

# **PMO APPENDIX N**

# **REMINDERS, UPDATES AND**

# **TETRACYCLINE PILOT PROGRAM**

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*Michigan Department of Agriculture & Rural Development*

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## TOPICS TO DISCUSS

- Appendix N 2400 forms and related documents
- Load Sample Retention
- DY 325 MOU between MDARD and Dairy Industry
- DY 327 Verification of Disposal of Confirmed Positive Antibiotic Milk
- Tetracycline Testing Pilot Program
- Updates from the 2019 NCIMS
- 2019 Appendix N Analyst Workshop



# APPENDIX N 2400 & RELATED DOCUMENTS

- 2400 series forms now available on NCIMS.org
  - per resolution #9 at 2011 NCIMS
  - Rev. 4/2019 List of 2400 forms

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**NCIMS**  
National Conference on Interstate Milk Shipments

LEADERSHIP CONFERENCES FACILITIES PROGRAMS 2400 FORMS ABOUT



**ASSURING THE SAFEST POSSIBLE MILK SUPPLY FOR ALL THE PEOPLE**

The Conference is a non-profit organization made up of persons involved in the dairy industry, from the dairy farmer, to processing plant personnel, to those persons involved in inspecting the dairy farmer's operation and/or the processing plant, to those persons who make the laws concerning the inspections, to those who enforce the laws, to the academic researcher and adviser, to the consumer of the dairy products.

<p><b>UPCOMING EVENTS</b></p> <p>2019 NCIMS Conference</p> <p>April 26 - May 1, 2019</p> <p>Hyatt Regency St Louis at the Arch</p> <p>St. Louis, Missouri</p> <p>The 2019 Conference will be held April 26 - May</p>	<p><b>CURRENT NEWS</b></p> <p>Keep up with what's new!</p> <p>Call for 2019 NCIMS Hall of Fame Nominations</p> <p>Genia Reich appointed to the NCIMS Executive Board - November 2018</p> <p>Appendix N Modification Committee</p>	<p><b>IMPORTANT DOCUMENTS</b></p> <p>2017 Grade "A" Pasteurized Milk Ordinance</p> <p>2017 PROCEDURES and NCIMS Constitution and Bylaws</p> <p>2017 Methods of Making Milk: Sanitation Ratings</p> <p>2017 Methods for Evaluation of Milk Laboratories</p>
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## APPENDIX N 2400 & RELATED DOCUMENTS

- MI LEOs send out updated forms as they are revised
  - 2400 form revisions from FDA → LEO → LABS
  - MI's Appendix N forms (DY and others) LEO → LABS
  - Table of Contents sent annually LEO → LABS
- Laboratory's responsibility to maintain and be using current revisions of all Appendix N documents
- Contact LEO for any forms needed or [ncims.org](http://ncims.org) for the current revisions of the 2400 forms



# LOAD SAMPLE RETENTION

- Recommend all load samples be kept until AFTER the DY 318 Drug Residue Screening Log has been reconciled with reader tapes & milk receiving logs
- Mistakes we have found:
  - A calibrator or control result was found to be invalid & testing continued
  - A test result was found to be positive on the reader tape but was documented as NF on the screening log



## DY 325 MOU

- DY 325 MOU Between the dairy industry & MDARD
  - MI requires all processing facilities to have a DY 325 on file with MDARD to meet Appendix N requirements
  - This agreement documents the following:
    - 1) Source of incoming milk (name & BTUs)
    - 2) Where will the milk be screened for drug residues:
      - Purchasing pre-screened milk (results with delivery)
      - Own/Purchase milk that will be sampled onsite & sent to a lab for testing (results sent to processing facility or wait for test results)
      - Drug residue screening sites/Industry labs
        - Screening site representative name and signature



## DY 325 MOU cont.

3) Where the presumptive positive load sample will be tested for confirmation, producer trace back and producer confirmation:

- Name and Signature of Confirming Site Representative required
- Milk Owner's (Representative) Name and Signature required





## DY 325 MOU cont.

- 4) Where is the negative follow up sample tested:
  - Name and Signature of Confirming Site Representative required
  - Milk Owner's (Representative) Name and Signature required
  - May be the same Confirming lab or an alternate
- 5) Where will the disposal of positive loads take place:
  - Documents the address of the physical location where load will be disposed
  - Milk Owner's (Representative) Name and Signature required



## DY 325 MOU cont.

- LEOs work with individual sites to address specifics as needed
- The DY 325s are being updated to the new revision during biennial lab evaluations, sooner if time allows
- Completed and submitted to the LEO
- Revised by processing facility and resubmitted as needed
- Facilities may choose to prepare an individual DY 325 for each milk source
- The DY 325 is required for all types of processing facilities
- A DY 325 instructions/companion document is available
- The LEOs are available to assist in completing the DY 325



## DY 327 VERIFICATION OF DISPOSAL

- DY 327 Verification of Disposal of Confirmed Positive Antibiotic Milk (Presumptive + if applicable)
  - A required part of the positive reporting documents sent to MDARD per Appendix N of the PMO
  - Available through the MDARD LEOs, MDARD Dairy Inspectors and at Testing Sites
  - Industry is encouraged to provide the DY 327 to the hauler of the positive load of milk
    - Lab Analysts at drug residue testing sites
    - Milk Transportation Companies (MTC)
    - Dispatch office of milk cooperatives, field reps, etc.
    - Discussed during the Hauler/Sampler required training, online and in person



# TETRACYCLINE PILOT PROGRAM

- Pilot program ran from July 1, 2017 to Dec. 31, 2018
- No official report has been released to date
  - Not all data has been submitted to NMDRD
  - Unofficially, there were 9 positives across the program
- In Michigan:
  - ~75% of grade A laboratories participated
  - No positive tetracyclines were discovered
  - Thank You to all that participated in this first pilot
- The future... Gentamycin



# 2019 NCIMS LABORATORY UPDATES

- **Proposals 215/221**
  - Combined at Appendix N committee
  - Underwent a series of rewrites during the conference
  - Meant to ensure that an equivalent test is used to clear a violative farm to return to the market
  - passed



# 2019 NCIMS LABORATORY UPDATES

- **Proposals 223**
  - Submitted by FDA
  - Meant to allow:
    - LPET/LEOs to conduct evals up to 60 days before due w/o moving due date
    - LPET to extend LEO certification up to 6 years w/o on-site triennial
  - Modified to remove 2<sup>nd</sup> bullet
  - Passed as amended



## 2019 NCIMS LABORATORY UPDATES

### New test methods approved:

- Modified Colitag-presence/absence (228)
- Modified Colitag-mpn (229)
- Charm BL30SEC (240)

### Modified methods/forms:

- Charm Paslite-additional reader (239)
- Peel Plate-storage temps modified (241)

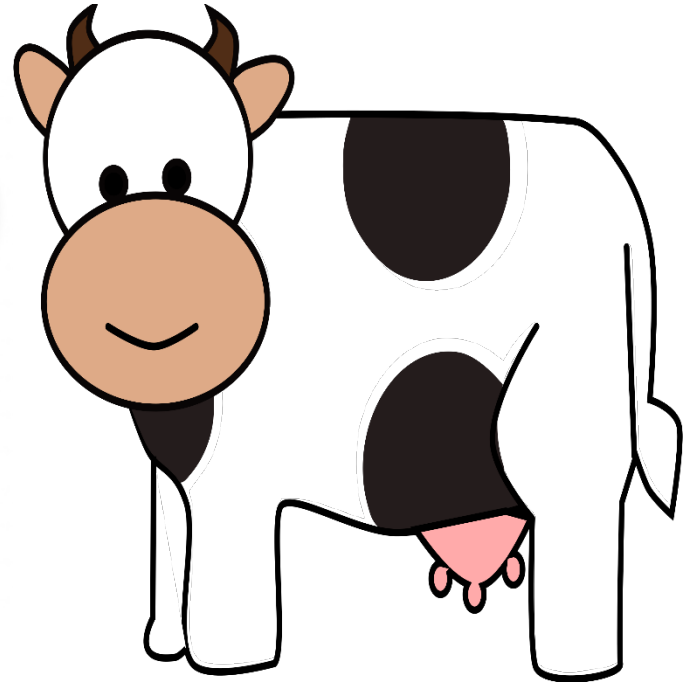


## Appendix N Analyst Workshop

- Analyst Workshop to be held October 2019
  - Date October 17, 2019
  - Will be held at Joint Forces Readiness Center in Lansing
  - Email with details will be sent soon
  - All are welcome; course geared toward:
    - Potential processors/lab analysts
    - New and existing processors/lab analysts
      - Screening sites, CIS and Accredited labs
    - MDARD inspectors



# Questions



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## Stay connected with MDARD!



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