New In-Line Sampling Technology 2019 Eastern Milk Seminar

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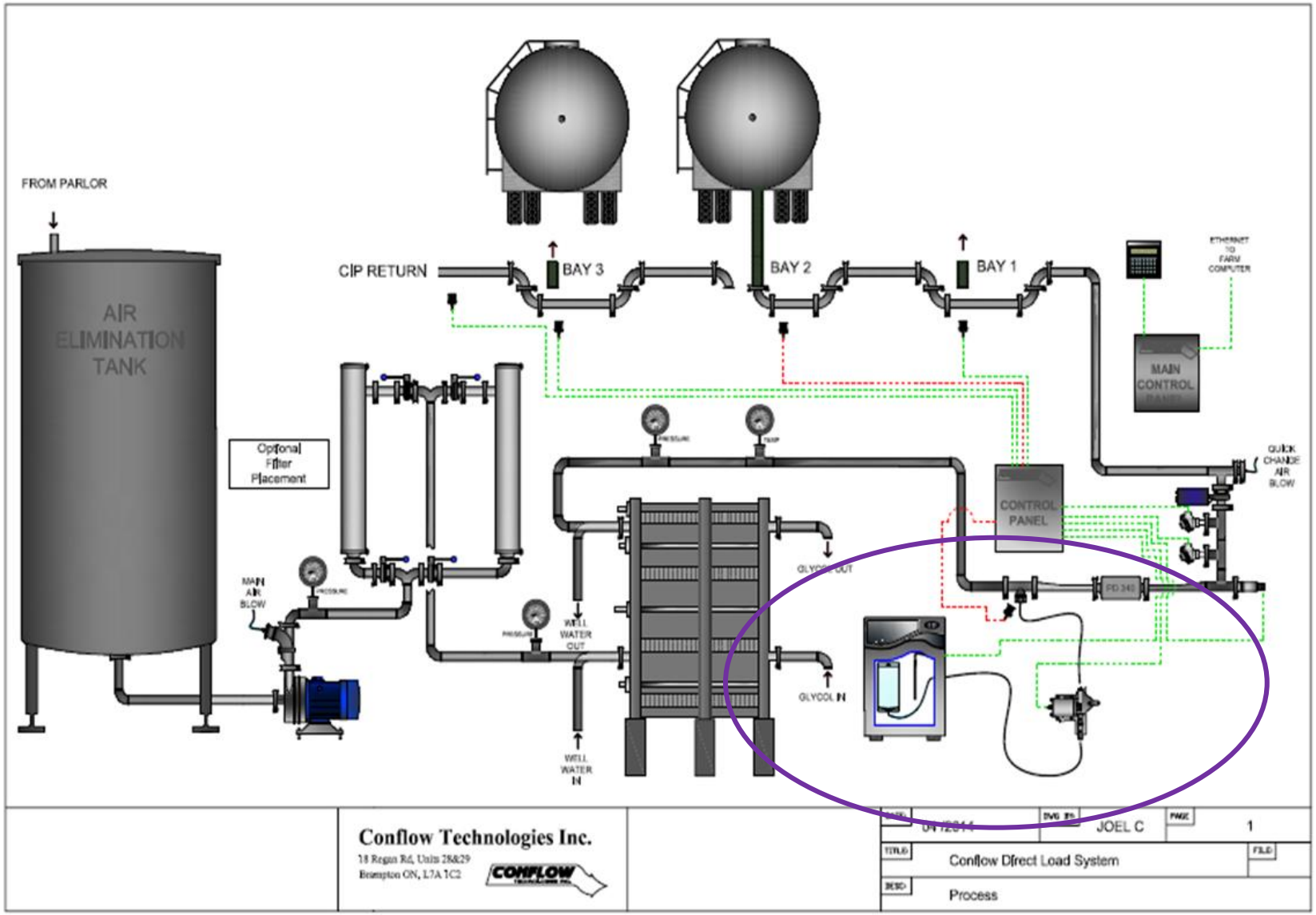
Points for Discussion

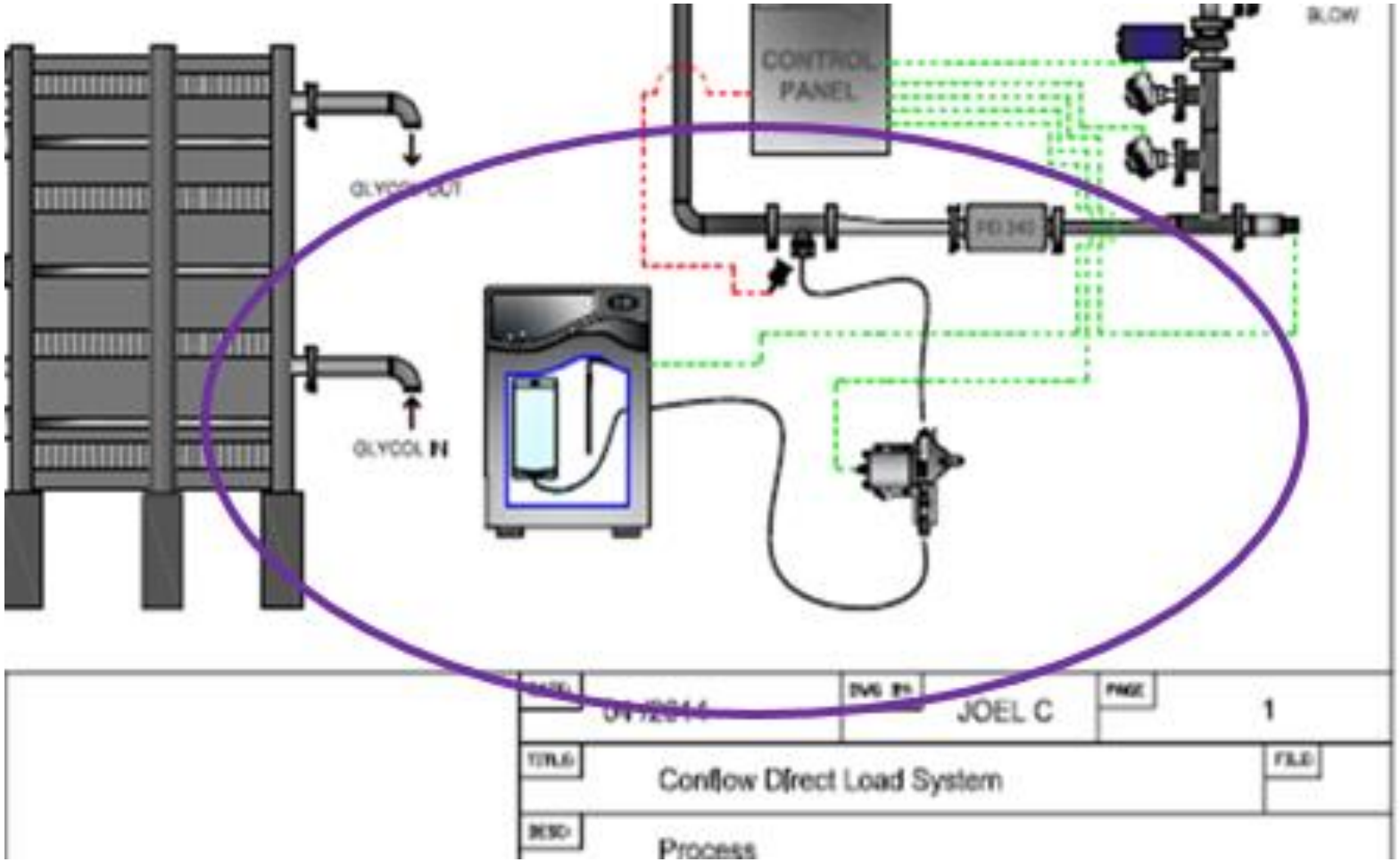
- In-line sampling - overview
- Case Study: Piper DynaStream
  - From concept to PMO acceptance
- Takeaway - Lessons learned and unanswered questions about the approval process

What is In-line sampling?

- Definition - Not really defined in the PMO
- Goal: Obtain a representative sample over the duration of the loading process – equivalent to a dip sample taken from an agitated tank
- Current technology - on farm systems
  - Direct Load Samplers– M-I-06-6
  - Direct Load Systems*
- Use of septum and peristaltic pump as allowed by M-I-12-4 (??)
- “Latest” technology - ON-TANKER FARM BULK MILK TANK ASEPTIC SAMPLER – Proposal 210 to the 2019 NCIMS

Typical layout for direct fill system with in-line sampling




CONTROL PANEL
GLYCOL IN
JOEL C
1
Conflow Direct Load System
Process

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Latest Technology: ON-TANKER FARM BULK MILK TANK ASEPTIC SAMPLER

Big change

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Proposal #210 Passed as Amended – 2019 NCIMS – language change to App. B

V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK ASEPTIC ~~SAMPLING SYSTEM~~ **SAMPLER** FOR MULTIPLE AND/OR SINGLE FARM PICKUPS

1. A protocol specific to the use of an on-tanker farm bulk milk tank aseptic ~~sampling system~~ **sampler** which may be used for the acquisition of official milk samples from multiple and/or single farm pickups shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer ~~and the milk buyer~~ and FDA. ~~As~~ **At** a minimum, the protocol (SOP) ~~should~~ **shall** include the following:

a. A description of how the milk sample is to be collected, identified, handled and stored.

b. A description of the means used to maintain the sample at the required temperature (between 0.0 **(32F)** to 4.5 **(40F)** degrees Celsius, as per this Appendix) during the sample collection period.

c. A description of the process used to obtain the temperature of milk being loaded from the farm bulk milk tank.

d. A description of how and when the ~~sampling system~~ **sampler** is to be cleaned and sanitized if not of a single use design.

e. A description of the method and the means used to ensure **the representative nature of and** ~~the~~ integrity of the milk sample acquired from every farm bulk milk tank.

f. A description of the method and means that will be used to determine weight of the milk in the farm bulk milk tank.

Proposal #210 Passed as Amended – 2019 NCIMS – language change to App. B (cont.)

2. The on-tanker farm bulk milk tank ~~sampling system~~ **sampler** shall be installed in consultation with the Regulatory Agency, according to the manufacturer's recommendations and in a manner that is compatible with its' intended use.

3. The State Regulatory Agency ~~should~~ **shall** ~~keep~~ **be provided** a list~~ing~~ of the licensed bulk milk hauler/samplers who have been trained to maintain and operate ~~clean and sanitize~~ the aseptic ~~sampling system~~ **sampler** as well as to collect, identify, handle and store the milk sample.

4. A copy of the approved on-tanker farm bulk milk tank aseptic ~~sampling system's~~ **sampler** SOP shall be on file ~~at the location where the system is utilized~~ **on the tanker**.

Proposal 210 submitted by Leigh Hamilton, Piper Systems

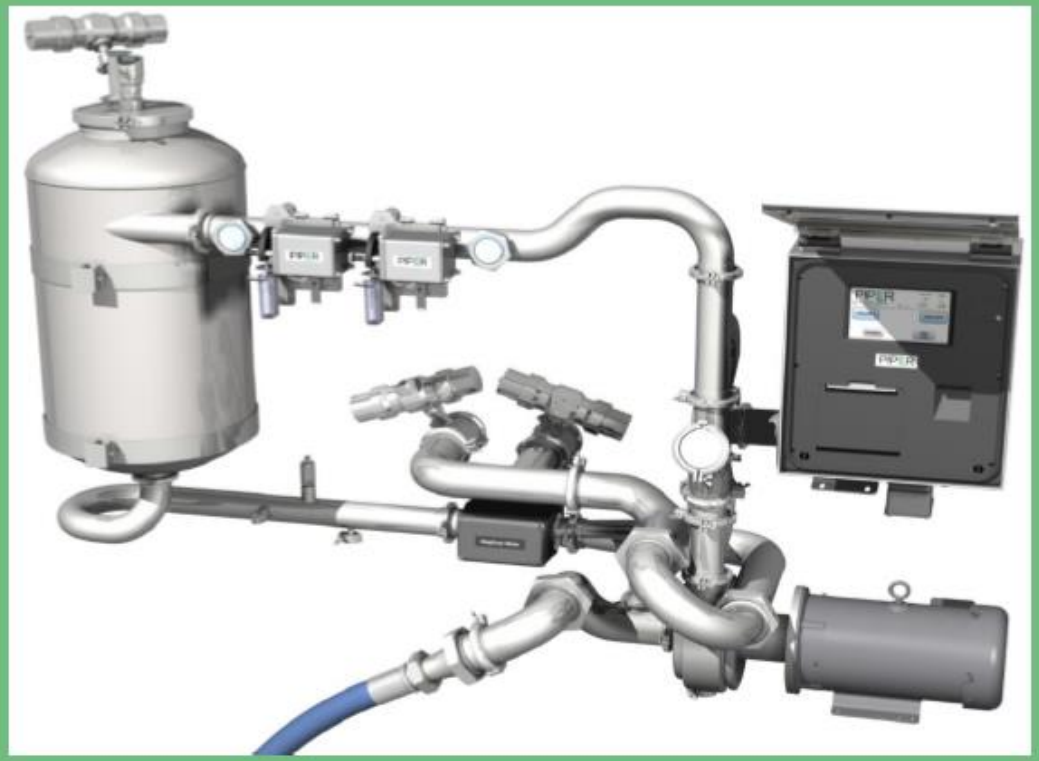
Who is Piper?

Products

PIPER

Tanker Based Systems

- Single pump systems
- Twin Pump systems



Farm Based Systems

- Direct Load Systems
- Silo and Bulk Tank Systems

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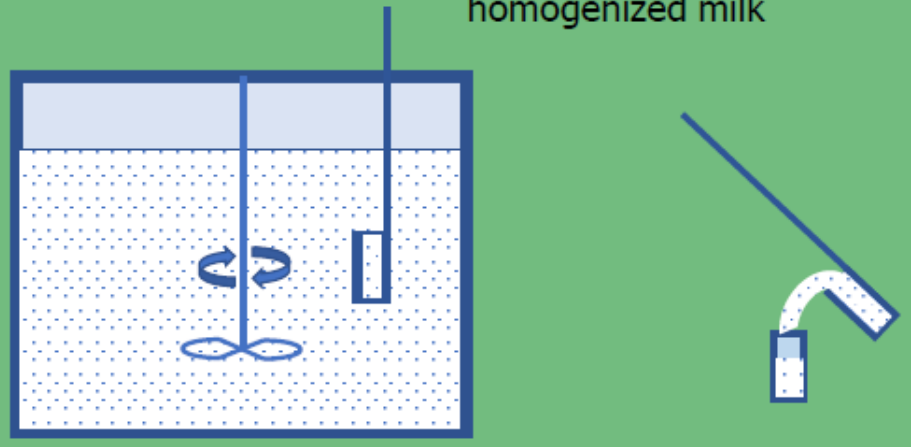
Representative Sample Standard method v Piper DynaStream

Standard farm tank sampling SOP overview

- Truck Arrives
- Observe milk and start agitation
- Tank agitated (as per tank spec), to homogenize milk for representative sample collection
- Dip sample taken
- Tank settles
- Measure tank level & associated weight wall chart
- Pump milk onto truck

Representative Sample: Milk is homogenized via agitation and a dip sample is taken of the homogenized milk

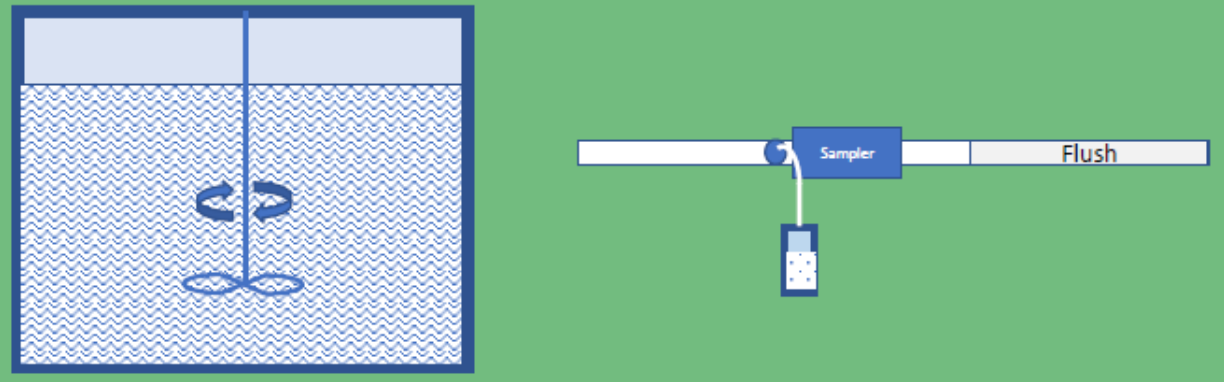


Piper Farm tank sampling SOP overview

- Truck Arrives
- Observe milk and start agitation
- Farm and sample ID verification on Piper DynaStream
- Milk weight is metered while pumping milk onto truck
- The Piper DynaStream takes a representative sample, using single use consumables*, over the volume of milk collected

(* Consumables are a PMO approved vial-tube-needle assembly & septum port)

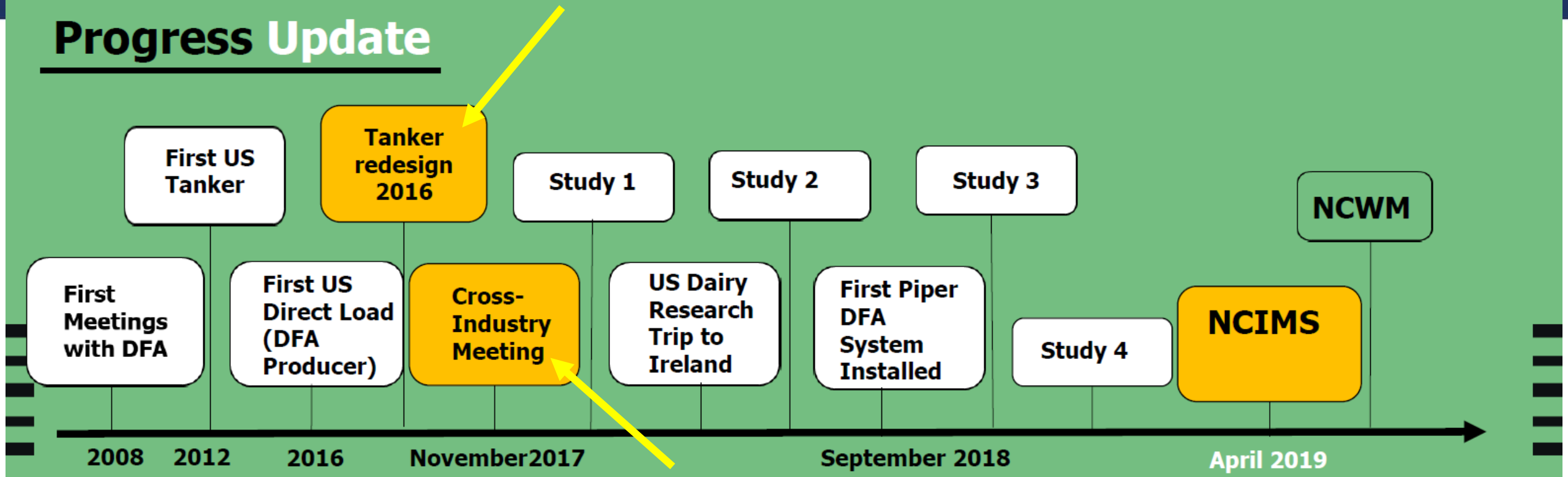
Representative Sample: After initial flush volume, milk is continuously sampled over the remaining volume collected



How did NY get involved?

- Was already working with Bob Gilchrist on side-manhole tanker
- Feb 2016 – Bob G. asks me about the tanker
- ***June 2016 – initial on-site review of the system***
- Provided feedback to Agri-Mark on construction
- Some initial discussion with FDA

Progress Update



Understanding US Dairy Challenges

Design to US requirements

Working toward US Approvals

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Stakeholders Engaged

- NY's role:
  - Equipment evaluation
  - Some oversight of studies
  - ***Interpretation of the PMO and the Grade A program***
  - Review of proposal language
  - Review of SOPs in consultation with FDA
- USDA Market Administrator
  - Sample collection for bacteria, SCC, components
  - Weigh meter comparisons
- Reps from milk cooperatives and hauling companies
- Consultation with representatives from FDA LPET, FDA MST, & NCIMS Lab Committee to determine necessary studies and data that would be required

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PIPER System Redesign

Piper worked with NY Department of Ag & Markets to ensure that we met US sanitary requirements:

- **Design Updates (Valve design, AEV top design)**
- **PMO Approved Single Use Consumables**
- **US Sanitary Design Standards (e.g. 3A)**
- **US Power Sources**

Agrimark trailer

Single use consumables

System flush validation trial

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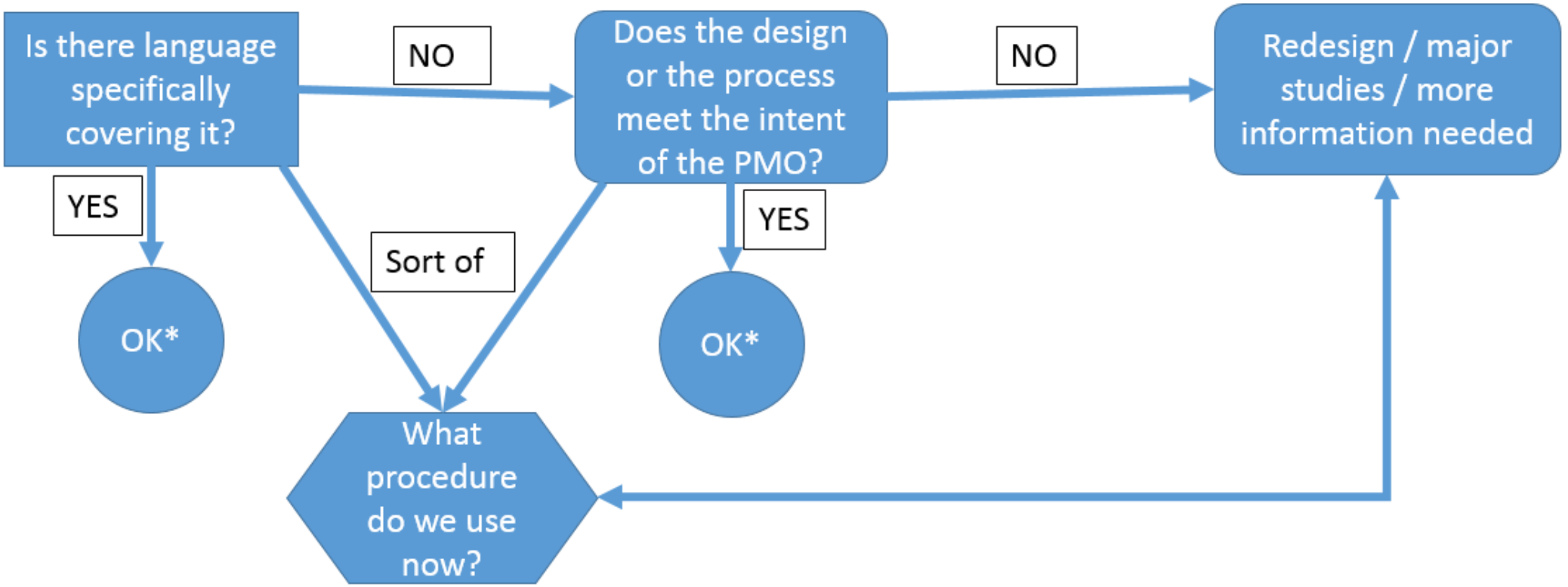
Challenges - How do we handle new technologies?

Does it meet the requirements of the PMO and the Grade A Program?



Thoughts on the process - Challenges

- **Spent a great deal of time interpreting the PMO and the NCIMS process**

Initial questions that were expected:

- What is the overall sanitary design?
- How is a representative sample obtained? – Equivalency to traditional method
- ***How is sample integrity ensured?***
  - ***Temperature during the loading process***
  - ***Protection from contamination***
  - ***AB carryover from one farm to the next***

Thoughts on the process - Challenges

Questions that were better than their answer:

- Does the system meet current language residing in the PMO?
  - Does it meet the ***intent*** of the PMO?
  - Does language exist in the PMO that precludes the use of this sampling system?
  - Will a proposal for this technology need to be submitted to the NCIMS?
  - Past precedent set in Appendix B – somewhat generic language in the PMO with an M-I containing an SOP and general approval
- Who should be conducting the evaluations? States? FDA? Both? Regional Equipment Review Committee?

Thoughts on the process - Challenges

Questions that were better than their answer:

Proving Equivalence:

- What type of data would be required to prove equivalency to the standard dip sample taken from an agitated bulk tank?
  - Assumed bacteria, somatic cells, antibiotics but…..
    - How to analyze? Who approves that? Is there guidance on that?
- Carry-over

Takeaway - Lessons Learned – Questions still to be answered

- Is there a way to get to an agreed upon process for the types of information and data that is required when requesting a change to the PMO?
- How do we decide when something needs a proposal submitted to the NCIMS?
- How do we avoid vendor specific language in the PMO and how do we protect companies proprietary information during that process?

Takeaway - Lessons Learned – Questions still to be answered

- What will be the future of FDA issued M-Is?
  - Past precedent set in Appendix B – somewhat generic language with an M-I containing an SOP and general approval
- There is opportunity to continue fine tuning the PMO – descriptive language vs. prescriptive vs. a combination of the two
  - Are we precluding the use of new technologies by having overly specific language in the Appendices of the PMO?

Thank you!

Questions?