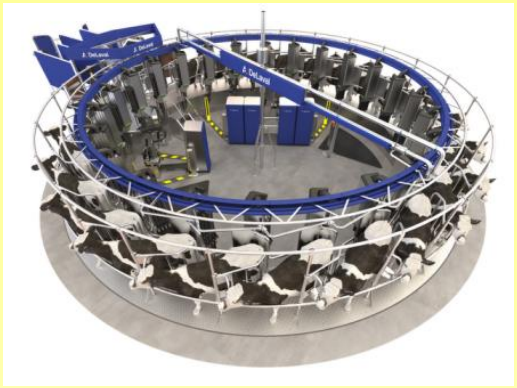

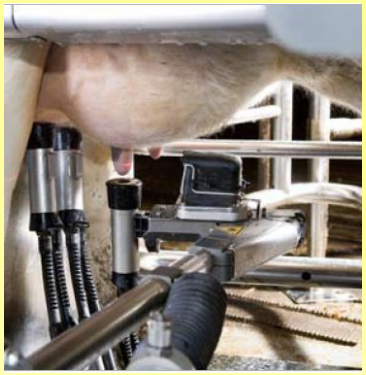

AUTOMATIC MILKING: FDA Issues

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Appendix Q to the Pasteurized Milk Ordinance (PMO)

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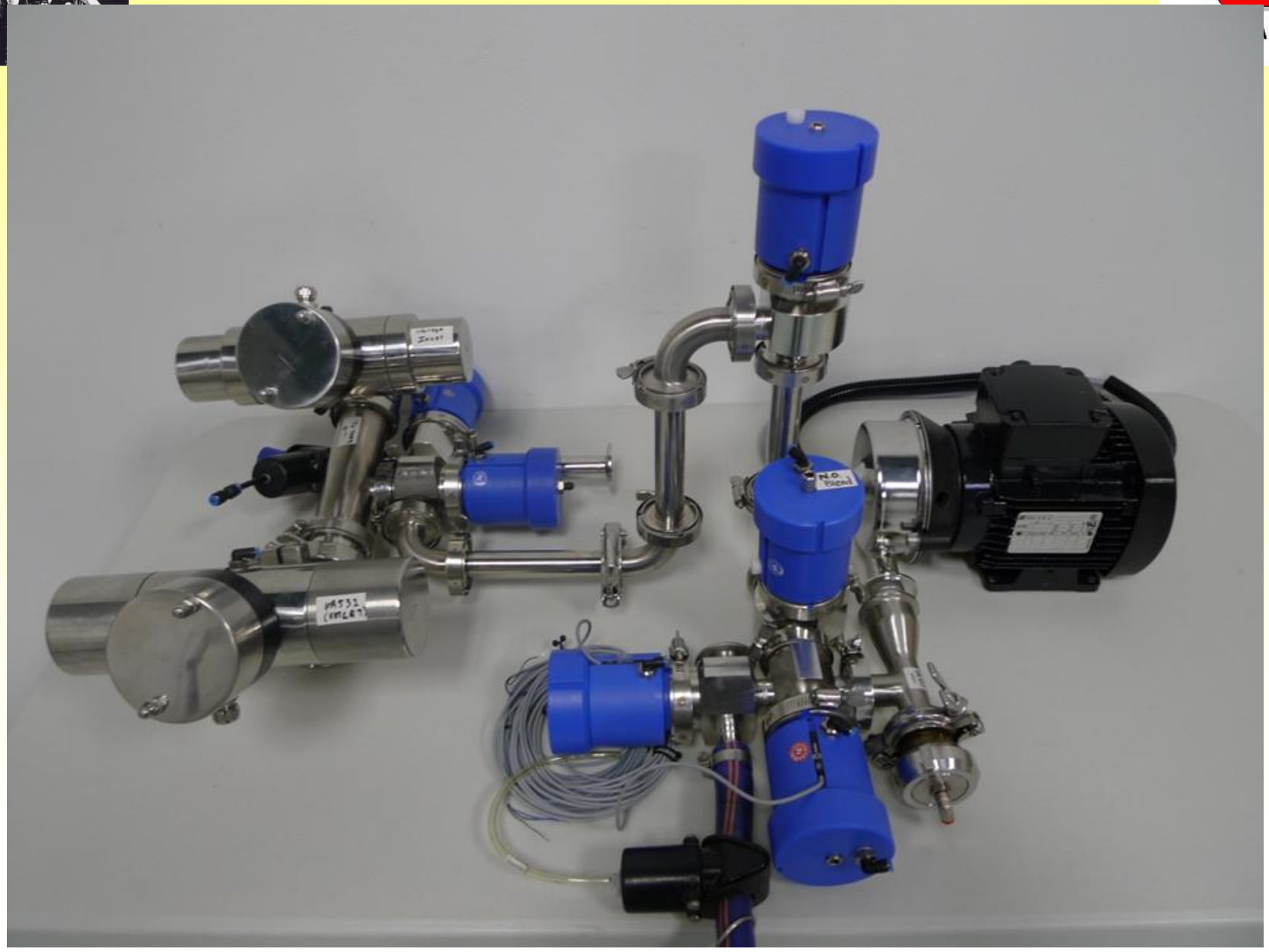
- AMI for the Production of Grade "A" Raw Milk approved in 2003
  - AMI shall identify and discard milk with abnormalities.
  - points of contact with abnormal milk will be cleaned and sanitized after milking such an animal
  - box shall be kept as clean as any milking and equipment cleaning area.
  - All ventilation air must come from outside the cattle housing area.

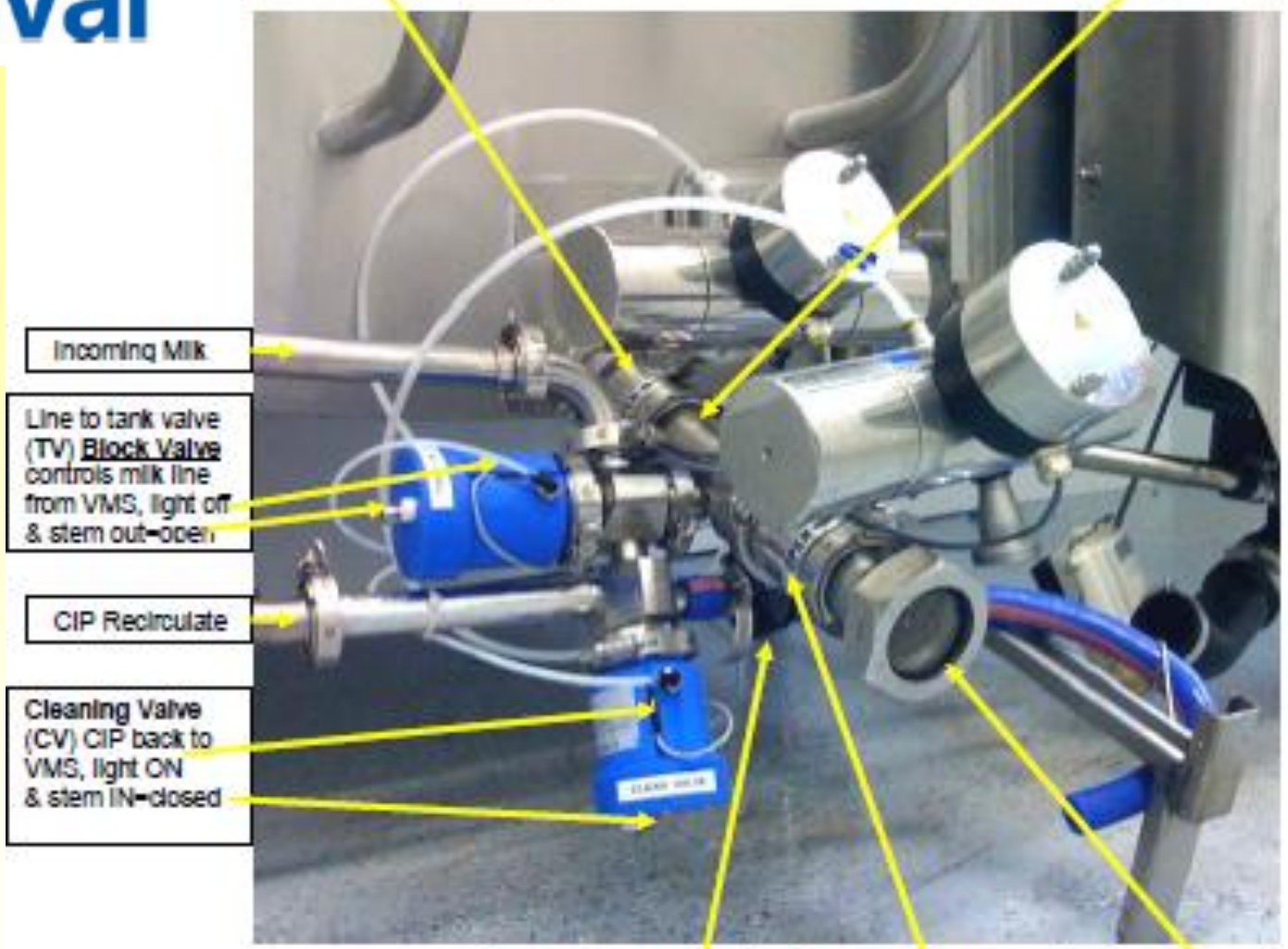
The Issue

- Allowing cleaning of tank valve and t-piece connection assembly and bleed valve (pick up or outer valve).
  - Screened outlet to prevent contamination is difficult to verify automatically – outlet could be plugged by operator or failure
- Supply specific proof that milk in the tank is not at risk of product contamination (public health) with single-seal separation (inner valve).

DeLaval VMS Valve Package



DeLaval


Inner milk tank shutoff BLOCK Valve against milk in storage (IN)
Tank T-Piece close coupled connection for Block-Bleed-Block valve assembly
Incoming Milk
Line to tank valve (TV) Block Valve controls milk line from VMS, light off & stem out=open
CIP Recirculate
Cleaning Valve (CV) CIP back to VMS, light ON & stem IN=closed
Pinch Valve Drain (DV) Normally-open low point drain for line & valves outside tank T-Piece, closed during recirculation
(PV) Pick-Up / Outer BLEED Valve drains and vents T-Piece connection in Block-Bleed-Block operation
Perforated drain / vent cover when in automatic operation

Lely Configuration Horizontal

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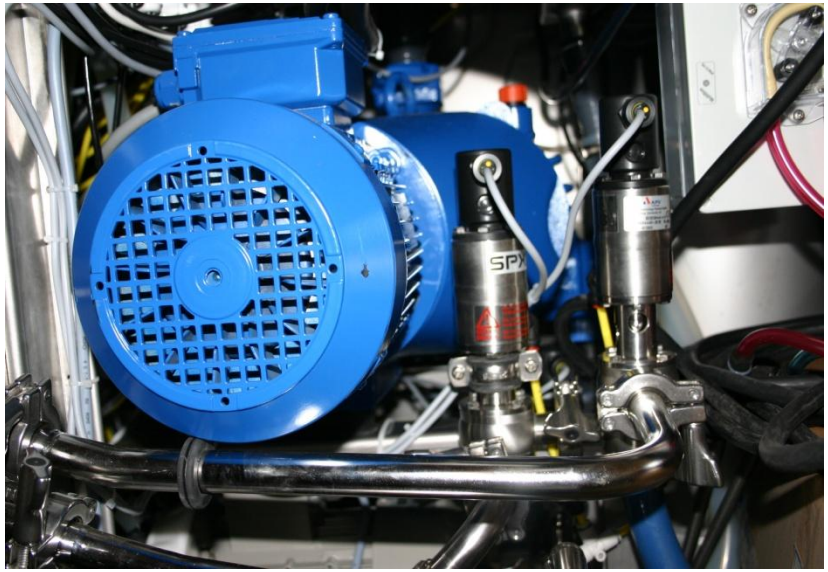
‘A future that makes sense’

On the right are the block bleed block valves on the milk transfer line for protection from waste milk.



Proposal accepted in 2009 NCIMS

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- Un-link the raw milk language in Appendix Q Item 14R with pasteurized / processing Item 15P(b) as requirement basis of safety separation
- Deviation from pasteurized / processing Block+Bleed required only for robotic milking
- Providing protection equivalent to blok+bleed as defined in PMO 15P(b)

The Situation

- FDA is asking the industry to present a proposal to NCIMS addressing equivalency
- Steve Sims
  - each manufacturer might make their own proposal
  - Better to get a consensus proposal
  - Method to test and confirm

Challenges

- Proposal for non-traditional Block+Bleed should be supported by data
  - historic data based on stem operated dairy plant compression valves
- AMS industry is using 2 single-seat valves in combination
  - equivalent in terms of safety and sanitation?
  - dead-leg distance requirement considered

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Lely configuration Vertical

Questions from Harrisburg FDA meeting

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- Can single-seat valves in a block+bleed meet the intent of 15P(b)?
  - Challenge pressures when valves are nearly closed or just becoming open? ("Water hammer" over-pressure)
  - Cleaning flow during tank cleaning
  - Valve/seal impingement/pressure concern
  - What is the proof of equivalency claim?
  - Differences between compression valves versus non-traditional (15P(b): butterfly, disc, ball) valves?

Suggestions from Harrisburg FDA Meeting

- Substitute "seat lift" with "seat pulsing" to deliver a specific pressure
  - lifting the seat is interpreted as "out-of-position"

Manufacturers Response

- Seat pulsing duration or displacement (distance) tests did not produce uniform cleaning volume or pressure
  - Difficult to adjust and verify
- Can evidence (data) with a proprietary valve assembly be used as proof of concept for other configurations?

FDA Feedback

- Industry consensus on generic construction and operation
- manufacturers individually responsible for validating their construction and operation method.
- consider the history of the non-mix, double-seat, double-lift valves
  - shows there can be "ratcheting" progress upwards towards compliance

VMS Test Guide
Tank Block-Bleed-Block
Flow Control Cooling (FCC)

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1. Milk Tank in cooling mode
2. Milk Station in cleaning mode
   - Milk tank in separation mode
   - B-B-B valves in 'fail-safe' position
3. Identify valves and their position
4. Identify testing override switches
5. FAILURE MODE TEST
   - VMS milks tation cleaning stops, opens alld rains, milkpump and vacuum stop
   - VMS milk station 'touch screen' displays STOP alarm: "TANK VALVE IN WRONG POSITION"

FDA Feedback

- Validation of a method is a 3-legged stool
  - Design Criteria
  - Performance Criteria
  - Testing Criteria
- Individual "Scope of Proposal" should also include the separations at milking stations

Other Issues

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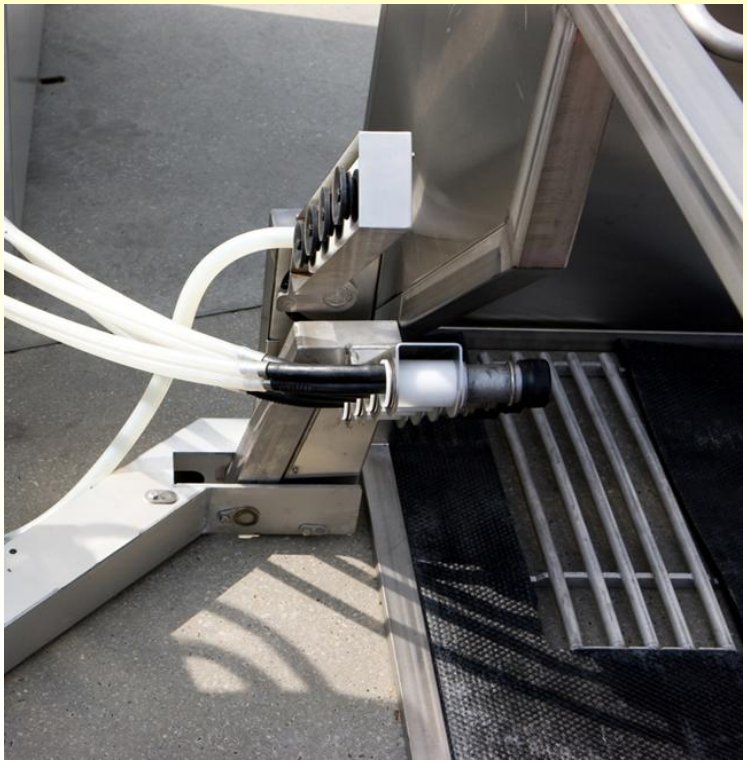
- Jeter and teat cup protection
  - In process component
  - Cover, Shielding, Location, Self cleaning

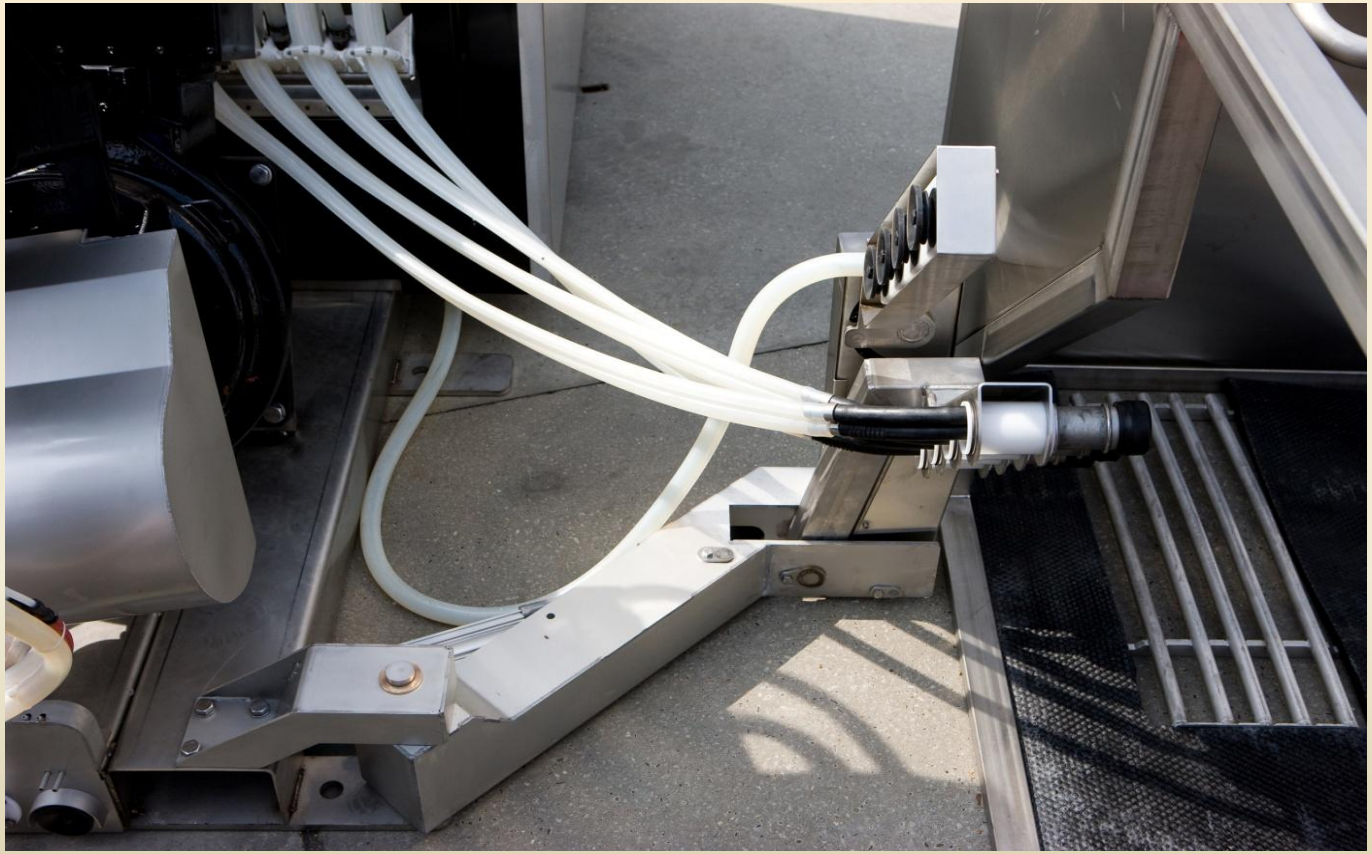


AMS Galaxy USA
Welcome to a future that makes sense

Other Issues

- Well Water backflow prevention
  - Central point well protection
  - Cross contamination between AMS units
  - Hot/Cold separation within AMS unit
- Cover for AMS stall when not in dedicated milking area
  - Positive pressure ventilation requirement
- Conversion from EU standard components to US FDA approved

Teatcups / jetters must be covered during the prep procedure.



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