm during the course of the work or as directed by supervisor. As a sworn peace officer, the position may also be called upon to assist federal, state, and local law enforcement agencies with arrests, investigations, roadblocks, etc.

3. **KNOWLEDGE, SKILLS, AND ABILITIES:**

**Knowledge:**

The position requires knowledge of animal behavior and accepted methods for trapping, hazing, and removal of diseased bison; state, and federal laws and regulations related to disease control requirements; the operations and jurisdictions of various agencies involved with the issue; and a practical knowledge of animal science and herd management including basic herd health standards, and disease control and eradication procedures. The position requires knowledge of departmental policies and procedures; supervisory principles and practices; contracting and procurement principles and practices; interviewing methods and techniques; laws of search and seizure; criminal behavior; and the state and federal court and criminal justice systems.

**Skills:**

The position requires expert skill and experience in operating snow removal equipment, and in handling a snowmobile and four-wheel ATV. The position requires verbal and written communication and conflict management skills; skill in the handling and care of wild animals; riding horses; and performing routine maintenance of DOL vehicles and equipment.

**Abilities:**
The position requires the ability to plan, define objectives, evaluate accomplishments, facilitate effective teamwork, and use those methods to negotiate and mediate complex issues. The position requires the ability to deal with the public in a regulatory capacity; operate a personal computer; and use a variety of research methods. The position requires the ability to understand the concerns of, and to effectively communicate with special interest groups and the public.

**Education and Experience:**
The necessary knowledge, skills and abilities are typically acquired through a combination of education and experience equivalent to graduation from a law enforcement academy, post-secondary education or training in herd management and/or animal health, and 5 years experience including livestock, law enforcement, and supervisory experience.

**Special information:**
The position requires that the incumbent live within 15 miles of the west side of Yellowstone Park (e.g., West Yellowstone) to ensure appropriate response time for emergencies and other situations, and to minimize travel costs.

The position requires graduation from the law enforcement academy and POST certification, or the ability to attain POST certification within one year of hire.

The incumbent must be a citizen of the United States, be eighteen years of age, and pass a criminal history record check including fingerprinting (i.e., no felony convictions that could have resulted in imprisonment in a federal or state penitentiary; misdemeanors will be reviewed on a case-by-case basis).

4. **MANAGEMENT and SUPERVISION of OTHERS:**
The position is responsible for lead worker supervision of a variety of DOL, other agency, and contract personnel assigned to the YNP bison/brucellosis disease control project. Duties include recommending overall responsibilities and allocations of positions, allocating staff resources among the various operational activities, assessing and making recommendations regarding performance (for contract and DOL staff), handling corrective action, and making recommendations regarding terminations as necessary.

Exact positions and number of FTE will vary based on project needs. The position will supervise approximately 1 - 3 FTE DOL and contract staff (annual average).

5. **SUPERVISION RECEIVED:**
The position reports to the Brucellosis/Bison Control Program Manager (position #75). Work activities are subject to federal, and state laws and regulations, and guidance such as Board directives and the interim operating plan. The position is responsible for determining the methods and procedures necessary to carry out operations, and for solving most problems independently. The position is expected to provide direction to subordinates on operational issues, and keep the supervisor informed of program activities and issues.
6. **SCOPE and EFFECT:**
Actions directly affect the administration of bison brucellosis control activities. The position is responsible for protecting the citizens of the state from disease by implementing approved operating procedures and methods to capture, test, remove, or haze bison to ensure disease control requirements are met, that animals are treated in a humane manner, and that project staff are performing work safely. This position has a significant effect on the services provided to the livestock industry and public by the Department. The position ensures compliance of program operations with state and federal laws, the interim operating agreement, and DOL policies and directives.

7. **PERSONAL CONTACTS:**
Contacts are with department management, subordinate staff, and staff of other divisions to coordinate work activities; discuss rules, regulations, and expectations; and coordinate the use of staff and other resources. The position also involves contact with the public and special interest groups to mediate disputes, encourage cooperation, and resolve conflicts. The position also involves contacts with criminals to interrogate, witnesses to interview and elicit information regarding crimes, and with other law enforcement agencies to coordinate multi-agency animal control, law enforcement, and other projects.
From: Steve Smith | Division/Program: MVDL | Meeting Date: 12/6/2017

**Consent Agenda Item: Request for Out-of-State Travel**

Travel to CDC Atlanta for training in rabies testing. This is an important training course that other staff members have participated in previously. The cost is completely covered by a grant provided through the Department of Public Health which also helps cover some of the costs associated with the rabies testing. Training is scheduled for February 5-9, 2018 with travel days on the 4th and 10th.

**Expected costs include:**

- Airfare: $650
- Hotel: $690
- Ground Transportation: $70
- Per Diem: $322

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3) Justification
Travel to CDC Atlanta for training in rabies testing. This is an important training course that other staff members have participated in previously. The cost is completely covered by a grant provided through the department of Public Health, which also helps cover some of the costs associated with rabies testing.

Expected costs include:
- Airfare (~$650)
- Hotel (~$690)
- Ground transportation (~$70)
- Per diem ($322)

Total: ~$1732

4) Itinerary
February 5-9, 2018. Travel on the 4th and 10th.

5) Submitted By
Requested By
Steve Smith
Title
Acting Director
Date
11/17/2017

Approval - to be Completed by Agency Authorized Personnel

Date Approved by Board
Board Chair / EO
Date
12/6/17

NOTE: A travel expense voucher form must be filed within three months after incurring the travel expenses, otherwise the right to reimbursement will be waived.

REVISED 11/2015
The job profile is a streamlined position description and may serve as the core document for all human resource functions such as recruitment, selection, performance management and career and succession planning. It was developed, initially, for use in classifying positions in Pay Plan 020.

If you are converting a position to Pay Plan 020 and the position has not changed simply cut and paste the information needed from the current position description. The position description contains sections that are no longer used to classify the position, such as: Working Conditions and Physical Demands; Management and Supervision of Others; Supervision Received; Scope and Effect; and Personal Contacts. These may still be important to the position and may be included in Section IV – Other Important Job Information.

When working with a new position, classification request or change to a position in Pay Plan 020, complete the information below to provide the required documentation for classification.

### SECTION I – Identification

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<tr>
<th>Working Title</th>
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<tr>
<td>Department of Livestock</td>
<td>Central Services</td>
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<tr>
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<tr>
<td>Work Phone</td>
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<td>Helena, MT 59601</td>
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**Work Unit Mission Statement or Functional Description** - This section should include a complete statement of the mission or function as it relates to the work unit.

The Central Services Division consists of the following bureaus:
Information Technology Services Bureau provides all MDOL's technological services including systems development, computer networking, device management, Internet services, information storage, web page development and desktop publishing.

The Fiscal Services Division administers the biennial budget of over $14 million. This bureau provides centralized accounting, payroll, accounts receivable, accounts payable, cash management, budgeting, financial reporting, and purchasing services; distributes and fiscally monitors Federal grants/reimbursements received from several different Federal agencies. This bureau is also responsible for the analysis and pricing of user fees for department services. In most cases this requires ensuring user fees are cost commensurate and in keeping with good practice for pricing in the public sector. In the case of the enterprise funding associated with the department's Veterinary Diagnostic Lab the bureau determines appropriate cost, margin and market analysis more comparable to retail and wholesale pricing of products and services in the private sector.

The Milk Control Bureau is administratively attached to the Department of Livestock, which provides staff to assist the Board of Milk Control in administering the Milk Control Act. The mission of the Milk Control Bureau is to regulate and control the transfer of milk among producers and distributors by enforcing Montana milk control laws and rules. Regulation of the milk market promotes public welfare and helps to maintain a stable market for milk within the State of Montana. The role of the division administrator is to ensure MDOL provides appropriate staffing and resources to the Board of Milk Control to perform its mission and carry out the policies the Board enacts without having direct oversight of the Board.

The Livestock Loss Bureau is administratively attached to the Department of Livestock which provides staff to assist the Livestock Loss Board in carrying out its statutory requirements. The program administers the payment of reimbursements and grants to offset the loss of livestock owners to predators such as Grizzly bears, Wolves and Mountains Lions as well as incentivize conflict mitigation efforts. The role of the division administrator is to ensure MDOL provides appropriate staffing and resources to the Livestock Loss Board to perform its mission and carry out the policies the Board enacts without having direct oversight of the Board.

**Describe the Job’s Overall Purpose:**

This position is the Department of Livestock’s deputy executive officer, chief financial officer and chief technology officer, serving as the Central Services Division Administrator and having primary responsibility for the management of that division.

**SECTION II - Major Duties or Responsibilities**
This section should be a clear concise statement of the position's duties. Well written thorough task duty statements are required here to accurately evaluate the position.

1. What are the major duties or responsibilities assigned to this position? Group duties in order of importance and estimate the percent of time needed to perform each duty.  
   NOTE: Because you are identifying major duties usually 3-5, the quantity of time probably will not be less than 20%. If a duty is essential but not performed routinely you should list it. For example, lobbying during the legislative session may not take up a large percent of total work time, but can be an essential duty.

1. Central Services Division Administration

The incumbent performs the administrative, management and professional duties necessary to direct activities performed by four bureaus in the Central Services Division.

Examples of types of problems solved, decisions made, or procedures followed when performing the most frequent duties:

A. Directs the Division’s activities to accomplish MDOL’s mission, goals and objectives by implementing sound management practices, organizing and assigning work to subordinate supervisors and staff; establishing priorities, methods and deadlines; allocating human and financial resources; providing general guidance and technical assistance to staff; and monitoring outcomes to ensure objectives are met and tasks completed. Hires, evaluates performance and disciplines staff.

B. Interprets and implements federal and state laws, rules, regulations and Board of Livestock (BOL) policies that affect MDOL’s funding and operations. Develops systems and recommends policies, legislation and administrative rules to the BOL; integrates changing federal programs and requirements in to existing state financial systems, processes and procedures.

C. Ensures the financial policies and processes associated with administering the office’s federal funds, including those related to federal funds passed through to other organizations, facilitate the office’s ability to use federal funds to the best possible advantage and meet related compliance requirements.

D. Provides in-house expertise to MDOL management and staff regarding the coordination of their state and federal funds and requirements related to the administration of state and federal funds.

E. Coordinates and develops staff training designed to strengthen overall knowledge of the financial management of state and federal funds.

F. Prepares, submits and negotiates the office’s indirect cost proposal in accordance with state law and federal regulations.

G. Manages the Department’s long-range building and facility needs as well as other capital equipment replacement needs.

H. Ensures the department is collecting statutorily required per capita revenues and devises strategy to increase compliance among per capita payers; analyzes and projects future per capita collections; makes appropriate recommendations for future per capita rates to meet budgetary and statutory needs.
I. Works with information technology staff to create and maintain a department technology plan which envisions greater usage of software and online services to meet customer service needs as well as increasing regulatory compliance.

2. Enterprise Management for Montana Veterinary Diagnostic Lab and MDOL Fee Determination

A. Manages Montana Veterinary Diagnostic Lab pricing for a complex state of services that takes into account the national and regional market place for diagnostic lab activities, depreciation of capital assets, debt service, etc. Also tracks revenues at product and service level to determine cost recovery and/or profit by service and section.

B. Manages purchasing of capital equipment and supplies as well as oversees contracts for such assets

C. Manages and plans financially for long range building and facility needs for the MVDL such as maintaining a cost of replacement schedule, needed financing, debt service, life span of facility, etc.

D. Determines appropriate pricing structure for department user, license, permit and recording fees by analyzing fixed and variable costs of department activities to achieve full cost recovery.

3. Executive Management Team

This position is a member of the Executive Officer's management team and is responsible for developing and implementing the department's initiatives. Examples of types of problems solved, decisions made, or procedures followed when performing the most frequent duties:

A. Represents the Executive officer and Board of Livestock at legislative sessions, recommending and drafting legislation, developing and presenting testimony before legislative committees, and presenting and defending the MDOL budget before appropriations committees.

B. Participates in strategic planning along with the Executive Officer and Division Administrators to develop MDOL's mission and long and short-term goals and objectives. Develops work plans for Central Services staff that are intended to achieve those goals/objects.

C. Monitors and manages the department's financial affairs to ensure MDOL business is conducted in a manner that is efficient and effective; complies with all relevant laws, rules and regulations; is fair both in fact and appearance; and ensures accountability for all public funds administered. Reviews and investigates large, unusual and high-risk transactions and makes recommendations to the Executive Officer for policies, internal control systems and/or improved management practices that are needed to address any problem areas identified.

D. Represents the Executive Officer at Interim Legislative Committee meetings, Board of Livestock meetings, special commission and task force meetings and at meetings with the Governor's Budget Office and senior staff in other state agencies to provide and gather information on matters involving MDOL finance.
4. Coordinating Work for the Montana Board of Livestock

Participates directly with the Montana Board of Livestock providing special expertise when the topic involves information systems or finances.

Provides information, assistance and advice to Board members on a wide range of fiscal and technology related topics including, for example, the state’s biennial budget process, state contracting requirements, purchasing and records retention policies, MDOL’s technology plan, auditor recommendations and communications, and the status of MDOL budgets and appropriations.

3. Give specific examples of the types of problems solved, decisions made or procedures followed when performing the most frequent duties.

4. What do you consider the most complicated part of the job?

Duties related to the operation and financing of the office’s diverse activities, including numerous state and federal grant programs, IT programs and services, require careful attention to a multitude of state, federal laws and regulations. These requirements are often complex, integrated, and fast-changing.

5. What guidelines, manuals or written established procedures are available to the incumbent?

Montana Code Annotated (MCA)                              USDA Grants Handbooks
Administrative Rules of Montana (ARM)                      Federal OMB Circulars
MDOL Policy Manuals                                          GAAP and GASB reference materials

5. If this position supervises other positions, complete the following information.

The number of employees supervised is: 4 Bureau Chiefs (Finance, IT, Milk Control, Livestock Loss) and 11 associated staff.

List the complexity level of the subordinates
Immediate subordinates include 4 Bureau Chiefs.

Please list the Position Number(s) for those supervised:

Is this position responsible for:

- [x] Hiring  - [ ] Firing  - [x] Performance Management  - [x] Promotions
- [x] Supervision  - [x] Discipline  - [x] Pay Level  - [ ] Other:
6. Please attach an Organizational Chart (optional).

SECTION III - Minimum Qualifications - List the minimum requirements for first day of work.

Please list the main knowledge and skill areas required for the job:

At least six years increasingly responsible experience supervising, managing and leading teams of professional and non-professional staff in areas of finance and information technology. The incumbent should have a minimum of six years’ experience in the management of accounting, reporting, budgeting and internal control systems, including experience in developing policies and interpreting laws and regulations. The incumbent should have documented experience within this component developing pricing and capital replacement models in both private and public-sector contexts. Two years’ experience in software equivalent to WORD and Excel. Or any equivalent combination of education and experience with demonstrated ability to meet the goals and objectives of the position.

Extensive, advanced knowledge of state and federal laws and regulations relating to state and local government finance, is preferable.

A. Extensive knowledge of the theories, principles and practices of accounting and budgeting.
B. Knowledge and skill in management, organization, implementation and operation of many diverse programs and information systems is essential.
C. The ability to quickly gain knowledge and ability in the operation of the State Accounting Budgeting and Human Resources System (SABHRS), the Budget Office Biennial Budget process, and the Legislative appropriation process is essential.
D. Thorough knowledge of the Montana political and legislative processes, including strong negotiation, presentation and lobbying skills.
E. Thorough knowledge of governmental audit requirements and of generally accepted auditing standards.
F. Ability to interpret laws, regulations, administrative rules, policies and contracts.
G. Ability to analyze, understand and explain complex financial issues, to identify potential concerns and problems related to those issues, and to recommend effective courses of action.
H. Ability to effectively work with others, to resolve conflict and negotiate.
I. Strong computer proficiency. Extensive knowledge and ability in Microsoft Office, Word and Excel.
J. Ability to communicate effectively, orally and in writing.
K. Strong leadership skills and extensive knowledge of effective personnel practices. Ability to supervise, discipline and direct the activities of subordinate staff through intermediate supervisors.
What behaviors are required to perform the duties? NOTE: Identifying behaviors used for recruitment and selection and other HR functions are part of building a competency model (see Creating Competency Models in Guide). A position description will provide helpful information if a model has not been developed. Often “abilities” from the current PD can be stated as desired and observable behaviors. For example, “the ability to communicate clearly in writing” can be restated “writes clearly and concisely”.

**Education and experience:** Please check the one box that indicates the minimum educational requirements for this job, as it relates to a new employee on the first day of work (not the educational background of the person now in the position):

- No education required
- High school diploma or equivalent
- 1 year job-related college or vocational training
- 2 year job-related college or vocational training
- College degree (Bachelor’s)
- Post-graduate degree or equivalent (e.g. Master’s, JD)

There may be a variety of fields of study that are acceptable. A Human Resource Specialist may have a Bachelor’s in Human Resources, Business Administration, Public Administration or another related field. Please specify the acceptable fields of study:

Degree in accounting or degree in business administration with an accounting emphasis

Other education, training (software), certification (CPA), or licensing (pilot, psychologist) required (please specify):

CPA required

Please check the one box that indicates the minimum amount of job-related work experience needed as a new employee on the first day of work (not the experience of the person now in the position):

- No prior work experience required
- 1 to 2 years of job-related work experience
- 3 to 4 years job-related work experience
- 5 or more years of job-related work experience

Specific experience (optional):

- This agency will accept alternative methods of obtaining necessary qualifications.

For recruiting purposes please list examples of acceptable alternative methods of obtaining those qualifications. These examples should appear on a vacancy announcement.
SECTION IV – Other Important Job Information

List any other important information associated with this position, such as working conditions, supervision provided or received, scope and effect and personal contact.
SECTION V – Signatures

My signature below (typed or hand written) indicates the statements in Section I to IV are accurate and complete.

**Employee:**

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**Immediate Supervisor:**

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**Division Administrator:**

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**Assistant Superintendent:**

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**Personnel Director:**

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MEMORANDUM

TO: Mike Honeycutt, Executive Officer, Department of Livestock
FROM: Joe Murray, Deputy Legislative Auditor
       Performance and Information Systems Audits
DATE: November 30, 2017
CC: John H. Leffeldt, Chair, Board of Livestock
    John Scully, Vice Chair, Board of Livestock
RE: Performance Audit Follow-Up (18SP-03): Montana Veterinary Diagnostic Laboratory (orig. 15P-04)

Enclosed is a copy of the performance audit follow-up report Montana Veterinary Diagnostic Laboratory (orig. 15P-04), to be given to the Legislative Audit Committee at its December 12 and 13, 2017, meeting. A formal presentation for the follow-up report is not planned. The official agenda for the meeting has been posted to the Audit Division website at http://leg.mt.gov/audit

We do not want to discourage you from attending the meeting, but Committee members have not typically been asking questions of agencies for performance audit follow-up reports. Should the Audit Committee have questions, we will arrange to have agency representatives available at a later date. Should you wish to appear before the Audit Committee, please notify our office and arrangements can be made for the upcoming or a future Committee meeting.

S:\admin\Correspondence\18\DOL\Honeycutt-MT-Vet-Diagnostic-Lab-PtA.docx\cr
To: Legislative Audit Committee Members
From: John Harrington, Senior Performance Auditor
CC: Mike Honeycutt, Executive Officer, Department of Livestock
     John H. Lehfeldt, Chair, Board of Livestock
     John Scully, Vice Chair, Board of Livestock
Date: November 2017
Re: Performance Audit Follow-Up (18SP-03): Montana Veterinary Diagnostic Laboratory (orig. 15P-04)
Attachments: Original Performance Audit Summary

Introduction
The Montana Veterinary Diagnostic Laboratory (15P-04) report was issued to the Legislative Audit Committee in June 2016. The audit included five recommendations to the Department of Livestock (department). We conducted follow-up work to assess implementation of the report recommendations. This memorandum summarizes the results of our follow-up work.

Overview
Our audit found opportunities for the Montana Veterinary Diagnostic Laboratory (lab) to improve the way it assesses the costs for each test performed, and to more regularly and thoroughly review the fees it charges for the tests it performs. We found the department should determine a consistent and sustainable amount of per capita funding to contribute to the lab’s budget each biennium, and should fully implement all of the contractually obligatory features and functions of its new information management system. We also recommended the department develop a detailed and specific plan for eventual replacement of the lab, which is located in an outdated and unsafe building in Bozeman. Follow-up work found the department has made substantial progress toward implementation of these recommendations, with four implemented, and implementation of the recommendation related to the lab building still in progress.

Background
The department is overseen by a seven-member Board of Livestock (board), whose members are appointed by the governor and who represent various segments of the livestock industry. The executive officer of the department serves at the pleasure of the board. The Montana Veterinary Diagnostic Laboratory is a division of the Department of Livestock and is located on the campus of Montana State University-Bozeman (MSU). The lab is the only accredited, full-service veterinary laboratory in Montana, performing more than 200,000 tests annually on a wide variety of animal species, as well as regulatory milk testing and testing on suspected rabies cases. The lab’s mission is to “protect the public health, promote a compliant state dairy industry and assist in the control and prevention of zoonotic diseases,” as
well as to "fulfill requirements and surveillance duties directed by regulatory and guidance agencies." The division provides disease diagnostic support to veterinarians, livestock producers, and companion animal owners, as well as many state and federal agencies. Our performance audit found the lab did not maintain a regularly updated accounting of the costs associated with the majority of its testing services, and did not have a process for monitoring and reviewing the fees it charged for those testing services. Initial audit work also found the department was inconsistent in providing per capita funding to the vet lab; had not received all contractually obligated functionality of a new information management system; and is housed in a building that is outdated and in some ways not safe.

Audit Follow-Up Results
The following sections summarize the progress toward implementation of the report recommendations. To complete our follow-up work, we solicited information from the department regarding implementation of the report’s recommendations; reviewed documentation of cost analysis and fee review performed by the department and the board; interviewed staff; reviewed department budget documents for the current biennium; and reviewed the activities of the Legislative Finance Committee’s Montana State Labs Subcommittee.

RECOMMENDATION #1
We recommend the Department of Livestock regularly analyze and document the Montana Veterinary Diagnostic Laboratory’s material and overhead costs of the tests performed at the lab.

Implementation Status – Implemented
Our initial audit work determined the department and the lab did not regularly assess the costs associated with all of their testing services. In response to the audit, the department indicated it undertook a full cost analysis on the lab in late 2016. As part of our follow-up work, we reviewed a cost analysis developed by the lab and determined it broke down direct material testing costs by lab section, and also allocated all administration and general overhead costs among the various sections of the lab. Documents reviewed and interviews conducted indicate the lab allocated some indirect costs to various sections based upon the square footage of the building occupied by the section, and other costs based upon the size of the section (as measured by number of FTE). Department management reported they intend to update the cost analysis annually at the end of each calendar year, so that the board can use the information for an annual review of the fees the lab charges, to be conducted each spring.

RECOMMENDATION #2
We recommend the Department of Livestock biennially review the Montana Veterinary Diagnostic Laboratory fees in a systematic, documented manner that takes into account the direct and indirect material costs of the tests and regional lab fees for competitive analysis.

Implementation Status – Implemented
In addition to not assessing the costs associated with testing services, our initial audit work found that the department did not review fees charged for testing services in a regular and documented way. Our review of the subsequent cost analysis work conducted by the department determined that information on both direct and indirect testing costs was used to create a revised fee schedule in the spring of 2017. As a result of this work, the board approved a 10 percent increase in the fees charged for selective tests. Some test fees were not increased because they are already competitive with charges at other labs, while other fees were left alone to encourage compliance by producers. The department also recommended, and the board approved, an accession fee of $4 for each submission to the lab by a veterinarian or producer. The department expects this fee may generate $100,000 per year and help defray a measure of the indirect and
overhead costs of maintaining the lab. Management indicated intent to present the board with its fee
schedule each spring.

RECOMMENDATION #3
We recommend that when developing a budget for the Montana Veterinary Diagnostic Laboratory,
the Department of Livestock determine a recurring, consistent, and sustainable level of per capita
funding to be contributed to the lab budget as one source of non-fee revenue.

Implementation Status – Implemented
The original audit found the department was inconsistently contributing per capita amounts to the lab’s
budget from one biennium to the next. Our audit work found that a more consistent per capita
contribution to the lab’s operations would reduce uncertainty on the part of the legislature regarding the
amount of general fund support the lab would need from year to year. Department leadership indicated
this recommendation was addressed by analyzing the difference between cost and revenue for tests that
primarily benefit the livestock industry in Montana (as opposed to those tests that are more aimed at
providing public health). Per capita fees are paid by the livestock industry, thus it was felt that per capita
funding was an appropriate source of funds to cover the shortfall in the area of tests that largely benefit
the industry. The department allocated approximately $430,000 per capita each year for the current
biennium, and signaled its intent to maintain this level of per capita funding.

RECOMMENDATION #4
We recommend the Department of Livestock fully implement all features and functionality
indicated in its information management system contract.

Implementation Status – Implemented
At the time of our audit, our work found the department had paid for but not fully implemented the
functionality of a new information management system that improves communication between the lab in
Bozeman and staff in Helena. During follow-up work, a demonstration of the system at the Helena office
indicated the department has achieved what was promised in the system contract and has the ability to
monitor test results via an interface between the lab’s system and the system used in Helena. While the
department has implemented the recommendation related to ensuring contractually obligated functionality
of the information management system, additional work is ongoing to establish full messaging integration
with the National Animal Health Laboratory Network and an interface for veterinarians across Montana.

RECOMMENDATION #5
We recommend the Department of Livestock develop a detailed and specific plan and timeline for
replacing the Montana Veterinary Diagnostic Laboratory.

Implementation Status – Being Implemented
Our initial audit work found the MSU-owned building that currently houses the lab is at the end of its safe
and useful life. The building’s facility condition index score indicates a number of deficiencies with the
building’s major systems, and the national accrediting organization indicated the facility may become a
hindrance to accreditation for the lab going forward. While a detailed and specific timeline for replacing
the lab is not complete, the department has engaged with two different stakeholder groups to develop a
plan for a new lab building serving multiple interests in Bozeman. An industry group was convened with
representatives from various segments of the livestock industry, and for this group the lab prepared a
needs analysis on what facilities would be necessary to maintain and enhance available services. Also,
subsequent to the release of our audit report, the legislature authorized a Montana State Labs Study
Subcommittee, a subcommittee of the Legislative Finance Committee. Review of subcommittee meeting
recordings showed the department has also been active and responsive, providing a needs analysis for what it would require in a new facility, potentially to be shared with other state-operated labs. Department leadership said the department is currently analyzing funding needs for its portion of a joint building, how such a facility might be funded through the legislature, and how the department would cover presumed debt service on its portion of any new facility.
The Montana Veterinary Diagnostic Laboratory plays an important role in protecting both animal and human health. The department needs to improve its processes for determining the costs associated with the lab's tests, as well as for determining the fees the lab charges for its tests. A consistent contribution from per capita funds would help the department in preparing the lab's budget. The Montana State University building that the lab occupies is at the end of its useful life, and the department needs to be proactive in developing a specific plan for finding new space for the lab.

Context

The Montana Veterinary Diagnostic Lab (lab) is the only accredited, full-service veterinary laboratory in Montana. The lab typically performs over 200,000 tests annually on a wide variety of animal species, as well as performing regulatory milk testing and testing on suspected rabies cases. This testing serves the livestock industry as well as public health concerns through providing valuable surveillance data regarding animal and zoonotic diseases, meaning diseases that can be transmitted between animals and humans. In recent years, the lab has experienced some budgetary difficulties, and the lab's budget alongside that of the Department of Livestock (department) in general have been a subject of legislative interest.

Audit work also touched on a wide variety of concerns relating to the lab's operations and future, including the lab's role in protecting public health and the lab's relationships as a facility on the campus of Montana State University–Bozeman (university). We held interviews with the Department of Public Health and Human Services, and reviewed the lab's reporting relationship with public health entities at the state and federal level. We additionally reviewed documents relating to the lab's arrangements with the university and interviewed officials involved with the university's facilities services, school of agriculture, regional veterinary medicine program, and agricultural extension service.

Results

Our audit found that the Montana Veterinary Diagnostic Lab does not maintain a regularly updated accounting of the costs associated with the majority of its testing services, and there is not a recurring, standard process in place for monitoring or reviewing the fees charged for these testing services. Further, though the lab certainly has a role to play in monitoring diseases that can impact public health.
health, attempting to quantify this role to provide a basis for the lab's budget presents concerns. The department and lab could do more to provide for a consistent and stable lab budget in the long term. Additionally, the facility housing the lab is at the end of its useful life. As such, the department needs to take detailed and specific steps to plan for future lab space, particularly in light of the fact that the university displays little interest or willingness to pursue a closer relationship with the lab.

Among the items addressed in our report's five recommendations:

- The lab should create and maintain detailed, documented information on the costs associated with its testing services.
- The lab should perform and document reviews of the fees it charges for testing services.
- The department should develop a stable budget for the lab, in part by determining a consistent and sustainable contribution of per-capita funding for the lab.
- The lab should ensure that all features of its lab information management system are fully operational, including features relating to the public-health reporting role of the lab.
- The department should develop a plan and timeline for the replacement of the lab's current facility.

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<th>Do Not Concur</th>
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Source: Agency audit response included in final report.
The job profile is a streamlined position description and may serve as the core document for all human resource functions such as recruitment, selection, performance management and career and succession planning. It was developed, initially, for use in classifying positions in Pay Plan 020.

If you are converting a position to Pay Plan 020 and the position has not changed simply cut and paste the information needed from the current position description. The position description contains sections that are no longer used to classify the position, such as: Working Conditions and Physical Demands; Management and Supervision of Others; Supervision Received; Scope and Effect; and Personal Contacts. These may still be important to the position and may be included in Section IV – Other Important Job Information.

When working with a new position, classification request or change to a position in Pay Plan 020, complete the information below to provide the required documentation for classification.

### SECTION I – Identification

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<th>Working Title</th>
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<td>Central Services</td>
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<tr>
<td></td>
<td>301 N Roberts St.</td>
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<th>Profile Produced By</th>
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**Work Unit Mission Statement or Functional Description** - This section should include a complete statement of the mission or function as it relates to the work unit.

The Central Services Division consists of the following bureaus:
Information Technology Services Bureau provides all MDOL’s technological services including systems development, computer networking, device management, Internet services, information storage, web page development and desktop publishing.

The Fiscal Services Division administers the biennial budget of over $14 million. This bureau provides centralized accounting, payroll, accounts receivable, accounts payable, cash management, budgeting, financial reporting, and purchasing services; distributes and fiscally monitors Federal grants/reimbursements received from several different Federal agencies. This bureau is also responsible for the analysis and pricing of user fees for department services. In most cases this requires ensuring user fees are cost commensurate and in keeping with good practice for pricing in the public sector. In the case of the enterprise funding associated with the department’s Veterinary Diagnostic Lab the bureau determines appropriate cost, margin and market analysis more comparable to retail and wholesale pricing of products and services in the private sector.

The Milk Control Bureau is administratively attached to the Department of Livestock, which provides staff to assist the Board of Milk Control in administering the Milk Control Act. The mission of the Milk Control Bureau is to regulate and control the transfer of milk among producers and distributors by enforcing Montana milk control laws and rules. Regulation of the milk market promotes public welfare and helps to maintain a stable market for milk within the State of Montana. The role of the division administrator is to ensure MDOL provides appropriate staffing and resources to the Board of Milk Control to perform its mission and carry out the policies the Board enacts without having direct oversight of the Board.

The Livestock Loss Bureau is administratively attached to the Department of Livestock which provides staff to assist the Livestock Loss Board in carrying out its statutory requirements. The program administers the payment of reimbursements and grants to offset the loss of livestock owners to predators such as Grizzly bears, Wolves and Mountains Lions as well as incentivize conflict mitigation efforts. The role of the division administrator is to ensure MDOL provides appropriate staffing and resources to the Livestock Loss Board to perform its mission and carry out the policies the Board enacts without having direct oversight of the Board.

Describe the Job’s Overall Purpose:

This position is the Department of Livestock’s deputy executive officer, chief financial officer and chief technology officer, serving as the Central Services Division Administrator and having primary responsibility for the management of that division.

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<th>SECTION II - Major Duties or Responsibilities</th>
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Last Revised June 2007
This section should be a clear concise statement of the position's duties. Well written thorough task duty statements are required here to accurately evaluate the position.

1. What are the major duties or responsibilities assigned to this position? Group duties in order of importance and estimate the percent of time needed to perform each duty. **NOTE:** Because you are identifying major duties usually 3-5, the quantity of time probably will not be less than 20%. If a duty is essential but not performed routinely you should list it. For example, lobbying during the legislative session may not take up a large percent of total work time, but can be an essential duty.

1. Central Services Division Administration

The incumbent performs the administrative, management and professional duties necessary to direct activities performed by four bureaus in the Central Services Division.

Examples of types of problems solved, decisions made, or procedures followed when performing the most frequent duties:

A. Directs the Division's activities to accomplish MDOL's mission, goals and objectives by implementing sound management practices, organizing and assigning work to subordinate supervisors and staff; establishing priorities, methods and deadlines; allocating human and financial resources; providing general guidance and technical assistance to staff; and monitoring outcomes to insure objectives are met and tasks completed. Hires, evaluates performance and disciplines staff.

B. Interprets and implements federal and state laws, rules, regulations and Board of Livestock (BOL) policies that affect MDOL's funding and operations. Develops systems and recommends policies, legislation and administrative rules to the BOL; integrates changing federal programs and requirements in to existing state financial systems, processes and procedures.

C. Ensures the financial policies and processes associated with administering the office's federal funds, including those related to federal funds passed through to other organizations, facilitate the office's ability to use federal funds to the best possible advantage and meet related compliance requirements.

D. Provides in-house expertise to MDOL management and staff regarding the coordination of their state and federal funds and requirements related to the administration of state and federal funds.

E. Coordinates and develops staff training designed to strengthen overall knowledge of the financial management of state and federal funds.

F. Prepares, submits and negotiates the office's indirect cost proposal in accordance with state law and federal regulations.

G. Manages the Department's long-range building and facility needs as well as other capital equipment replacement needs.

H. Ensures the department is collecting statutorily required per capita revenues and devises strategy to increase compliance among per capita payers; analyzes and projects future per capita collections; makes appropriate recommendations for future per capita rates to meet budgetary and statutory needs.
I. Works with information technology staff to create and maintain a department technology plan which envisions greater usage of software and online services to meet customer service needs as well as increasing regulatory compliance.

2. Enterprise Management for Montana Veterinary Diagnostic Lab and MDOL Fee Determination

A. Manages Montana Veterinary Diagnostic Lab pricing for a complex slate of services that takes in to account the national and regional market place for diagnostic lab activities, depreciation of capital assets, debt service, etc. Also tracks revenues at product and service level to determine cost recovery and/or profit by service and section.
B. Manages purchasing of capital equipment and supplies as well as oversees contracts for such assets
C. Manages and plans financially for long range building and facility needs for the MVDL such as maintaining a cost of replacement schedule, needed financing, debt service, life span of facility, etc.
D. Determines appropriate pricing structure for department user, license, permit and recording fees by analyzing fixed and variable costs of department activities to achieve full cost recovery.

3. Executive Management Team

This position is a member of the Executive Officer's management team and is responsible for developing and implementing the department's initiatives. Examples of types of problems solved, decisions made, or procedures followed when performing the most frequent duties:

A. Represents the Executive officer and Board of Livestock at legislative sessions, recommending and drafting legislation, developing and presenting testimony before legislative committees, and presenting and defending the MDOL budget before appropriations committees.
B. Participates in strategic planning along with the Executive Officer and Division Administrators to develop MDOL's mission and long and short-term goals and objectives. Develops work plans for Central Services staff that are intended to achieve those goals/objectives.
C. Monitors and manages the department's financial affairs to ensure MDOL business is conducted in a manner that is efficient and effective; complies with all relevant laws, rules and regulations; is fair both in fact and appearance; and ensures accountability for all public funds administered. Reviews and investigates large, unusual and high-risk transactions and makes recommendations to the Executive Officer for policies, internal control systems and/or improved management practices that are needed to address any problem areas identified.
D. Represents the Executive Officer at Interim Legislative Committee meetings, Board of Livestock meetings, special commission and task force meetings and at meetings with the Governor's Budget Office and senior staff in other state agencies to provide and gather information on matters involving MDOL finance.
4. Coordinating Work for the Montana Board of Livestock

Participates directly with the Montana Board of Livestock providing special expertise when the topic involves information systems or finances.

Provides information, assistance and advice to Board members on a wide range of fiscal and technology related topics including, for example, the state’s biennial budget process, state contracting requirements, purchasing and records retention policies, MDOL’s technology plan, auditor recommendations and communications, and the status of MDOL budgets and appropriations.

3. Give specific examples of the types of problems solved, decisions made or procedures followed when performing the most frequent duties.

4. What do you consider the most complicated part of the job?

Duties related to the operation and financing of the office’s diverse activities, including numerous state and federal grant programs, IT programs and services, require careful attention to a multitude of state, federal laws and regulations. These requirements are often complex, integrated, and fast-changing.

5. What guidelines, manuals or written established procedures are available to the incumbent?

Montana Code Annotated (MCA)  USDA Grants Handbooks
Administrative Rules of Montana (ARM)  Federal OMB Circulars
MDOL Policy Manuals  GAAP and GASB reference materials

5. If this position supervises other positions, complete the following information.

The number of employees supervised is: 4 Bureau Chiefs (Finance, IT, Milk Control, Livestock Loss) and 11 associated staff.

List the complexity level of the subordinates
Immediate subordinates include 4 Bureau Chiefs.

Please list the Position Number(s) for those supervised:

- [x] Hiring  - [x] Firing  - [x] Performance Management  - [x] Promotions
- [x] Supervision  - [x] Discipline  - [x] Pay Level  - [ ] Other:
6. Please attach an Organizational Chart (optional).

SECTION III - Minimum Qualifications - List the minimum requirements for first day of work.

Please list the main knowledge and skill areas required for the job:

At least six years increasingly responsible experience supervising, managing and leading teams of professional and non-professional staff in areas of finance and information technology. The incumbent should have a minimum of six years' experience in the management of accounting, reporting, budgeting and internal control systems, including experience in developing policies and interpreting laws and regulations. The incumbent should have documented experience within this component developing pricing and capital replacement models in both private and public-sector contexts. Two years' experience in software equivalent to WORD and Excel. Or any equivalent combination of education and experience with demonstrated ability to meet the goals and objectives of the position.

Extensive, advanced knowledge of state and federal laws and regulations relating to state and local government finance, is preferable.

A. Extensive knowledge of the theories, principles and practices of accounting and budgeting.
B. Knowledge and skill in management, organization, implementation and operation of many diverse programs and information systems is essential.
C. The ability to quickly gain knowledge and ability in the operation of the State Accounting Budgeting and Human Resources System (SABHRS), the Budget Office Biennial Budget process, and the Legislative appropriation process is essential.
D. Thorough knowledge of the Montana political and legislative processes, including strong negotiation, presentation and lobbying skills.
E. Thorough knowledge of governmental audit requirements and of generally accepted auditing standards.
F. Ability to interpret laws, regulations, administrative rules, policies and contracts.
G. Ability to analyze, understand and explain complex financial issues, to identify potential concerns and problems related to those issues, and to recommend effective courses of action.
H. Ability to effectively work with others, to resolve conflict and negotiate.
I. Strong computer proficiency. Extensive knowledge and ability in Microsoft Office, Word and Excel.
J. Ability to communicate effectively, orally and in writing.
K. Strong leadership skills and extensive knowledge of effective personnel practices. Ability to supervise, discipline and direct the activities of subordinate staff through intermediate supervisors.
**What behaviors are required to perform the duties?** NOTE: Identifying behaviors used for recruitment and selection and other HR functions are part of building a competency model (see Creating Competency Models in Guide). A position description will provide helpful information if a model has not been developed. Often “abilities” from the current PD can be stated as desired and observable behaviors. For example, “the ability to communicate clearly in writing” can be restated “writes clearly and concisely”.

**Education and experience:** Please check the one box that indicates the minimum educational requirements for this job, as it relates to a new employee on the **first day** of work (not the educational background of the person now in the position):

- [ ] No education required
- [ ] High school diploma or equivalent
- [x] College degree (Bachelor’s)
- [ ] 1 year job-related college or vocational training
- [ ] 2 year job-related college or vocational training
- [ ] Post-graduate degree or equivalent (e.g. Master’s, JD)

There may be a variety of fields of study that are acceptable. A Human Resource Specialist may have a Bachelor’s in Human Resources, Business Administration, Public Administration or another related field. Please specify the acceptable fields of study:

Degree in accounting or degree in business administration with an accounting emphasis

Other education, training (software), certification (CPA), or licensing (pilot, psychologist) required (please specify):

CPA required

Please check the one box that indicates the minimum amount of job-related work experience needed as a new employee on the first day of work (not the experience of the person now in the position):

- [ ] No prior work experience required
- [ ] 1 to 2 years of job-related work experience
- [x] 3 to 4 years job-related work experience
- [ ] 5 or more years of job-related work experience

Specific experience (optional):

- [ ] This agency will accept alternative methods of obtaining necessary qualifications.

For recruiting purposes please list examples of acceptable alternative methods of obtaining those qualifications. **These examples should appear on a vacancy announcement.**
SECTION IV – Other Important Job Information
List any other important information associated with this position, such as working conditions, supervision provided or received, scope and effect and personal contact.
SECTION V – Signatures

My signature below (typed or hand written) indicates the statements in Section I to IV are accurate and complete.

**Employee:**

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**Immediate Supervisor:**

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**Division Administrator:**

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**Assistant Superintendent:**

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**Personnel Director:**

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(Insert Company Name) Recall Policy

Plan Implementation Date: ____________________________
Revision Date: ____________________________

In the event that a food safety issue arises with our products, this company will protect public health by facilitating the efficient, rapid identification and removal of unsafe food from the distribution chain and, by informing consumers (where necessary) of the presence in the market of a potentially hazardous food.

There is a documented recall procedure in place and this will be periodically tested to ensure that it is comprehensive and fit for purpose in its ability to remove an unsafe product from consumers and/or the distribution chain.

Recall Procedure

Introduction
This procedure states the action/s [insert company name] will take to effectively manage the recall of a food which has been determined to be unsafe or unsuitable.

The following terminology is used to describe the situation when product is removed from the market.

A. Recall. A firm's removal of distributed (i.e., the product has left the firm's direct control) meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

B. Market Withdrawal. A firm's removal or correction, on its own initiative, of a distributed product that involves a minor company quality program or regulatory program infraction that would not cause the product to be adulterated or misbranded. For example, product does not meet company quality standards because of discoloration.

C. Stock Recovery. A firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm. For example, product is located on the premises owned by the producing firm or under its control, and no portion of the lot has been released for sale or use.

D. Recall Classifications. FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by FSIS, and classifies the concern as one of the following:

1. Class I. This is a health-hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Examples of a Class I recall include the presence of pathogens in ready-to-eat meat or poultry products, or the presence of E. coli O157:H7 in raw ground beef.

2. Class II. This is a health-hazard situation where there is a remote probability of adverse health consequences from the use of the product. Examples of a Class II recall include the presence in a product of very small amounts of undeclared 3 allergens typically associated with milder human reactions, e.g., wheat or soy or small sized, non-sharp edged foreign material in a meat or poultry product.

3. Class III. This is a situation where the use of the product will not cause adverse health consequences. An example of a Class III recall is the presence of undeclared, generally-recognized as safe, non-allergenic substances, such as excess water in meat or poultry products.
Regaining control of affected stock
If affected stock is directed to be returned to us then the recovered product/s will be stored in an area that is separated from any other food products. Accurate records will be kept of the amounts recovered and the codes of the product/s. If the recovered product/s is unfit for human consumption, it may be destroyed or denatured under the supervision of the company management and/or the regulatory authority where legally required.

If the food safety risk can be safely removed from the recovered product/s through relabeling or reprocessing this may be done once it is clear that public health will be protected.

Effectiveness of the Recall
To be effective, the product recall notification must reach as far as the product has been distributed. The effectiveness of the product recall is assessed on the basis of the amount of product returned as a proportion of the amount of product that left [insert company name] while taking into account time in the distribution chain and the retail turnover of the product.

Progress of the product recall must be reviewed so that its success can be monitored. If it is decided that there is now little risk to the public, the product recall can be judged to have been a success and brought to an end, however if there have been few returns and little response to a high risk problem the product recall procedure must be reassessed. The product recall may have to be repeated using different methods to reach the consumer.

Testing & Reviewing the Product Recall Plan
The recall committee will review this procedure every twelve months, and the contact list will be amended as required. The procedure will also be reviewed after any recall and changes will be made as necessary.

We will conduct a mock recall exercise within three months of the initial development of this procedure and additional mock recalls will be conducted on an annual basis. Records of these mock recalls will be documented and filed in the [insert file location here]

Once the mock recall is completed, a review must be carried out with the relevant recall committee members to correct and improve the process where necessary.

Recall Report
We will submit a recall report to the regulatory authorities within an agreed timeframe of the closure of the recall. The appropriate regulatory authority may conduct recall verification procedures to review compliance with current regulatory requirements.
An effective product recall will ensure that the unsafe or unsuitable food is contained and either destroyed or rendered safe.

Roles and Responsibilities

It is the responsibility of [insert company name] to effectively organize and manage the recall of food that has been demonstrated to be unsafe or unsuitable. The recall co-ordinator for the site is [insert name], who has been given authority from management to make recall decisions on behalf of [insert company name].

The Minnesota Department of Agriculture’s Meat Inspection Program wishes to work with us in our recall action and thus be satisfied that we are taking all reasonable steps to protect consumers. When a recall is initiated, our actions in recalling the affected food needs to be co-ordinated with the Minnesota Department of Agriculture’s Meat Inspection Program and any other local agency involved in the matter.

We shall notify Minnesota Department of Agriculture’s Meat Inspection Program as soon as a recall is likely.

It is our responsibility to manage the recall by clarifying the food safety issue and the exposure (who and where risk exists), and to provide details on distribution and the method of recall.

The Recall Committee

The recall co-ordinator [insert name] will initiate the formation of a committee and will co-ordinate actions with Minnesota Department of Agriculture’s Meat Inspection Program and our marketing and distribution agents.

Committee members may include personnel from across our company. Typically the committee would have a mix of knowledge across the following areas: (delete those that don’t apply)

- production
- quality
- purchasing
- marketing
- sales
- legal services
- distribution & supply
- consumer affairs/public relations

The recall committee is responsible for the management of all recall activities and to adhere to this procedure. Duties of the recall committee are to:

- assess the overall problem;
- notify the relevant regulatory authority;
- evaluate the hazard in the food and the extent of contamination;
- determine a strategy to be followed;
- make decisions about product still in manufacture or in storage;
- decide who makes any press statements;
- notify insurers (must be done immediately);
- notify legal counsel (insurance may require involvement of lawyers due to potential claims).

Recall Actions & Documentation

The recall committee shall reference and follow the actions outlined in the FSIS Directive 8000.1 Revision 6 (or most current revision) when we become aware that a product may be unsafe or unsuitable. We will ensure that records of all actions and decisions and who was responsible are recorded and retained.
Decision to Recall
The decision on whether to recall or withdraw a product/s or not will be based on the identification of a hazard that makes a foodstuff unsafe and its likelihood of affecting public health. This will be determined by careful, considered risk assessment. The recall committee will conduct a risk assessment using the Recall Hazard/Risk Analysis (Form A) and we will include the appropriate regulatory authority in the process. We will refer to FSIS Directive 8080.1 on the roles of regulatory authorities in regards to a recall.

Scope of Recall
The scope of a recall is a very important part of the process; it ultimately ensures the effective identification of all affected product/s, ingredient/s and location/s. We will follow the requirements set out in FSIS Directive 8080.1 to ensure our plan incorporates the details mentioned.

Notification of a product recall
If the decision is taken to initiate a Withdrawal / Recall we will notify:
- Senior management of (insert company name) supply chain personnel
- (insert name of appropriate regulatory authority)
- Anyone that has received our product, including distributors, wholesalers, retailers and caterers.

We have an up to date contact list filed in the (insert list location here).

If we are engaged in a Withdrawal but find that for whatever reason that it is not possible to contact all relevant consumers then we will consider expanding the Withdrawal to a Recall.

If the decision is taken to initiate a Recall we will notify:
- All people mentioned under initiation of a withdrawal, outlined above and;
- Consumers, via the media contacts included on our contact list.

The contact list must contain the contact details for the following:
- The product recall committee and senior management and key company personnel.
- Suppliers of all ingredients.
- Distribution company and business customers.
- Sources of technical advice and support including laboratory facilities.
- Regulatory authorities.

Communication
Notification in respect to the recall needs to be done promptly and should cover the following areas:

1. Regulatory Authority
   We will notify the appropriate regulator at the earliest opportunity, after an incident is identified that may lead to a recall. We will supply as much information as possible, using the Recall Hazard/Risk Analysis (Form A) and the FSIS Directive 8080.1. The regulatory authority will be updated throughout the process.

2. Distribution Chain
   We will notify contacts by telephone and fax or email. A draft notification form is located in (insert location of document).

3. Consumer
   Communication to the consumer will be by the most effective method. It is anticipated that we will communicate with the consumer either by a media release or paid advertisement in newspapers, on radio or television. The form of media used will depend on the circumstances involved and advice received from the Regulatory Authority. We may also place notices at locations where the product has been sold. A sample of a paid
FSIS Food Recalls

Who regulates food products? The Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture inspects and regulates meat, poultry and processed egg products produced in federally inspected plants. FSIS is responsible for ensuring that these products are safe, wholesome, and accurately labeled. All other food products are regulated by the Department of Health and Human Services’ Food and Drug Administration (FDA).

What is a food recall?

A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death. A recall is intended to remove food products from commerce when there is reason to believe the products may be adulterated or misbranded.

Who decides when a recall is necessary?

Recalls are initiated by the manufacturer or distributor of the meat or poultry, sometimes at the request of FSIS. All recalls are voluntary. However, if a company refuses to recall its products, then FSIS has the legal authority to detain and seize those products in commerce.

How are unsafe products discovered?

There are four primary means by which unsafe or improperly labeled meat and poultry products come to the attention of FSIS:

- The company that manufactured or distributed the food informs FSIS of the potential hazard;
- Test results received by FSIS as part of its sampling program indicate that the products are adulterated, or, in some situations, misbranded;
- FSIS field inspectors and program investigators, in the course of their routine duties, discover unsafe or improperly labeled foods; and
- Epidemiological data submitted by State or local public health departments, or other Federal agencies, such as the Food and Drug Administration (FDA) [http://www.fda.gov] or the Centers for Disease Control and Prevention (CDC) [http://www.cdc.gov] reveal unsafe, unwholesome or inaccurately labeled food.

As soon as FSIS learns that a potentially unsafe or mislabeled meat or poultry product is in commerce, the Agency conducts a preliminary investigation to determine whether there is a need for a recall.

What occurs during a preliminary investigation?

The preliminary investigation may include some or all of the following steps:

- Contacting the manufacturer of the food for more information;
- Interviewing any consumers who allegedly became ill or injured from eating the suspect food;
- Collecting and analyzing food samples;
- Collecting and verifying information about the suspected food;
- Discussions with FSIS field inspection and compliance personnel;
- Contacting State and local health departments; and
- Documenting a chronology of events.

How does FSIS notify the public when a product is recalled?

FSIS notifies the public through a Recall Release for Class I and Class II recalls, and issues a Recall Notification Report (RNR) for Class III recall issues. (The RNR provides substantially the same information as the Recall Release; however, it is not distributed to media wire services or media outlets.) The Recall Release is issued to media outlets in the areas where the product was distributed. Both Recall Releases and RNRS are posted on the FSIS Website and distributed to FSIS email subscribers. When possible, FSIS also includes pictures of the recalled product labels as part of the FSIS online Recall Release posting.
For every Class I recall, FSIS develops a list of retail consignees that have, or have had, the recalled products in their possession. The list of retail consignees includes the name, street address, city and state of each retail consignee and is posted within approximately 3 to 10 days of the date of the recall. The retail consignee list is updated periodically as additional retail consignee information becomes available.


The public can request to receive FSIS press releases and recall announcements by subscribing to the Agency's email subscription service. For more information or to subscribe, go to www.fsis.usda.gov/News_Event/Email_Subscription/index.asp. FSIS' newsletters, including the Constituent Update, are also available via email subscription at www.fsis.usda.gov/News_Event/Newsletters/index.asp.

If the recalled product was purchased by USDA and distributed through a food distribution program, such as the National School Lunch Program, FSIS notifies the Federal agency responsible for the food program, and that agency will hold the product.

**What is FSIS' role during a recall?**

When there is reason to believe that adulterated or misbranded product has entered commerce, the FSIS Recall Management Division convenes the Recall Committee, a standing committee within FSIS. The Committee, consisting of FSIS scientists, technical experts, field inspection managers, enforcement personnel and communications specialists, evaluates all available information and then makes recommendations to the company about the need for a recall.

If the Recall Committee recommends a recall, the Committee classifies the recall based on the relative health risk, as follows:

- **Class I** - A Class I recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.
- **Class II** - A Class II recall involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food.
- **Class III** - A Class III recall involves a situation in which eating the food will not cause adverse health consequences.

In addition to determining the class of the recall, the Recall Committee verifies that the company has identified production and distribution information to facilitate the recall.

The Recall Committee advises the company of its recommendation and also provides an opportunity for the firm to offer any information it wishes FSIS to consider regarding the recall after completing its investigation.

**How does FSIS ensure that a recall is effective?**

FSIS field personnel conduct "effectiveness checks" to ensure that the recalling firm makes all reasonable efforts to notify the consignees of the recalled product that there is a need to remove the product from commerce. FSIS conducts a sufficient number of effectiveness checks throughout the distribution chain to verify that the recalling firm has been diligent in notifying the consignees of the need to retrieve and control recalled product, and that the consignees responded accordingly.

If FSIS determines that the recalling firm has been successful in contacting its consignees, and has made all reasonable efforts to retrieve and control products, the Agency notifies the firm that the recall is complete and no further action is expected.

**Does FSIS keep documentation on recalls?**

The Recall Management Division maintains comprehensive case files for all recalls coordinated by FSIS. Information on open and closed Federal cases can be found on the FSIS Web site at www.fsis.usda.gov/Fsis_Recalls/index.asp.

**How can consumers identify recalled products?**

All containers of meat, poultry, and egg products must be labeled with a USDA mark of inspection and establishment (EST) number, which is assigned to the plant where the product was produced.

The establishment number may appear on the package within the USDA mark of inspection such as pictured on page 3. It may also appear elsewhere on the exterior of the package container or package labeling (for example, on the lid of a can) if shown in a prominent and legible manner and in a size sufficient to insure easy visibility and recognition.
MEAT Product "EST" Number
Besides appearing on meat product packaging, the Est. Number is also permitted to appear off the exterior of the container (for example, on a metal clip to close casings) or on aluminum trays placed within containers. If so, a statement of its location must be printed near or connected to the official inspection legend, such as "EST. No. on Metal Clip" or "EST. No. on Pan." The number may not be applied over any required labeling information.

POULTRY Product "EST" Number
Establishment numbers for poultry plants can be identified with the prefix "P" -- for "Plant" -- prior to the number. The plant number is also permitted to appear off the exterior of the container (for example, on a metal clip to close casings) or on aluminum trays placed within containers. If so, a statement of its location must be printed near or connected to the official inspection legend, such as "P. No. on Metal Clip" or "P No. on Pan." The number may not be applied over any required labeling information.

EGG PRODUCTS "EST" Number
Establishment numbers for processed egg products are found within the egg products shield or on the principal display panel prefaced with the term "Plant" or the prefix "P."

Where can consumers find information on recalls?
For additional information on recalls of food and other products, consumers may receive information from the following:
- The USDA Meat and Poultry Hotline at 1-888-MPHotline (1-888-674-6854) weekdays from 10 a.m. to 4 p.m. ET (English or Spanish).
- AskKaren.gov (knowledge base, live chat during Hotline hours, and submit a question).
- Via email subscription on the FSIS homepage, or from http://www.fsis.usda.gov/Fsis_Recalls/index.asp and click on "Receive email notification when recalls or public health alerts are issued."
- For information on all government recalls, go to www.recalls.gov.

Related Item

Call the USDA Meat & Poultry Hotline
If you have a question about meat, poultry, or egg products, call the USDA Meat and Poultry Hotline toll free at 1-888-MPHotline (1-888-674-6854).
Send E-mail questions to MPHotline.fsis@usda.gov.

AskKaren.gov
FSIS' automated response system can provide food safety information 24/7 and a live chat during Hotline hours.
Mobile phone users can access m.askkaren.gov
PreguntelleaKaren.gov
Differences between Federal and State Appeal Documents

1. Language specific to Montana ARM’s in opening paragraph.
2. Chain of Command changed to specify state personnel.
3. Simplified language from the federal version in regard to what may be appealed, states that any decision made by staff outside of recall is appealable.
4. Added language or requirements on appeals made by an entity to conform with state protocols of administrative and judicial review.
5. Requires that all appeals be made in writing, federal allows oral appeals.
6. Specifies that asking the first level employee to reconsider their own decision does not warrant the appeal process and therefore can be less formal, otherwise made orally.
7. Document attempts to separate information that is extraneous to appeal and not related to a decision made by staff out of the process.
8. The state document does not provide for typical timelines like the federal document. This is because of the specialized nature of the DOL chain of command (i.e. Board that does not meet on regular schedule) and state’s lack of personnel compared to the federal.
9. Department handling of the appeals is written to accommodate the state chain of command, legal requirements and staffing.
Montana Department of Livestock
Meat and Poultry Inspection Bureau

Appeals Guideline

***DRAFT*** August 30, 2017, version

The Montana Department of Livestock (Department) administers a state meat and poultry inspection program that must be “at least equal to” the provisions of the Federal Meat Inspection Act. See 21 U.S.C. 661. The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture administers the Federal rules applicable to the inspection and enforcement actions. Certain Federal regulations were adopted as state rules by the Department. See ARM 32.6.712. The Department administers these rules through its Meat and Poultry Inspection Bureau (MPI).

The rules provide a right of appeal from a decision of an MPI employee to that employee’s immediate supervisor. 9 CFR 306.5. This Guideline discusses the process for how the Department handles the appeals.

The appeal process is a mechanism for ensuring that disagreements between regulated parties and MPI staff are reviewed. The Department encourages regulated parties to appeal inspection decisions they believe are not consistent with applicable standards. Regulated parties may file an appeal without fear of retaliation. An appeal encourages communication between a regulated party and MPI staff that may lead to a better understanding of the food safety system and the standards that apply to both parties. For example, an appeal may uncover a long held misunderstanding of a standard by the plan that MPI staff can further explain.

**Chain of Command**

The appeal process follows the MPI chain of command. The chain of command ensures that program employees most familiar with the appeal facts evaluate the appeal first to minimize response time. The chain of command also allows a plant to appeal to the next highest level if unsatisfied with an appeal outcome. The MPI chain of command is:

1. MPI inspector
2. MPI regional supervisor
3. MPI bureau chief
4. Animal Health division administrator
5. Department executive officer
6. Board of Livestock
**Appeal Process**

*What may be appealed?*

Any inspection decision that adversely affects a regulated party may be appealed to the next highest level up the chain of command. Decisions that may be appealed include, for example, a non-compliance record (NR) and a review of an appeal at a lower level in the chain of command. Decisions that may not be appealed include a recall, which is an action by the regulated party, or a decision for which no adverse action was taken by the Department.

*Who may appeal?*

When the regulated party adversely affected by an inspection decision is an individual, that individual may pursue the appeal individually or through legal counsel.

When the regulated party adversely affected by an inspection decision is not an individual, the regulated party may pursue the appeal through the plant manager up until the fifth level of the chain of command or through legal counsel. An appealing regulated party that is not an individual must be represented through legal counsel for appeals reaching the fifth or sixth level of the chain of command.

*How must appeals be made?*

All appeals must be in writing at each level of the appeal. Appeal must be delivered to the Department at the following address:

Executive Officer  
Montana Department of Livestock  
301 N Roberts  
Helena, MT 59620

*What is not an appeal?*

Requests for reconsideration by the regulated party to the Department employee making the initial inspection decision are not appeals. However, these requests may be made orally to that Department employee for consideration.

Requests for consideration of actions that:

1. have not occurred (e.g., an anticipated action);
2. have been resolved (e.g., the remedy sought has been received);
3. are not adverse (e.g., a recommendation by the Department); or
4. are not by the Department (e.g., a party’s decision to issue a recall);

are not appeals. Requests for damages or for a remedy other than revision of an initial inspection decision are not appeals. Personal attacks against Department personnel are not appeals.
Every non-appealable request contained within an appeal must be dismissed without consideration of the merits of the non-appealable request.

When must appeals be made?

Appeals must be made within 30 days of the prior decision being appealed. If an appeal is denied, the regulated party may subsequently appeal to the next level up the chain of command. The time limitation applies both to the appeal of the initial inspection decision and to any subsequent appeal up the chain of command.

What must be included in an appeal?

The regulated party must provide in the initial appeal:

1. A statement of the facts supporting revision of the initial inspection decision;
2. All documentation supporting the statement of facts;
3. A statement of the legal basis supporting revision of the initial inspection decision;
4. An explanation of how the statement of facts and the legal basis demonstrate that revision of the initial inspection decision is merited; and
5. A request for the specific remedy sought on appeal.

The regulated party must provide in any subsequent appeal up the chain of command:

1. All documentation provided in the prior appeal up the chain of command.
2. An explanation of why the regulated party believes that revision of the prior appeal decision is merited.

What must be demonstrated in an appeal?

The regulated party must demonstrate that revision of the appealed decision is merited by a preponderance of the evidence. A preponderance of the evidence means that it is more likely than not that the appealed decision must be revised.

When will an appeal be decided?

There are no specific time frames for an appeal to be decided because each appeal has a unique set of facts that needs to be considered. Time is needed for Department employees or the Board to become familiar with the facts as the appeal moves up the chain of command. Generally speaking, the higher up the chain of command an appeal moves, the longer it will take for that level of appeal to be decided.

How will an appeal be decided?

The Department employee or the Board decides the merits of the appeal based on the facts and law presented including, if necessary, review of Department documentation and consultation.
with subject matter experts and legal counsel. There is no right to a hearing on an appeal, except as otherwise may be provided by law.

**Department Handling of Appeals**

**Process**

Upon receipt of an appeal by a Department employee or Board member, the appeal and any related materials must be forwarded to the Executive Officer. The Executive Officer will distribute the appeal materials to the appropriate review level in the chain of command. The Department employee or the Board, as appropriate, must issue a written decision on the appeal that explains the basis for the decision. The Department employee or the Board must provide that decision to the Executive Officer, who will distribute the appeal decision to the regulated party.

**Appeal File**

The Department will organize all appeal materials in an identifiable appeal file that contains, at a minimum:

1. The appeal filed with the Department;
2. The documentation in support of the appeal filed with the Department;
3. Additional documentation of facts considered by the Department for the appeal; and
4. The Department’s decision on the appeal.

The Department’s organization of appeal documentation should be separate and complete for each level of appeal.

**Legal Counsel**

The Department employee or the Board, as appropriate in the chain of command, may seek the opinion of legal counsel about questions of law that arise at each level of review of the appeal. They may also seek a recommendation from legal counsel about the application of law to the facts at each level of review of the appeal. Legal opinions and recommendations, including communications with legal counsel, are privileged documents that are not part of the appeal file.

**Judicial Review**

The decision on appeal of the Board of Livestock is final. Any party aggrieved by the Board’s decision may, within 10 days after the date of the decision, seek judicial review in the district court of the district in which the licensed premises are located. §§ 81-9-231 and -235(3), MCA.

**Resources**

Some of the language in this Guideline is adapted or copied from the FSIS Compliance Guideline for Small and Very Small Plants Appealing Inspection Decisions.
Compliance Guideline for Small and Very Small Plants Appealing Inspection Decisions

At various industry forums, small and very small plants identified a need to FSIS for guidance on how to appeal inspection decisions. As a result, FSIS developed this guideline to help small and very small plants understand the appeals process and learn how to make an appeal, when a plant thinks it’s necessary, in accordance with 9 CFR 306.5 and 9 CFR 381.35. This guideline includes the following sections:

- Appeals Process Information
- Noncompliance Record (NR) Appeal
- Written vs. Verbal Appeals
- Appeal Response Timeline
- Notice of Intended Enforcement (NOIE) Challenge
- Questions and Answers

Appeal Process

FSIS regulations, 9 CFR 306.5 and 9 CFR 381.35, provide plants with the opportunity to appeal any inspection decision. An appeal is part of a plant’s due process according to the Rules of Practice. If FSIS program personnel issue an NR, the plant can appeal the whole decision or part of the decision. Any enforcement action taken in accordance with the Rules of Practice, 9 CFR 500, may also be appealed.

A plant should file an appeal without fear of retaliation. FSIS encourages plants to appeal decisions they believe are unfair or are not consistent with applicable standards. The appeal process is a mechanism for ensuring that any disagreements between plant managers and FSIS program personnel are reviewed.

The appeal process follows the Office of Field Operations (OFO) chain of command. The chain of command ensures that program employees most familiar with the appeal facts evaluate the appeal first to minimize response time. The chain of command also allows a plant to appeal to the next highest level if unsatisfied with an appeal outcome. The OFO chain of command is:

1. Program employee who made the finding (e.g. Consumer Safety Inspector (CSI), Public Health Veterinarian (PHV), Inspector in Charge (IIC))
2. PHV IIC or Mini-Circuit Supervisor
3. Frontline Supervisor (FLS)
4. District Manager (DM)
5. Executive Associate for Regulatory Operations
6. OFO Assistant Administrator
7. FSIS Administrator
NR Appeal

The most common FSIS program employee decision is the NR; therefore an NR was used as the example on how, step-by-step, a plant should appeal an inspection finding.

- A plant decides to appeal an NR because the plant believes it can demonstrate that the FSIS program employee does not have the correct facts, that the FSIS program employee incorrectly applied a regulation or statute, or that there are facts that were not considered by the FSIS program employee when the finding was made.

- As soon as possible, plant management prepares and submits a written appeal. The appeal can be made to the FSIS program employee who made the finding or to that employee’s supervisor. The regulations give the plant the right to appeal directly to the FSIS program employee’s supervisor; however, a plant may wish to appeal to the employee who made the finding because that person’s familiarity with the facts may expedite the appeal.

- In situations involving retained fresh product, the appeal can be made orally. An oral appeal can ensure that the FSIS program employee evaluates the facts before the fresh product’s shelf-life is jeopardized. A written appeal can be made later. In most other cases, the plant should prepare a written appeal, containing a narrative explanation of why the plant disagrees with the finding. The appeal should include the appropriate NR reference number and any supporting documentation (e.g. technical information, scientific data, or factual information) that the FSIS program employee would need to evaluate the appeal.

- The FSIS program employee documents the appeal in PBIS 5.1.3 and evaluates the plant’s reason for the appeal, the initial inspection findings, and the pertinent regulatory provisions.

- The FSIS program employee issues a written response to the plant’s appeal, typically within 2-5 working days. The FSIS program employee should address all of the disputed findings in the appeal. The FSIS program employee may verbally render a decision prior to the written decision, especially if fresh product is involved.

- If the appeal or any part of the appeal is granted, the FSIS program employee granting the appeal makes appropriate modifications or completely deletes the NR and documents the changes in PBIS 5.1.3. If the appeal is denied, plant management has the option to accept the decision or to appeal to the next level of the OFO chain of command. A further appeal up the chain should be written and include all pertinent appeal documents including any denials.

Written vs. Oral Appeals

FSIS recommends that plants appeal in writing whenever possible, although written appeals are not required by regulation. There are a number of advantages to written appeals. A written appeal allows the establishment to fully explain why it believes the FSIS program employee’s decision is wrong. A written document is also a record of the appeal. A written appeal gives the FSIS program employee a document to respond to in
writing, instead of a potentially misunderstood oral appeal. A misinterpreted oral appeal can add time to resolving the appeal.

It is essential that an appeal be written as it moves up the OFO chain of command. The FSIS program employee evaluating the appeal is not located at the plant and was not present at the time the event occurred. If the appeal is not in writing, it will take more time to gather all the necessary facts.

**Appeal Response Timeline**

FSIS recognizes that plants want a response to appeals as soon as possible, especially when an appeal involves retained product. It is important for plants to make an appeal as soon as possible after a finding is made and to provide the FSIS program employee with all the necessary information to get a timely response.

Time is needed for program employees to become familiar with the facts as an appeal moves up the OFO chain of command. Plants should understand that every inspection decision is based on a different set of facts: There are no specific time frames because each appeal has a unique set of facts that need to be considered, but these times are typical.

- Within 2-5 working days for a level 1, program employee who made the decision, appeal response
- Within 2 weeks for a level 2, PHV IIC or Mini-Circuit Supervisor, level 3, FLS, or level 4, DM, appeal response
- Within 30 days for a level 5, OFO Executive Associate for Regulatory Operations, level 6, OFO Assistant Administrator, or level 7, FSIS Administrator, appeal response

These are only typical appeal response times because each case presents a unique set of facts and can cause response times to be much shorter or longer than the timeframes listed. If a plant does not receive a decision within the timeframes given above and is concerned, the plant should contact the FSIS program employee for an explanation. The plant should contact the next level in the OFO chain of command if unsatisfied with the explanation.

**NOIE Challenge**

There is a slightly different appeal procedure when a DM issues an NOIE. First, a plant challenges the NOIE to the DM. The appeal should provide an explanation of why the establishment disagrees with the findings, including the date the NOIE was issued and any supporting documentation (e.g., technical information, scientific data, or factual information) that the DM would need to evaluate the appeal. A challenge to an NOIE should be in writing, although not required, since the issues are usually too complex or

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*In situations where product shelf life is in jeopardy, the timeframe may be expedited.*
extensive to be communicated orally. The establishment must also respond to the NOIE within 72 hours. In challenging the NOIE, the establishment provides an argument with supporting documentation. The Agency may enforce the NOIE or rescind it in whole or part.

The OFO chain of command for NOIE appeals is:

1. DM
2. OFO Executive Associate for Regulatory Operations
3. OFO Assistant Administrator
4. FSIS Administrator

Questions and Answers

1. Can an NR be appealed if there is a clerical error, documented regulatory reference error, or an incorrect trend indicator cited?

Yes, plants can appeal particular documentation errors. However, if there is no disagreement that the underlying non-compliance existed, the NR will be corrected by the program employee and reissued. Clerical errors, incorrect trend indicators, incorrect regulatory citations, dates, names, times, etc., are not the basis for removing an NR from the system using the appeal process.

2. If a plant receives an NR and decides not to appeal, can that NR later be linked to another NR?

Yes.

3. What NRs should a plant appeal?

The plant decides whether or not to appeal an NR. FSIS recommends that plants appeal a NR based on a legitimate disagreement of the facts listed in the NR or the application of a regulatory provision cited in the NR.

4. When should an appeal be made?

Since most NRs are issued by the end of a shift, an appeal should be made by a plant as soon as possible after the NR is issued. A prompt appeal helps to assure a timely response from the FSIS program employee and avoids the suggestion that the establishment accepts the inspection finding or decision.

5. Is there a time limit for appealing an NR?

No, but an appeal should be made as soon as possible because it is easier to remember the facts around the event for both plant employees and FSIS program employees.
6. Can a plant appeal part of an NR, or must the plant appeal all aspects of an NR?

Plant management can appeal a part of an NR. The plant’s appeal should clearly state the particular finding or findings that the plant is challenging.

7. In what form should an appeal be made?

There is no requirement that an appeal be made in writing, but a written appeal is the best way to communicate the basis for the appeal and to create a record of the appeal. The appeal should provide an explanation of why the plant disagrees with the NR, including the NR reference number and any supporting documentation (e.g., technical information, scientific data, factual information, regulatory information) that the program employee needs to evaluate the appeal.

8. Once a plant submits an appeal of an NR, what does an FSIS program employee do?

The program employee will document the appeal in PBIS 5.1.3 for an official record. The program employee will evaluate the plant’s reason for the appeal, the supporting documentation, the original inspection finding, and the pertinent regulatory provisions. The program employee will prepare and present a written response in a timely manner to the plant.

9. What happens if the NR appeal is granted?

If the program employee concludes that the appeal should be granted, he/she will note the action in PBIS 5.1.3, remove the NR from the file, and remove any tags. When the NR is rescinded officially, the plant should be given a copy of the rescinded NR documents.

10. What happens if the NR appeal is denied?

If the program employee denies the appeal, the plant has the right to appeal to the next level in the OFO chain of command. The appeal should be made in the same manner as at the previous level, including a copy of the lower level appeal responses. An appeal to each level in the chain of command follows the same process.

11. How does the plant determine who and how to contact the FSIS program employees who receive appeals?

The FSIS program employee who made the finding should provide contact information to the plant for his/her direct supervisor. Depending on the District’s hierarchy, the supervisor could be the PHV IIC, Mini-Circuit Supervisor, or FLS. In addition, the particular District Office where the plant is located can provide the establishment with the necessary points of contact. OFO (DM, Executive Associate for Regulatory
Operations, and Assistant Administrator) and FSIS Administrator contact information can be found on the FSIS web page at:

http://www.fsis.usda.gov/Contact_Us/Key_Agency_Contacts/index.asp

12. What should plants do if an appeal is not responded to by in-plant FSIS program personnel in a timely manner?

After providing a reasonable time for the FSIS program employee to respond to the appeal, plants should express their concern about response delays to the individual reviewing the appeal. If the plant does not receive a satisfactory explanation, the plant should contact the next level in the chain of command about the delay, likely resulting in a decision by the next supervisory level of the appeal.

13. Does a FSIS program employee’s response to an appeal need to be in writing?

Yes, a response should always be in writing and explain the basis for the decision. Plants should expect a written response to an appeal.

14. What information should a plant forward to the next level in the OFO chain of command if it chooses to appeal further?

A plant is expected to forward all information supporting the appeal to the next level in the OFO chain of command. To ensure a timely response, it would also be useful if the plant included earlier appeal responses by the lower levels in the OFO chain of command.

15. What effect would a granted appeal have on a linked NR?

If an appeal of an NR is granted, and the NR is rescinded, then any linkage between that NR and another NR is also rescinded and will be documented in the program employee’s written response. If only a portion of an NR was granted, and that granted portion included the cause used to link the two NRs, then that linkage is rescinded. On the other hand, if the cause used to link the two NRs is upheld, the linkage stands.

16. Should plants fear retaliation or intimidation by FSIS program personnel as a result of an appeal?

No, 9 CFR 306.5 and 9 CFR 381.35 provide for an appeals process, giving plants due process. FSIS does not tolerate retaliation or intimidation by employees. Plants should immediately report any FSIS program employee retaliation or intimidation to the District Office.

17. Can a plant appeal any inspection decision?
Yes, a plant may appeal any inspection decision. The supporting documentation should explain the disagreement with the inspection decision.

18. How can an appeal be a learning process?

The appeal process can be a learning opportunity for both plant management and FSIS inspection program employees. An appeal can start conversation between the plant and inspection personnel that may lead to further understanding of the plant's food safety system and the pertaining regulations by both parties. As an example, an appeal may uncover a long held misunderstanding of a regulation by the plant that an inspection program employee can further explain.

The appeal process can also be an opportunity for inspection program employees to inform plant management of the numerous resources available such as compliance guides, the Technical Service Center and the expanded small and very small plant outreach program that the Agency has initiated. FSIS has provided IKE scenarios on its website. They are an additional resource in understanding the appeals process. They can be found at:

http://www.fsis.usda.gov/FSIS_Employees/IKE_Scenarios/Index.asp
Rule: 32.6.712
Rule Title: FOOD SAFETY AND INSPECTION SERVICE (MEAT, POULTRY)

Department: LIVESTOCK
Chapter: ANIMAL FEEDING, SLAUGHTER, AND DISPOSAL
Subchapter: Slaughterhouses, Meat Packing Houses, Meat Depots, and Mobile Slaughter Facilities

Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

32.6.712 FOOD SAFETY AND INSPECTION SERVICE (MEAT, POULTRY)

(1) The Department of Livestock incorporates by reference the following as they were effective August 22, 2016:
   (a) 9 CFR 300.1 through 9 CFR 321.3;
   (b) 9 CFR 325 through 9 CFR 325.21;
   (c) 9 CFR 329.1 through 9 CFR 329.9;
   (d) 9 CFR 352 through 9 CFR 362.5;
   (e) 9 CFR 381.1 through 9 CFR 381.103;
   (f) 9 CFR 381.190;
   (g) 9 CFR 381.194;
   (h) 9 CFR 381.115 through 9 CFR 381.182;
   (i) 9 CFR 381.210 through 9 CFR 381.218;
   (j) 9 CFR 381.300 through 9 CFR 381.524; and
   (k) 9 CFR 416.1 through 9 CFR 500.8.

(2) These regulations set forth the federal rules on meat and poultry inspection with the following exceptions and clarifications thereto:
   (a) Any reference to the "U.S. Department of Agriculture" will mean the "Montana Department of Livestock."
   (b) Any reference to "U.S. inspected and passed" will mean "Montana inspected and passed."
   (c) Any reference to "U.S. passed for cooking" will mean "Montana passed for cooking."
   (d) Any reference to "U.S. passed for refrigeration" will mean "Montana passed for refrigeration."
   (e) Any reference to "U.S. inspected and condemned" will mean "Montana inspected and condemned."
   (f) Any reference to "U.S. retained" will mean "Montana retained."
   (g) Any reference to "U.S. suspect" will mean "Montana suspect."
   (h) Any reference to "U.S. condemned" will mean "Montana condemned."
   (i) Any reference to "regional director" will mean the official in charge of the program within a particular region.
   (j) Any reference to "U.S.D.A. food inspector" will mean "Montana meat inspector."
   (k) Any reference to "U.S.D.A. approval for export" will mean "Montana approval for export."
   (l) Any reference to "U.S.D.A. letterhead and seal" will mean the "State of Montana letterhead and seal."
   (m) Any reference to "U.S. rejected" will mean "Montana rejected."
   (n) Any reference to "U.S.D.A. inspection legend" will mean "Montana inspection legend."
   (o) Any reference to the "Standards and Labeling Division, Meat and Poultry Inspection Technical Services, in Washington, D.C." will mean the "Montana Department of Livestock."
   (q) Any reference to "U.S. government seals" will mean "state of Montana seals."
(r) Any reference to the "Department of Agriculture or divisions thereof in Washington, D.C." will mean "Montana Board of Livestock acting through Montana Department of Livestock" in Helena, Montana.

(s) Any reference to "Compliance Staff, Meats and Poultry Inspection Field Operations, Food Safety and Inspection Service, U.S.D.A., Washington, D.C. 20250" will mean "Chief Inspector in Charge, Meat and Poultry Inspection Program, Montana Department of Livestock, P.O. Box 202001, Helena, Montana 59620-2001."

(t) Any reference to "federally inspected and passed" will mean "Montana inspected and passed."

(u) Any reference to "federal meat inspection" will mean "state meat inspection."

(v) Any reference to "Treasurer of the United States" will mean "Montana Department of Livestock."

(w) Any reference to "general services administration" will mean "Montana Department of Livestock."

(x) Any reference to "secretary" will mean the "Montana Board of Livestock or its delegate."

(y) Any reference to "food safety and inspection service" will mean the "chief inspector in charge, Meat and Poultry Inspection Program, Montana Department of Livestock."

(2) Any reference to "overtime and holiday inspection service" shall be subject to those provisions set forth by the state of Montana for those individuals deemed to be "public employees."

(aa) Any reference to "hearing clerk of the food safety and inspection service" will mean "chief inspector in charge, Meat and Poultry Inspection Program, Montana Department of Livestock."

(ab) Any reference to the "U.S. court of appeals for the District of Columbia" will mean "district court of the state of Montana."

(ac) Any reference to "imported into the United States" will mean "imported into the state of Montana."

(ad) Copies of the above are on file with the Department of Livestock and may be reviewed at that office. In addition, copies of each document are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 for a fee by requesting the appropriate rule number(s).

(ae) Any reference to the word "act" will mean the Montana "Meat and Poultry Inspection Act."

(af) Any reference to the term "administrator" will mean the "chief inspector in charge, Meat and Poultry Inspection Program, Montana Department of Livestock."

(ag) Any reference to the term "program" will mean the Montana "Meat and Poultry Inspection Act."

(ah) Any reference to the term "circuit supervisor" will mean the "meat inspector designated to inspect meat in a particular circuit" or "area."

(al) Any reference to specific provisions of federal law will mean specific provisions of corresponding laws of the state of Montana.

(3) The Code of Federal Regulations is available for review at the Montana State Law Library, 215 North Sanders in Helena or online at www.ecfr.gov

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### Wolves

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Remaining funds  $202,244.66
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<td>Report expenditure to budget comparison report by division and/or bureau and attached boards. This report also compares current YTD expenditures to prior same-period expenditures.</td>
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<p>| Recommendation: |
| Time needed: | Attachments: | Yes X No |
| Board vote required: | Yes No |</p>
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<td>Tahnee Szymanski</td>
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**Agenda Item:** Request to initiate rule change process for ARM 32.2.401

Background Info: The Animal Health Bureau recently printed new alternative livestock certificate of veterinary inspection (CVI) books. The format for the books was changed to bundles of 25 certificates vs. books of 25 certificates. This allowed the certificates to be printed with the State of Montana print services at a greatly reduced cost. We have proposed new language for ARM 32.2.401 to reflect the change in printing costs. The new proposed fee reflects a cost of $11.65 for printing costs and $8.35 for processing time.

\[
32.2.401 \text{ DEPARTMENT OF LIVESTOCK ANIMAL HEALTH DIVISION} \\
\text{FEES} \quad (1) \text{ through } (4)(e) \text{ remain the same.} \\
(f) \text{ SV-7GF - alternative livestock cvi book } 35.00 \quad 20.00 \\
(g) \text{ through (l) remain the same.} \\
\]

AUTH: 81-2-102, MCA
IMP: 81-1-102, 81-2-502, 81-2-704, MCA

Recommendation: Board Approval to proceed with public comment on the proposed language.

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**Agenda Item:** Update on Preparation for 3-Day Functional FMD Exercise (May 8-10, 2018)

Background Info: The Animal Health Bureau is preparing for a 3-day functional Foot and Mouth Disease (FMD) exercise. The exercise will occur May 8-10, 2018 in real-time. The goal of participating in this exercise is to evaluate our current preparedness efforts and to identify systemic gaps in our program in order to improve emergency preparedness planning. To prepare for the upcoming exercise, AHB is working to complete certain recommended activities ahead of the exercise date.

In October, AHB held a facilitated discussion with DES officials on resource management and establishing an Incident Command. A summary of this meeting is included as an attachment. Examples of issues identified during this discussion include:

- How will non-animal health DOL staff be involved in a large-scale disease response? There is a need for more widespread ICS training in the department
- MOA/MOU with other state agencies needed for support – this includes covering functions such as movement control, carcass disposal, decontamination, incident command staff, PIO, logistics and finance, tracking assets, etc.

Additional preparation includes:

- December 5 (10-12 am) – Establishing a state/federal unified command
- January 9 (half day) – Requesting a National Incident Management Team
- February 6-7 and February 20-21 – Incident Command System (ICS) 300 and 400, working with DES to get trainings in Helena to which we could send multiple people
- April 25 – National Veterinary Stockpile (NVS) table top, hopefully working with national NVS team to make this an official NVS table-top exercise

Recommendation: NA

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Montana Resource Management and ICS Discussion

October 25, 2017

Summary:

This discussion focused on a large-scale foot-and-mouth disease (FMD) outbreak in which multiple states were involved, spread across the continental US, with affected premises in Montana. The discussion covered a variety of topics, and more details are listed below. The major conclusion of the discussion was that Department of Livestock (DOL) resources would very quickly be used up in an FMD response, and a governor’s declaration of emergency would be necessary to facilitate access to other state resources. DOL should work with other state agencies (and other states) now, pre-event, to put MOUs/MOAs in place that would be used to access the necessary equipment, personnel, expertise, etc. at the time of a foreign animal disease outbreak. Examples of resources that would be required include: law enforcement personnel for road blocks and monitoring controlled movements, decontamination equipment, carcass disposal, public communications, personnel to fill an IC structure, and methods for tracking resources supplied by other agencies for reimbursement.

Details:

The discussion started by focusing on what resources DOL would need that we don’t currently have. The first thing that came up was support from local law enforcement to help control movement in and out of any disease control zones. This might come from local sheriff’s departments or highway patrol. DOL would need to work with Montana Disaster and Emergency Services (DES) to coordinate and access those law enforcement resources. There would need to be some way to permit people to move out of the control zone, and those doing traffic control on the roads would need to check those permits. The most urgent movements will be for milk, swine, and poultry/eggs. Right now, DOL does not have a mechanism in place to track other agencies’ resources that were used as part of an animal disease response. In addition to law enforcement, DOL would also need to ask for support for truck washes. If vehicles leave premises in a control zone they would need to be washed. At this point we don’t know who in Montana has that equipment and who would be willing/able to share it during an outbreak.

Early on in an outbreak, a governor’s declaration of emergency would be necessary. DOL personnel would be used up very quickly, so would need the governor’s declaration to facilitate access to support from other agencies. It would be good to have some language pre-planned for that emergency declaration that considers what extra authority, or suspension of normal laws, will be necessary for the response (i.e. how would normal brand inspection requirements need to be changed). DES can coordinate resource requests, start with other state agencies, then go inter-state with EMAC requests. Secretary of Agriculture for United States would also declare an emergency as soon as there was a confirmed case anywhere in the US.

The discussion also covered issues of carcass disposal. If Montana is the first state affected, or if we initially only have one affected premises, and we think we can get ahead of the outbreak with a stamp-it-out strategy, we will be depopulating. With DOL personnel alone, could probably euthanize several thousand cattle in a few days. Would need to consider how to dispose of thousands of cattle carcasses. Right now, we don’t have the arrangements in place with Department of Environmental Quality (DEQ) to pre-approve disposal methods. Montana will run into extra problems with carcass disposal because
unburied or improperly disposed of carcasses are attractants for bears and other predators/scavengers. If the outbreak were wider spread, it is unclear at this point if depopulation would still be the primary control strategy.

When discussing what ICS structure would be deployed, DOL has limited personnel to use, would rely on other agencies to fill roles in logistics, finance, PIO, etc. In the case of an FMD outbreak, all DOL personnel in all divisions would be re-tasked to work on the response. The discussion also included issues that might arise depending on the time of year during an outbreak. Forest Service and others have personnel with lots of Incident Command System (ICS) training, but during fire season those people won’t be available. DOL should plan for a worst-case-scenario in which an outbreak occurs either in the middle of fire season or in the middle of the winter. Also consider a scenario in which Montana is not the first affected states, so federal resources have already been used elsewhere.

Consistent public outreach will be important. All agencies involved will need to have the same message and coordinate those outreach efforts. In terms of communication with other states – we will need to work closely with other state animal health officials on permitting movement of animals/animal products out of control zones and across state lines (i.e. cattle moving out of control zone to slaughter in another state). USDA is going to want to know how many infected premises there are and where they are; ideally this information is shared daily or twice daily. In terms of how that information is going to be shared, USDA would like everything in EMRS. If Montana doesn’t get resources from USDA to help with data entry into EMRS, we will be using USAHerds. One thing to work on now is to reach out to other USAHerds states that have used the permitting feature and see how well it worked.

USDA has 5 NIMTs that are two deep in each position. District 5, in which MT is located, also has an IMT, however, those personnel would be used up quickly during a response. Would probably end up with a USDA representative in Montana, but maybe not a whole team.
### Board of Livestock Meeting

**Agenda Request Form**

<table>
<thead>
<tr>
<th>From: Steve Smith</th>
<th>Division/Program: MVDL</th>
<th>Meeting Date: 12/6/2017</th>
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</table>

#### Agenda Item: Fee Update (Clinical Pathology and supplies)

**Background Info:**

When laboratory fees were last updated, testing in the clinical pathology section was omitted from the process. Using the cost analysis data from last year, these fees can be adjusted at this time, to better cover costs while remaining at a competitive market level.

In addition, the laboratory has traditionally provided a number of forms, shipping materials, kits, and other materials to clients. These items have not been previously evaluated for cost or included in administrative rule, and need to be addressed at the same time.

**Recommendation:**

Approval to move forward with a limited fee adjustment in administrative rule and published fee schedule, to address clinical pathology testing and laboratory supplies.

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<th>Time needed: 10 min</th>
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<th>Board vote required:</th>
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#### Agenda Item: Chronic Wasting Disease update

**Background Info:**

Chronic wasting disease (CWD) has been identified in Montana, and it is highly desirable that the laboratory develop and validate in-house testing for this disease, to decrease turn-around time, contribute to public health, and strengthen ties with the department of Fish, Wildlife and Parks. I will provide an update on what it will take to get CWD testing performed at the lab, as well as a possible recommendation for associated action.

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#### Agenda Item:

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</table>
October 29, 2017

Dr. A.W. Layton, Director
Montana Veterinary Diagnostic Laboratory, Montana Department of Livestock
1911 Lincoln Street
Bozeman, MT 59718

Dear Dr. Layton,

The Accreditation Committee of the American Association of Veterinary Laboratory Diagnosticians reviewed the site visit report for the August 20-22, 2017 site visit to the Montana Veterinary Diagnostic Laboratory at the October 2017 meeting of Committee. A copy of the report is enclosed. Following discussion of the report, the Committee granted MVDL Full Accreditation for one year, expiring on December 31, 2018.

Full accreditation is granted contingent on a satisfactory written response by July 1, 2018 for review at the Committee’s August 2018 review of the following:

1. Non-conformances, including documentary evidence, as enunciated in the site visit report.
2. Update on how laboratory with provide adequate oversight of the Bacteriology laboratory section
3. Update on funding for new laboratory facility

You may submit the response electronically by using your laboratory log in on the AAVLD website and following the instructions on uploading documents. Any questions related to uploading documents should be referred to the Accreditation Committee email accreditation@avld.org. Following review of your laboratory response to the audit report, the Committee will reconsider your accreditation status. If you feel you would benefit from a conference call please let us know and we would be happy to arrange one.

On behalf of the Committee, we would like to extend congratulations to you and the staff of the Montana Veterinary Diagnostic Laboratory on implementation of a quality management system that is consistent with the high standards of the AAVLD Accreditation Program and maintaining Full Accreditation through December 31, 2018. We look forward to your future participation in AAVLD activities and wish you continued success in providing the highest quality diagnostic service.

Sincerely yours,

Tim Bazzler, DVM, PhD
Co-Chair
AAVLD Accreditation Committee

cc: Joey Kellum

David Korcal, BS, MT
Co-Chair
AAVLD Accreditation Committee
American Association of Veterinary Laboratory Diagnosticians

Accreditation Committee
Accreditation Audit Report

MONTANA VETERINARY DIAGNOSTIC LABORATORY
MONTANA DEPARTMENT OF LIVESTOCK
BOZEMAN, MT

AUGUST 20 – 22, 2017

Mr. Joseph Kellum, Chair

Dr. Keith Bailey

Mr. Trevor Alexander

Mr. Aaron Stachowiak (Observer)
AAVLD Accreditation Audit Report

TABLE OF CONTENTS

A. Background and General Findings / Executive Summary ....................... 3
   a. Overview / Current accreditation status .................................. 3
   b. Response to previous audit and accomplishments ...................... 5
B. Commendations ............................................................................. 7
C. Conclusions .................................................................................. 7
   a. Requirements ............................................................................ 7
   b. Observations ............................................................................ 7
D. Nonconformances .......................................................................... 8

A. BACKGROUND AND GENERAL FINDINGS / EXECUTIVE SUMMARY
Overview / Current Accreditation Status

The AAVLD accreditation review of the Montana Veterinary Medical Diagnostic Laboratory (from here on called "the lab", "the laboratory", or "MVLD") consisted of a review of the laboratory’s application for accreditation, the quality manual, system support documents, and records of internal audits, corrective actions and management reviews prior to visiting the laboratory facility located in the Marsh Laboratory on the campus of Montana State University in Bozeman, MT on August 20-22, 2017. The AAVLD site visit focused on conformance to the MVLD Quality Manual, quality system procedures, each location’s internal documents, and demonstration of compliance to the AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory (AC1 v 2016-17). Both vertical and horizontal audits were conducted of technical areas, information technology, and administrative/business units of the laboratory. The MVDL site visit report includes information provided in the AAVLD accreditation application, supporting documentation provided by MVDL, on-site observations, as well as interviews with laboratory personnel, the State Veterinarian, and the Board of Livestock (consisting of appointed lab stake-holders). The site visit team was hosted by the Director, Dr. Bill Layton, Pathologist, Dr. Steve Smith, and the Quality Manager, Tess Moore. Their hospitality and assistance before and during the site visit was greatly appreciated by the entire team.

The MVDL is a full service veterinary diagnostic laboratory and is governed by the Montana Department of Livestock. The MVDL provides testing in support of surveillance activities performed by the Montana Department of Livestock for the detection of foreign and regulated domestic diseases. The laboratory also supports Montana livestock and agriculture by assisting in the control, prevention and eradication of animal diseases, promoting a compliant state dairy industry, and promoting the marketability and reproductive health of Montana livestock. MVDL supports veterinarians, livestock producers and companion animal owners by continuously improving client service and satisfaction by providing high quality, cost effective testing, consistent turnaround times, excellent customer service, and accurate data processing and reporting. Emerging opportunities for new and expanded services include the continually stable Brucella testing, potentially CWD testing if identified in MT (has been identified in surrounding states), wildlife testing with increased emergence of new diseases in MT, and potentially avian testing with the expansion of poultry egg production in the state.

The Montana Veterinary Diagnostic Laboratory has made several changes since the last site visit in 2012. Since the last site visit, the Montana legislature zeroed the budget base for the Department of Livestock due to perceived upper management insufficiencies and lack of active participation by the governing body, the Board of Livestock (BOL). This potentially could have closed the MVDL. However, despite the 2015 legislative session being difficult, it resulted in overwhelming support for MVDL and the laboratory received an increase in funding from the General Fund (the funding shifted from the Per Capita Fee to the State General Fund. The Governor’s budget for the next legislative session provided similar General Fund contributions as the previous. Change and restructuring within the Department of Livestock and of the Board of Livestock have resolved the initial concerns and budget cuts, and the legislature and industry are now fully aware of the value and importance of a veterinary diagnostic
laboratory in Montana, as evidenced by the increased funding. In May of 2016, a legislative audit was completed and the findings fully supported the laboratory in the areas of overall importance to the state regarding animal health, revising fee structure to bolster lab budget, obtaining and implementing a new laboratory information management system (LIMS), address building needs, and providing a stable budget for the MVDL.

Several personnel and personnel-related changes have occurred since the last site visit. The MVDL lost several experienced personnel due to retirement or change in employment (i.e. Bacteriology Section Head/Supervisor, on-site IT personnel). There is was no plan on filling these positions. Open positions are being covered by existing personnel. Employees received substantial pay raises due the Department of Livestock not adhering to pay policies. Additional refinement of compensation is underway, including increasing pathologist pay to regional standards. Currently, there are three pathologists at MVDL. All rotate pathology duties while having multiple other functions in the laboratory – one is Director, another is the safety officer and in-house LIMS/IT person, while the third oversees molecular diagnostic test development. The most significant gap in personnel is the lack of a Microbiology/Bacteriology Section Head. This position was requested, but the Governor’s budget did not grant funding for it. There is an off-site IT person housed in Helena, MT, that assists the laboratory, primarily through remote access. However this appears to be insufficient, since additional duties are being placed on lab personnel for on-site IT duties.

Other significant changes or accomplishments since the 2012 site visit were:

- Membership in the NAHLN provided funding that was used to pay the salary of the Quality Manager and to purchase molecular diagnostic equipment.
- In 2015, the MVDL received a $200,000 grant from Homeland Security. The funding was used to purchase a new laboratory information management system. VADDS was purchased and fully implemented in August of 2015.
- In 2016, the MVDL Milk Laboratory was granted full accreditation by the U.S. Food and Drug Administration (FDA) which allows for continued support of the MT dairy industry.

The Marsh Laboratory is an outdated facility that was built in the 1960’s. The MVDL struggles with maintaining proper operation of facility equipment, such as HVAC. It structurally challenges the Lab’s ability to maintain proper test environments (inadequate ambient temperatures), as well as maintaining proper safety, biosafety and biosecurity. Operational controls (procedures) are in place where structural and engineering controls are failing, but increasing age will eventually overcome this and will increasingly adversely affect diagnostic testing and personnel safety. The MVDL, the Department of Livestock and the Board of Livestock are aware of this immediate concern and are in discussions to spearhead a funding proposal for a multi-agency laboratory complex, which will provide a new facility for the laboratory.

Meeting with the State Veterinarian, the Board of Livestock and Legislatures

The site visit team met with Martin Zaluski (Montana State Veterinarian and former interim BOL Executive Officer) and four members of the Board of Livestock – Mike Honeycutt (current Executive Officer), Nina Baucus (cattle/dairy stakeholder and
member), Sue Brown (dairy/egg stakeholder and member), and John Scully (cattle stakeholder and member).

Discussions started with any feedback that they had about the lab. All four complimented the lab in other areas, such as turnaround times, service to the state, and quality of testing. There was one larger concern expressed by all in attendance. They feel that the current Marsh Laboratory facility is badly outdated and is increasingly not able to handle current workloads and future growth.

Mr. Scully provided historical information of MVDL. In the 90’s, the MT legislature and Board of Livestock were split as to whether or not to dissolve the laboratory, but then Brucella in the state increased and, consequently, so did funding to keep the laboratory. The lab was faced with this issue again in 2015 (as detailed in paragraph 3 above), but again not only surviving, but receiving additional funding for operation. Mr. Scully also discussed the laboratory’s presence on Montana State University’s campus not being as beneficial to the lab as it could be (because the MVDL has no teaching or research duty). Lack of attention and funding from the university is contributing to the problems the lab is having with its current facility. He stated (with the confirmation of others) that there is a concentrated effort by industry and the BOL for the consolidation of both administrative oversight by the state (from Helena, MT) and professional oversight by the lab. Along with this effort, there is the potential for a new facility for MVDL.

The new facility being discussed is slated to be in a complex of other state and federal laboratories, and this group fully supports it. Discussions at this point include seeking approval and funding. Actual planning will not happen until after it’s approved. If this happens, they feel that they could increase test capacity beyond previous numbers, and increase the level of service to the state, such as avian testing for poultry egg production industry.

The group acknowledged the importance and overall value of the MVDL’s accreditation through the AAVLD accreditation, even though it’s “still an expense.” The group supports the MVDL fully and will continue to do so into the future.

b. Response to Previous Audits and Accomplishments

1. Requirements

   i. Respond to the non-conformances cited in this report in writing, with documentary evidence, by the date requested in the accompanying letter from the Accreditation Committee Chair.

   **MVDL Response:** "MVDL AAVLD Audit Action Plan, which has links to closed CAPA reports, is attached. Original submission was on 6/11/13 (date requested on report). Second submission is on 7/26/2013 to show continued progress to date:

   - 53 of 87 Corrective Action Reports (CAPAs) have been closed.
   - 22 section CAPAs remain open.
   - 12 QA (systems) CAPAs remain open.
Most of the open section CAPAs involve a systems-wide necessity (i.e. revision of the systems policy and or procedures or further development of a uniform system for all of MVDL). While the QA Manager realizes that the goal of the corrective action process is to achieve timely continuous improvement, she also feels that closing a CAPA before the system is well developed to fully meet the AAVLD requirement will only lead to MVDL QMS user’s frustration as well as future nonconformance.”

**Site Visit Team Observation:** The laboratory successfully responded to all nonconformances from the 2012 site visit (and subsequent follow-up visit in 2014). Only two findings for this site visit were related to non-conforming work and corrective actions. The open/closed status of current corrective actions seemed appropriate.

ii. Complete implementation of the revised MVDL Quality System in all laboratory sections, with emphasis on staff training on the new system, implementation of the document control procedures, training records, preventive actions, and internal audits.

**MVDL Response:** “Progress continues in the development of a more robust QMS. Since the AAVLD Site Visit, the MVDL QA Committee, which is composed of the Lab Director, the QA Manager, the Safety Officer, the Second-in-Command Pathologist and all Section Supervisors has met 12 times.

**QAC Meeting Agendas & Attendance**

Meetings have included report authorizations revisions, audit action plan progress, document control (x6), environmental monitoring, equipment monitoring and training program requirements. Several WADDL/USDA modules have been reviewed to facilitate QMS training. Group revision of systems test report completion has also been very beneficial.”

**Site Visit Team Observation:** The implementation of the quality system was observed to be complete and any observed issues were recorded as findings in this report.

2. Recommendations

i. Identify additional training opportunities for the Quality Manager to increase knowledge and interpretation of AAVLD requirements and quality systems in diagnostic laboratories.

**Site Visit Team Observation:** To increase knowledge and interpretation consistency of AAVLD Requirements and quality systems, the Quality Manager has contacted and used other accredited laboratories as a resource for information, as well as, attended AAVLD events, such as the Quality Symposia and Quality Committee meetings and trainings.
ii. Continue working aggressively with the Board of Livestock, BOL Executive Officer, and Montana State University on funding for a new facility to replace the Marsh Laboratory. The Marsh Laboratory is reaching the end of its lifespan as a facility that can house a modern, accredited laboratory supporting animal health testing of vital importance to the livestock industry in the State of Montana and to public health. All laboratory stakeholders should be cognizant of the economic, health, and public relations impact of a single adverse event arising from an inadequate laboratory facility.

Site Visit Team Observation: The laboratory stakeholders, the MT State Veterinarian, and MT legislature are very aware of the vital importance and benefits of the MVDL to the livestock industry and to public health. An organized effort is underway to obtain approval for funding to build a new facility for MVDL. This will continue to be an ongoing issue until this happens.

B. COMMENDATIONS

1. Records for PCR validation and select control charts for ELISA were extremely well organized and detailed.

C. CONCLUSIONS

a. Requirements

1. Respond to the nonconformances cited in this report in writing, with documentary evidence, by the date requested in the accompanying letter from the Accreditation Committee Chair.

2. Provide update on how the laboratory will provide adequate oversight of the Bacteriology laboratory (see nonconformance #1).

b. Observations

1. The lack of HEPA filtration in the Molecular Diagnostic lab increases the risk of potential contamination from outside airflow.

2. G-force can vary between centrifuges due to the rotor length effecting the rotational radius. Listing the relative centrifuge force (g) instead of RPM’s in the Parasitology procedure for fecal floatation may prevent test results from being adversely affected.

3. The use of “recommendation” terms, such as should, optimally, preferably, routinely in laboratory documents could be changed to “requirement” terms, such as will, must, shall, as necessary, to be more consistent with the AAVLD Requirements.
4. For weights that are used to calculate the fee charged for the disposal of carcasses and tissues, using a calibrated scales (none were observed to be present in necropsy) would enable accurate weights to be recorded (the current weights are being estimated).

5. IT support is insufficient since loaded on lab personnel. The laboratory has an off-site IT person housed in Helena, MT, that assists the laboratory, primarily through remote access. However this appears to be insufficient, since additional duties are being placed on lab personnel for on-site IT duties.

D. **NONCONFORMANCES NOTED DURING SITE VISIT**

**SPECIFIC REQUIREMENTS**

<table>
<thead>
<tr>
<th>4. Management Requirement</th>
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<tr>
<td><strong>4.1 Organization and Management</strong></td>
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<tr>
<td>4.1.4 The laboratory shall:</td>
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<tr>
<td>e) specify the responsibility, authority and inter-relationships of all personnel who manage, perform or verify work affecting the quality of the tests;</td>
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**AAVLD Requirements for Microbiology Section Head.**

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<th>Nonconformance: #1</th>
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<tr>
<td>The laboratory did not always:</td>
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<tr>
<td>e) specify the responsibility, authority and inter-relationships of all personnel who manage, perform or verify work affecting the quality of the tests;</td>
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**Example(s):**

a. System – The organizational chart (document #4.1.1.1) for the laboratory does not clearly show reporting authority, evidenced by no defined section head or supervisor for Microbiology. Neither person supervising the day-to-day operation of this laboratory meets the AAVLD Minimum Personnel Qualifications for Microbiology Section Head.

**Response:**

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<td>i) appoint backups or deputies for key managerial personnel such as the quality manager.</td>
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<th>Nonconformance: #2</th>
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<tbody>
<tr>
<td>The laboratory did not always:</td>
</tr>
<tr>
<td>i) appoint backups or deputies for key managerial personnel such as the quality manager.</td>
</tr>
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</table>

**Example(s):**
a. System – There was no observed (organizational chart) or stated backup or deputy for the quality manager position.

Response:

4.2 Quality system
4.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities, including the type, range and volume of testing it undertakes. The laboratory management shall document its policies, systems, programs, procedures and instructions to enable the laboratory to ensure to the extent possible, the quality of the test and diagnostic interpretations it generates. Documentation used in this quality system shall be communicated to, understood by, available to and implemented by the appropriate personnel.

Nonconformance: #3
Documentation used in the quality system was not always understood by and implemented by the appropriate personnel.

Example (s):

a. Histopathology – Several procedures (5.4.700.4, 5.4.700.6, 5.4.700.8) revised and issued by the laboratory were available to personnel on 06/02/2017, but bench records indicate that work was being performed by personnel that did not read and acknowledge the new procedures until 08/01/2017.

Response:

4.3 Document Control
4.3.1 The document control system shall ensure that only the current version of the correct document is in use in the laboratory and that documents needed for staff to perform their work are available at the work location.

Nonconformance: #4
The laboratory's document control system did not always ensure that only the current version of the correct document is in use in the laboratory and that documents needed for staff to perform their work are available at the work location.

Example (s):

a. Histopathology – Equipment manual/instructions for pH meter was not controlled.

b. Molecular Diagnostics – Posted document “Montana Department of Livestock ABI 7500 SOP” was not controlled.

c. Molecular Diagnostics – A notebook containing multiple uncontrolled documents was found (i.e. TF PCR procedure and Hemocytometer procedure).

   Auditor’s note: This was discarded during audit.

d. Serology – The Sentry 200 Calibration manual (Feb 2016 edition) was
observed to be in use but not controlled.

e. System – External documents (i.e. NAHLN procedures) are controlled, however, distributed versions are not marked as per laboratory document control procedure (4.3.1.0).

Response:

4.3 Document Control

4.3.2 The laboratory shall have documented policy, procedures and/or work instructions that describe how laboratory documents affecting the quality of tests, including test methods, are reviewed, approved, issued, updated, revised, amended, retained or archived and discarded. Procedures shall be reviewed and approved by authorized, qualified staff.

Nonconformance: # 5

The laboratory did not always have documented policy, procedures and/or work instructions that describe how laboratory documents affecting the quality of tests, including test methods, are reviewed, approved, issued, updated, revised, amended, retained or archived and discarded.

Example (s):

a. System – The laboratory’s document control procedure (4.3.1.0) did not have clear instructions for how to collect and discard obsolete documents.

Response:

4.3 Document Control

4.3.4 Documents shall be uniquely identified and accurately cross-referenced.

Nonconformance: # 6

Documents were not always uniquely identified and accurately cross-referenced.

Example (s):

a. System – The User Guide & Fee Schedule (revised & effective date 8/21/17) was not uniquely identified.

Response:

4.5 Subcontracting of test services

4.5.1 When a laboratory offers tests that are subcontracted, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting or agency arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with the AAVLD Requirements or ISO 17025 for the work in question.

Nonconformance: # 7

When the laboratory offered tests that are subcontracted, because of unforeseen reasons or on a continuing, the work was not placed with a competent subcontractor.
Example(s):

a. System – The laboratory quality manual (version 2017-02, section 4.5) states that the lab does not subcontract testing. However, when there was an equipment failure in Clinical Pathology on 07/07/2017, “referral” work was subcontracted to a laboratory that had no record of competency, as evidenced by reports #18-269 – 18-274).

Response:

4.6 Purchasing services and supplies
The laboratory shall have a policy and procedures to ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of test results. These procedures shall include a description of the criteria for selection, evaluation, use, handling and storage of materials and reagents having an effect or potential effect on test results.

Nonconformance: # 8
The laboratory does not always ensure that services and supplies meet pre-established specifications and do not adversely affect the quality of test results.

Example(s):

a. Microbiology/Media Prep – The record for the in-house preparation of the batch of Campylobacter Selective Agar currently in use was made with 5% Donor Sheep RBC (lot #S-49364) that expired on 08/17/2017.

b. Histopathology – pH buffer solutions with an expiration date of 1/2015 were observed in use.

Response:

4.8 Control of nonconforming testing and test results
4.8.1. The laboratory shall have a policy and procedures that ensure that nonconforming testing (conditions that exist which have or could adversely affect the reliability of test results) is detected and promptly corrected. The laboratory shall have procedures for informing clients if test results are questionable or incorrect, particularly if this possibility is identified after test results have been reported to the client. These procedures shall describe who has the authority to withhold test results, implement corrective action and authorize resumption of work.

Nonconformance: # 9
The laboratory does not always ensure that nonconforming testing (conditions that exist which have or could adversely affect the reliability of test results) was detected and promptly corrected.

Example(s):

a. Clinical Pathology – The LYPHO3 T4 control was high (14.4, acceptable range 9.65-13.69) and no record of action taken was available.
4.9 Corrective and preventive action
4.9.1 The laboratory shall have a policy and procedures for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system have been identified. The policy and procedures shall ensure:
   e) once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem; and

Nonconformance: # 10
The laboratory did not always ensure:
   e) once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem; and

Example (s):
   a. System – All laboratory section’s Issue & Nonconformance log did not have documented review by the QA manager or Designee since 2015 as required by SOP 4.8.1.0. Multiple trending events were observed throughout multiple records that had neither a record of being identified nor documented action taken.

Response:

4.10 Records
4.10.1 General
4.10.1.3 All records shall be held secure and in confidence.

Nonconformance: # 11
All records are not always held secure and in confidence.

Example (s):
   a. System – Diagnostic testing records were being maintained in unlocked file cabinets located in the publically-accessed front door area.

Response:

4.10 Records
4.10.2 Technical records
4.10.2.1 The laboratory shall retain for a defined period of time original observations, derived data, calibration records, staff records, a copy of each test report issued and any other information necessary to recreate the activity. The records for each test shall contain sufficient information to facilitate identification of factors affecting the quality of test results and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel.

Nonconformance: # 12
The records for each test does not always contain sufficient information to facilitate identification of factors affecting the quality of test results and to enable the test to be repeated under conditions as close as possible to the original.

**Example (s):**

a. Clinical Pathology – Reference ranges used for testing were validated, but there was no record maintained.

b. Histopathology – 0.1M NaCitrate observed in use was not traceable to the sections reagent/lot tracking log as required by SOP 5.6.1.0.

c. Molecular Diagnostics – In-use Vetmax Xeno internal positive control RNA (lot #1601002) labeled “XRNA 17-B2” does not match the lot (#1603006) associated with “XRNA 17-B2” recorded in the lot tracking record.

d. Parasitology – No lot tracking record observed for Zinc Sulfate as required by SOP 5.6.1.0.

e. Pathology – The unique ID of the thermometer (s/n #930368) being used for recording temperatures for the -30 freezer was not recorded.

**Response:**

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**4.10 Records**

4.10.2 Technical records

4.10.2.2 Observations, data and calculation shall be clearly and permanently recorded and identifiable to the specific test at the time they are made.

**Nonconformance: #13**

Observations, data and calculation were not always clearly and permanently recorded and identifiable to the specific test at the time they are made.

**Example (s):**

a. Pathology – Form 52.1000.1005 Pathology Guidelines, Responsibilities, Environmental Requirements included multiple daily, weekly, and monthly instructions for the Necropsy area, but contained no record of being performed. 

   *Auditor’s note: Instructions included cleaning of Necropsy, changing the footbath, and cleaning & disinfecting counters.*

b. Pathology – A ‘sticky’ note indicating a completed action of cleaning blood out of freezer for equipment #3281 was found in equipment maintenance folder in Receiving and not permanently recorded on equipment maintenance log.

**Response:**

---

4.10 Records

4.10.2 Technical records

4.10.2.3 When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible or deleted) and the correct value entered alongside. All such alterations to records shall be
dated, signed or initialed by the person making the correction. In the case of computer collected data, similar measures shall be taken to avoid loss or change of original data.

**Nonconformance: #14**

When mistakes occur in records, each mistake was not always crossed out (not erased, made illegible or deleted) and the correct value entered alongside.

**Example (s):**

a. Pathology – Multiple entry errors were observed to be improperly corrected in the MVDL Incinerator Burn & Maintenance Log (5.5.800/3901) as required by SOP 4.10.1.1.

b. Milk – Multiple entry errors were observed to be improperly corrected on the Milk Lab Postage Log (4.10.300.132) on a refrigerator/freezer.

**Response:**

**4.11 Internal audits**

4.11.1 The laboratory shall periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and the AAVLD Standard. The internal audit program shall address all elements of the quality system, including testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities, except when it can be demonstrated that an effective audit can be carried out.

**Nonconformance: #15**

The laboratory did not always conduct internal audits of its activities, periodically and in accordance with a predetermined schedule and procedure, to verify that its operations continue to comply with the requirements of the quality system and the AAVLD Standard.

**Example (s):**

a. System – There are no records of internal audits being conducted in 2016 (Laboratory procedure 4.11.1.0 requires them to be conducted annually).

**Response:**

**4.12 Management reviews**

4.12.1 The quality system and test related activities shall be reviewed by management at least once per year.

**Nonconformance: #16**

The quality system and test related activities were not always reviewed by management at least once per year.

**Example (s):**

a. System – There were no records of management reviews being performed for
5.2 Personnel
5.2.3 The laboratory shall have a system that ensures the establishment and maintenance of a training program relevant to the present and anticipated needs of the laboratory.

Nonconformance: #17
The laboratory had a system that did not always ensure the establishment and maintenance of a training program relevant to the present and anticipated needs of the laboratory.

Example (s):
  a. Histopathology – Incomplete training records observed for technical personnel for multiple SOPs in Histopathology including SOPs 5.5.700.03 and 5.5.700.75.

Response:

5.3 Accommodation and environmental conditions
5.3.2 The laboratory shall monitor, control and record environmental conditions as required by relevant specifications or where they may influence the reliability of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, radiation, humidity, airflow, electrical supply, temperature and sound and vibration levels, as appropriate to the technical activities concerned. Test activities shall be stopped when the environmental conditions jeopardize the test results.

Nonconformance: #18
The laboratory did not always monitor, control and record environmental conditions as required by relevant specifications or where they may influence the reliability of the results.

Example (s):
  a. Serology – EIA ELISA incubation was observed occurring at 25 +/- 2°C (SOP 5.4.500.701 states to incubate at “room temperature”), but the VMRD testing kit insert (version 150722) instructs incubation to occur at 23°C +/- 2°C.

Response:

5.3 Accommodation and environmental conditions
5.3.5 The laboratory shall ensure the establishment and maintenance of safety, biosafety, biocontainment and biosecurity programs relevant to present and anticipated needs. The programs will provide staff training and address all necessary elements to ensure a safe work environment.

Nonconformance: #19
The laboratory did not always ensure the establishment and maintenance of safety, biosafety, biocontainment and biosecurity programs relevant to present and anticipated needs.
Example (s):

a. System – No record of a safety meeting since 12/17/13 as required by SOP 5.3.3.0.

b. Sample Receiving – The counter top was made of a porous material and no preventive measures were taken to prevent the absorption of hazardous materials during a biological/chemical spill.

c. Virology – Laboratory staff was observed handling and reading prepared slides for rabies virus fluorescent antibody (FA) tests without donning disposal gloves or a lab coat as required by SOP 5.3.3.0 (section 5.0).

Response:

5.4 Test methods
5.4.1 General
5.4.1.1 The laboratory shall use appropriate test methods and related procedures for all animal disease diagnostic testing activities. Consideration shall be given to all factors that impact the relevance of the test method and test results to a specific diagnostic interpretation or application. These factors include the suitability of the test method, its acceptability by the scientific and regulatory communities, its acceptability to the client and its feasibility given available laboratory resources. See 5.4.3.1 note.

Nonconformance: # 20
The laboratory did not always use appropriate test methods and related procedures for all animal disease diagnostic testing activities.

Example (s):

a. Parasitology – Case 17-21 identification, by fecal floatation, of Strongyloides sp. with no measurement of ova size for accurate identification of ova as required by SOP 5.4.400.502.

Response:

5.4 Test methods
5.4.1 General
5.4.1.4 The laboratory shall have written instructions for all tests and related procedures used in its routine activities, the calibration and operation of all relevant equipment and the collection, handling, transport and storage of specimens and preparation of samples for testing.

Nonconformance: # 21
The laboratory did not always have written instructions for all tests and related procedures used in its routine activities, the calibration and operation of all relevant equipment and the collection, handling, transport and storage of specimens and preparation of samples for testing.

Example (s):

a. Microbiology – No specific procedure for the quantification of bacteria was
observed.

b. Parasitology – No specific procedure for quality check (specific gravity) when making sugar floatation solution were observed.

c. Virology – There was no work instructions observed for safely handling of non-human primate tissues and specimens.

Response:

5.4 Test methods
5.4.2 Selection of methods
5.4.2.3 Test methods shall contain enough critical and descriptive information such that experienced personnel can properly perform the test within pre-established control limits without reference to information sources outside the laboratory’s document control system. In addition, it shall include as appropriate:

Nonconformance: #22
Test methods did not always contain enough critical and descriptive information such that experienced personnel can properly perform the test within pre-established control limits without reference to information sources outside the laboratory’s document control system.

Example(s):

a. Microbiology –
   - Case 17-17249 – Staphylococcus pseudintermedius identified by only catalase and coagulase reactions.
   - Case 17-21799 – Pantoea sp. identified only by oxidase and indole reactions.
   - Case 17-21800 – Alpha-hemolytic Streptococcus sp. identified by hemolysis and catalase reaction only.
   - Case 17-1373 – Coagulase negative Staphylococcus sp. identified by Coagulase reaction only.

b. System – Laboratory procedure SOP 5.5.400.15 states that calibration of the CO2 ViaSensor “should” be done every 12 months. Due to the lack of requirement, the CO2 ViaSensor calibration has not been done since 11/03/2015.

Response:
g) a list of and specifications for equipment, materials and reagents, including software;

**Nonconformance: # 23**
Test methods did not always include as appropriate:
  g) a list of and specifications for equipment, materials and reagents, including software;

**Example (s):**

  a. System – MVDL Incubator Use, Monitoring & Maintenance Guidelines
     Systems SOP 5.5.100.41 does not specify at what CO2 tank pressure to change the CO2 tank for CO2 incubators.

**Response:**

---

### 5.4 Test methods

5.4.2 Selection of methods
5.4.2.3 Test methods shall contain enough critical and descriptive information such that experienced personnel can properly perform the test within pre-established control limits without reference to information sources outside the laboratory’s document control system. In addition, it shall include as appropriate:

k) a description of the controls used and their acceptance limits;

**Nonconformance: # 24**
Test methods did not always include as appropriate:

k) a description of the controls used and their acceptance limits;

**Example (s):**

  a. Virology – BRSV Neutralization Test SOP 5.4.600.401 does not specify the ATCC strain of bovine kidney cells to be used for testing.

**Response:**

---

### 5.5 Equipment

The laboratory shall possess or have access to all equipment necessary for the correct performance of all services. All equipment shall be identified, properly maintained and calibrated with maintenance and calibration procedures documented.

**Nonconformance: # 25**
All equipment was not always properly maintained and calibrated with maintenance and calibration procedures documented.

**Example (s):**

  a. Histopathology – Written instructions requiring weekly maintenance on MVDL General Equipment Maintenance, Calibration & Service Log 5.5.1.1 for TissueTek 6 is not specified in SOP 5.5.700.22.

**Response:**
5.5 Equipment
5.5.4 Each item of equipment used for test activities significant to a test result shall be uniquely identified.

**Nonconformance: # 26**
Each item of equipment used for test activities significant to a test result was not always uniquely identified.

**Example (s):**

a. Histopathology – No unique identification observed for pH meter.

Response:

5.5 Equipment
5.5.5 Records shall be maintained of each item of equipment significant to the tests performed. The records shall include at least the following:

c) verification that equipment complies with the specification;

**Nonconformance: # 27**
The laboratory equipment records did not always include verification that equipment complies with the specification;

**Example (s):**

a. Milk, Molecular Diagnostics – There was not a record of calibration check traceability for reference thermometer (#1145) that expired 01/30/2016. 
*Auditor’s note: The lab had a deviation in place (07/01/2014) to extend the expiration by 3 years, but it expired when the thermometer expired on 01/30/2016.*

Response:

5.5 Equipment
5.5.5 Records shall be maintained of each item of equipment significant to the tests performed. The records shall include at least the following:

g) maintenance carried out to date and the maintenance plan;

**Nonconformance: # 28**
Records were not always maintained of each item of equipment significant to the tests performed. The records did not always include at least the following:

g) maintenance carried out to date and the maintenance plan;

**Example (s):**

a. Histopathology – No record of monthly maintenance, as indicated on Equipment Worksheet, for TissueTek 6 equipment (s/n #4052) between dates 12/29/2016 – 05/02/2017.

b. Pathology – No record of monthly maintenance for BSC (s/n # 82490022403)
as required by SOP 5.5.100.06.

c. Pathology – There is no record of checking/maintaining hoist components on the Hoist Operation & Maintenance Log for each quarter of 2016-2017 as required by MVDL 5.5.800.34.

d. Molecular Diagnostics – BSC 4071 Equipment maintenance log instructs “deep cleaning” is performed once every three months, but was not recorded as being done from 10/06/2016 to 01/12/2017, as required by SOP 5.5.100.06.

e. Molecular Diagnostics – No equipment maintenance records observed for all freezers and refrigerators in Molecular Diagnostics before 2017.

Response:

5.6 Measurement Traceability

5.6.3 Reference equipment, standards or materials used in conjunction with testing activities shall be handled, maintained and stored in a manner that ensures proper performance and/or accuracy.

Nonconformance: # 29
Reference equipment, standards or materials used in conjunction with testing activities was not always maintained in a manner that ensures proper performance and/or accuracy.

Example (s):

a. Virology – The calibration plate (s/n #1302006676) used on 07/27/2017 to check the calibration and accuracy of the Sunrise plate reader (s/n #11110054456) expired on 06/08/2017.

Response:

5.6 Measurement Traceability

5.6.4 Biological reference material shall, where possible, be traceable to accepted international standards or to OIE reference materials (e.g., International Standard Sera).

Nonconformance: # 30
Biological reference material was not always, where possible, traceable to accepted international standards or to OIE reference materials (e.g., International Standard Sera).

Example (s):

a. Virology – NVSL BRSV QC strain (lot #090914) is not traceable to the NVSL BRSV QC strain (lot #110 BDV 1401).

Response:

5.9 Ensuring the quality of test results
The laboratory shall have quality control procedures for monitoring the validity of test results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) internal quality control schemes using statistical techniques (e.g., control charts);
Nonconformance: # 31
The laboratory did not always have quality control procedures for monitoring the validity of test results. This monitoring was not always planned and reviewed and include, but not be limited to, the following:
  a) internal quality control schemes using statistical techniques (e.g., control charts);

Example(s):
  a. Virology – No procedure for defining the process for generating and monitoring control charts for virus neutralization assays was observed.

Response:

5.10 Reporting test results
5.10.1 The results of each test performed by the laboratory shall be reported accurately, clearly, unambiguously and objectively and in accordance with any specific instructions in the test method or contract.

Nonconformance: # 32
The results of each test performed by the laboratory was not always reported accurately, clearly, unambiguously and objectively and in accordance with any specific instructions in the test method or contract.

Example(s):
  a. System – A laboratory test report (#17-32) contained the incorrect age and sex of the animal when compared to the submittal form.

Response:

5.10 Reporting test results
5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information:
  k) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report.

Nonconformance: # 33
The laboratory did not always have the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report.

Example(s):
  a. There was no function reported for authorizing personnel for the following reports: 17-16, 17-17, 17-33, 17-21, 17-16, 17-22, 17-212, and 17-404.

Response:
<table>
<thead>
<tr>
<th>Agenda Item:</th>
<th>Brand Policy and Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background Info:</td>
<td>Presentation of suggested changes to the 2013 Board-approved policy for new brands and transfers.</td>
</tr>
<tr>
<td>Recommendation:</td>
<td></td>
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<tr>
<td>Time needed:</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Attachments:</td>
<td>Yes</td>
</tr>
<tr>
<td>Board vote required?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

| Agenda Item: | Requests to Hire |
PRESCRIBED PRACTICE FOR
RECORDING, TRANSFERRING AND REREcORDING OF BRANDs

These rules are put into practice to implement the provisions of Title 81-1-102, MCA which allows the department to create and administer a program for recording, rerecording and transfer of livestock brands. The prescribed practices provide clarification and continuity of policies and procedures previously used as guidelines.

RECORDING AND TRANSFERRING OF BRANDs

All Montana brands must be issued through the Department of Livestock Helena Brand Office.

1. All forms or model letters issued for purposes of recording brands or clarifying brand recording requirements are considered part of the brand rules and practices of the Board of Livestock.
   a. Department employees have advanced opportunity to acquire desirable brands.
   b. Employees shall not take unfair advantage of this opportunity, and may not record:
      i. More than three brands at any time;
      ii. Brands by phone;
      iii. For others in any manner;
      iv. Any brand which has not been available for recording less than sixty days;
   c. Employees attempting to circumvent these rules are subject to disciplinary action.

2. The Department of Livestock, as one of its primary duties to the livestock industry, provides brands that are distinguishable with reasonable certainty from all other marks and brands.
   a. Department employees have advanced opportunity to acquire desirable brands.

3. Fees
   a. Brand fees are set by the Board of Livestock as authorized by statute. Current fees are available in ARM 32.2.404.
   b. Fees for new brands or transfers shall not be prorated.
   c. Fifty percent of the fee to record a new brand or transfer a brand is non-refundable.
      i. If an applicant fails to respond to Brand Office correspondence for a period of six months, the entire new brand or brand transfer fee becomes non-refundable.

4. Brand Owner Name
   a. The brand owner name on new brand applications and brand transfers must consist of individuals or entities with documentable proof of identity.
      i. Individuals must use legal names.
      ii. Businesses & trusts must be registered with Montana Secretary of State.
   b. Where multiple individuals or entities appear on a brand owner name, either “and” or “or” must be used between owner names per ARM 32.18.105. No other notation or description is allowed (ex. DBA, hyphens, commas, parentheses, in care of, “and/or”).
   c. Legal Name Change
      i. A legal name change, such as for marriage, may be completed with a Name Change Affidavit and appropriate duplicate certificate fee.

5. Changes to brand image, species, or position require submission of a New Brand Application.

6. New Brand Applications:
   a. Application forms for new brands are available on the Department website and at the Helena Brand Office.
b. The application and appropriate fee must be submitted to the Brand Recorder for processing.
   i. The applicant must list brand choices in preferential order.
   ii. One application may contain up to three different species with one position
       each and Freeze Brand for cattle per ARM 32.18.109.

c. Applications will be processed in the order in which they are received.

d. Notwithstanding any other provision or policy, a brand will not be held or checked
   for conflicts by phone.

e. The Brand Recorder shall process the application in the following manner:
   i. Verify that the application is complete and the correct fee has been submitted.
      1. If incomplete, the entire application and fee are returned with
         instructions to correct the information and resubmit.
   ii. Deposit fee.
   iii. Check for conflicts in the order listed on the application.
      1. The first brand on the application that does not conflict with existing
         brands will be issued to the applicant.
   iv. Issue brand and/or communicate results with applicant:
      1. If none of the applicant’s submissions are available, the Brand
         Recorder may check a similar brand for conflicts and offer it as an
         alternative.
      2. If an available brand was not on the original application, the applicant
         must complete a new application containing the exact image and
         location of the brand presented as available.
      3. The applicant will have 10 working days from the date of the offer
         letter to accept an available brand, whether it was submitted on the
         original application or offered as an alternative, after which the brand
         must be rechecked for conflicts.

7. Brand Transfers
   a. Brand transfer requests must be submitted to the Helena Brand Office with the
      appropriate fee.
   b. Transfer requests must be completed using the Assignment of Brand form, located
      on the reverse side of the current official brand certificate, or an approved Assignment
      of Brand included with the current official brand certificate.
   c. The Assignment of Brand must include the notarized signatures of the original
      owners as listed on the front of the official brand certificate;
   d. If the original owner of the transferring brand is deceased, a copy of the death
      certificate, personal representative papers, or appropriate documentation must be
      provided to complete the transfer;
      i. Certified copies may be required at the Department’s discretion to ensure the
         authenticity of the documents.

CONFLICT CHECKING PROCEDURES

1. Upon receipt of a brand application, the Brand Recorder checks conflicts as follows:
   a. Verify that brand contains only acceptable characters.
      ii. 2, 3, 4, 5, 6, 7, 8, 9

Modified 12/6/2017
iii. Box, Diamond, Heart, Triangle, Cross
iv. Bar, Slash, Quarter Circle

b. Verify that brand is in an acceptable format:
   'H' and 'B' may be replaced with any acceptable character in i.-iii. (above) and/or rotated 90 degrees either direction. Triangle and Heart may be rotated 90 degrees either direction or inverted.

\[
\begin{array}{ccccccc}
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
\end{array}
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\[
\begin{array}{ccccccc}
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
  H_B & H_B & H_B & H_B & H_B & H_B & H_B \\
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\end{array}
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c. Check brand for open positions;
d. Check for brand recordings in the same or adjoining county on the same side;
   i. Rib or Shoulder and Hip shall not be considered a conflict, but rib and shoulder may be (Contact the District Investigator(s) in the area)
e. Check for state-wide conflicts.
   May be rotated 90 degrees either direction or 180 degrees.

\[
\begin{array}{ccccccc}
  A = \Lambda & C = \subset & E = \varepsilon & L = \lambda & P = \wp & S = 5 & Z = 2 \\
  \square = \diamond & + = X & \downarrow = 4 & \left( = \right) \\
\end{array}
\]

f. Check for Regional Character Conflicts
   i. May be updated by the Brands Review Advisory Committee as needed in between BOL meetings for final approval.
REGIONAL CHARACTER CONFLICTS
Conflicts listed below are evaluated in the same county and adjacent counties indicated on the brand application. If the figures in the character column are rotated, the conflicts listed would rotate the same as the character. Conflicts listed for characters with symmetry would be a conflict in all orientations for which the symmetry exists.

<table>
<thead>
<tr>
<th>Character</th>
<th>Conflicts</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>Λ H R △</td>
</tr>
<tr>
<td>B</td>
<td>E K P R 3 8</td>
</tr>
<tr>
<td>C</td>
<td>G O 6 9 ≤ ≤</td>
</tr>
<tr>
<td>D</td>
<td>◊ O P b □ C △</td>
</tr>
<tr>
<td>E</td>
<td>F L Σ ε</td>
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<tr>
<td>F</td>
<td>E P = \</td>
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<tr>
<td>H</td>
<td>+ M N 4 ㅏ ㅏ W</td>
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<tr>
<td>J</td>
<td>J U J</td>
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<tr>
<td>K</td>
<td>B H R X Y</td>
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<tr>
<td>L</td>
<td>E ▎ V ▎ l</td>
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<tr>
<td>M</td>
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</table>
RECORDING OF BRANDS

1. Each 10th year after 1921 is the year for rerecording marks and brands.
2. The brand owner is responsible for rerecording their brand(s) during the rerecord year.
3. Brands that are transferred during the rerecord year must pay a separate fee, per ARM 32.18.111(3).
4. If the department receives a rerecord notice which appears to be different than the previous recording, it shall verify the ownership or treat it as if it were a transfer of the brand.
5. Brands that are not rerecorded prior to the rerecord deadline expire and are no longer the property of the last recorded brand owner.
   a. For a period of 90 days following the rerecord deadline, only the last recorded brand owner may apply for an expired brand.
      i. Expired brands must pass the conflict check process.
      ii. Expired brands that do not meet the current policies for new brand applications will not be reissued.

BRANDS REVIEW ADVISORY COMMITTEE

1. This committee makes recommendations to the Brand Recorder to assist in the resolution of issues and conflicts including those not specifically addressed in the Department's brand recording practice statement.
2. The committee shall meet as necessary to review brand applications that have conflicts per Brand Recorder research.
3. The committee is made up of the executive officer, brands division administrator, assistant administrator, brands recorder, and district investigator.

SCATTER BRANDS

1. Scatter brands are defined as a single brand recording in which an image or images must be applied to multiple locations on a single animal.
2. The use of scatter brands is inconsistent with the department's policy and responsibility of providing easily recognized and distinguishable brands to all livestock owners.
3. Scatter brands will no longer be issued; those on record will be continued subject to their cancellation where possible.

FEEDLOT BRANDS

1. Feedlot brands may be available, subject to the following:
   a. the use of the brand is restricted to the specific feedlot registering the brand;
   b. the brand may be recorded on either hip near the tail head;
   c. the recorded feedlot brand cannot be less than 2" in height.
JAW & NECK BRANDS

1. Except for Department of Livestock Animal Health Division use, jaw and neck brands for cattle shall not be issued.

BRAND POSITION

1. Brands will be recorded by position.
   a. Each position shall be a separate brand.
   b. Positions are available on horses, cattle, hogs, bison and sheep:
2. Horse Positions: There are eight primary positions available on horses:
   a. left thigh or right thigh
   b. left shoulder or right shoulder
   c. left jaw or right jaw (not worked for conflicts unless requested)
   d. left neck or right neck (not worked for conflicts unless requested)
3. Cattle Positions: There are six primary positions available for cattle:
   a. left hip or right hip
   b. left rib or right rib
   c. left shoulder or right shoulder (not worked for conflicts unless requested)
4. Hogs: Brands on hogs will be by request only and issued on a case by case basis.
5. Bison Positions: There are four primary positions available for bison:
   a. Left or Right Hip
   b. Left or Right Rib
6. Sheep: Paint brands will be issued for positions on left/right rib, left/right hip, left/right shoulder and back