Aseptic Failures Due to Inappropriate Maintenance

IFTPS Conference – San Antonio, Texas

Rick Rector

Ecolab Technical Support Group

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“The Devil Is In The Details”

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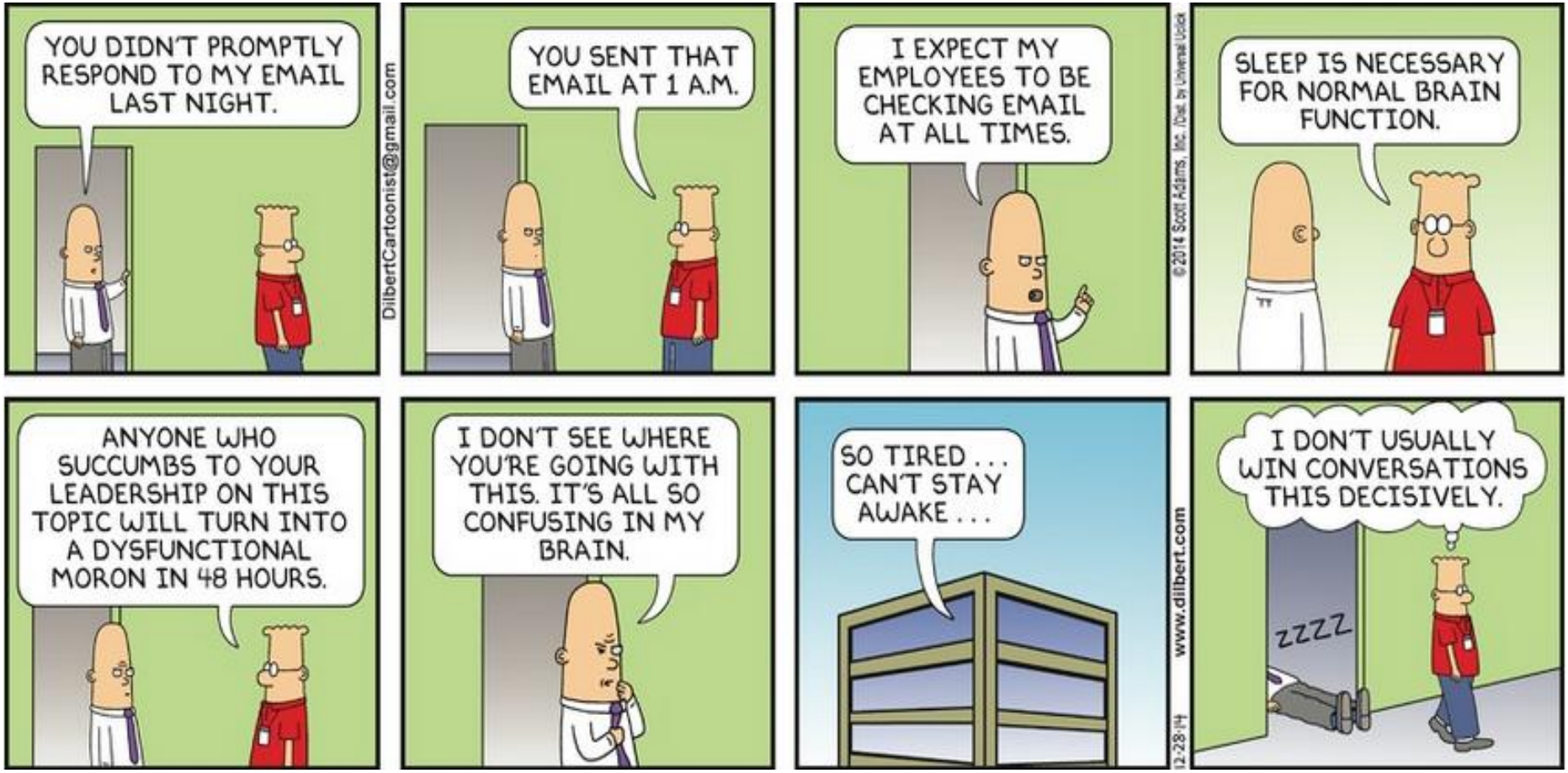
YOU DIDN'T PROMPTLY RESPOND TO MY EMAIL LAST NIGHT.
DilbertCartoonist@gmail.com
YOU SENT THAT EMAIL AT 1 A.M.
I EXPECT MY EMPLOYEES TO BE CHECKING EMAIL AT ALL TIMES.
© 2014 Scott Adams, Inc. /Dist. by Universal Uclick
SLEEP IS NECESSARY FOR NORMAL BRAIN FUNCTION.
ANYONE WHO SUCCUMBS TO YOUR LEADERSHIP ON THIS TOPIC WILL TURN INTO A DYSFUNCTIONAL MORON IN 48 HOURS.
I DON'T SEE WHERE YOU'RE GOING WITH THIS. IT'S ALL SO CONFUSING IN MY BRAIN.
SO TIRED . . . CAN'T STAY AWAKE . . .
www.dilbert.com
12-28-14
I DON'T USUALLY WIN CONVERSATIONS THIS DECISIVELY.
ZZZZ

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Sweet as Sugar: Buckeyes defeat Alabama, 42-35

Buckeyes advance to first ever College Football Playoff Championship Game

Jan. 2, 2015

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National Champions! Ohio State Wins First College Football Playoff

Ohio State beats Oregon 42-20

Jan. 13, 2015

Ohio State wins its eighth national championship in program history and the first since the 2002 season with the 42-20 win over No. 2 Oregon.

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Now

Where the rubber hits the road!!

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TODAY'S PURPOSE

How Does Maintenance Impact Product Quality

The True Definition Of……

ECOLAB®

New Acronyms For The Year

- S.O.P
  - Self Opening Packages
- S.O.C
  - Self Opening Containers
- KISS
  - Keep It Super Simple
- PPPM
  - “P” Poor Preventative Maintenance

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Typical Challenges – Processing Systems

- Water Fouling
  - Carbonate
  - Iron
  - Other impurities
- Steam Fouling
  - Boiler Priming – Corrosion
  - Iron Deposition
  - Failed Culinary Filtration
- Product Fouling
  - Overheating – Extended Process Times
  - Lack of AIC's (Aseptic Intermediate Cleaning)
  - Value Added Ingredients – Solubility
  - Hydration Issues – VAP's
- Cleaning
  - Cleaning Sequencing
  - Cleaner Selection – Delivery
  - Flooding – Flash Chamber Systems
  - Flow Rates

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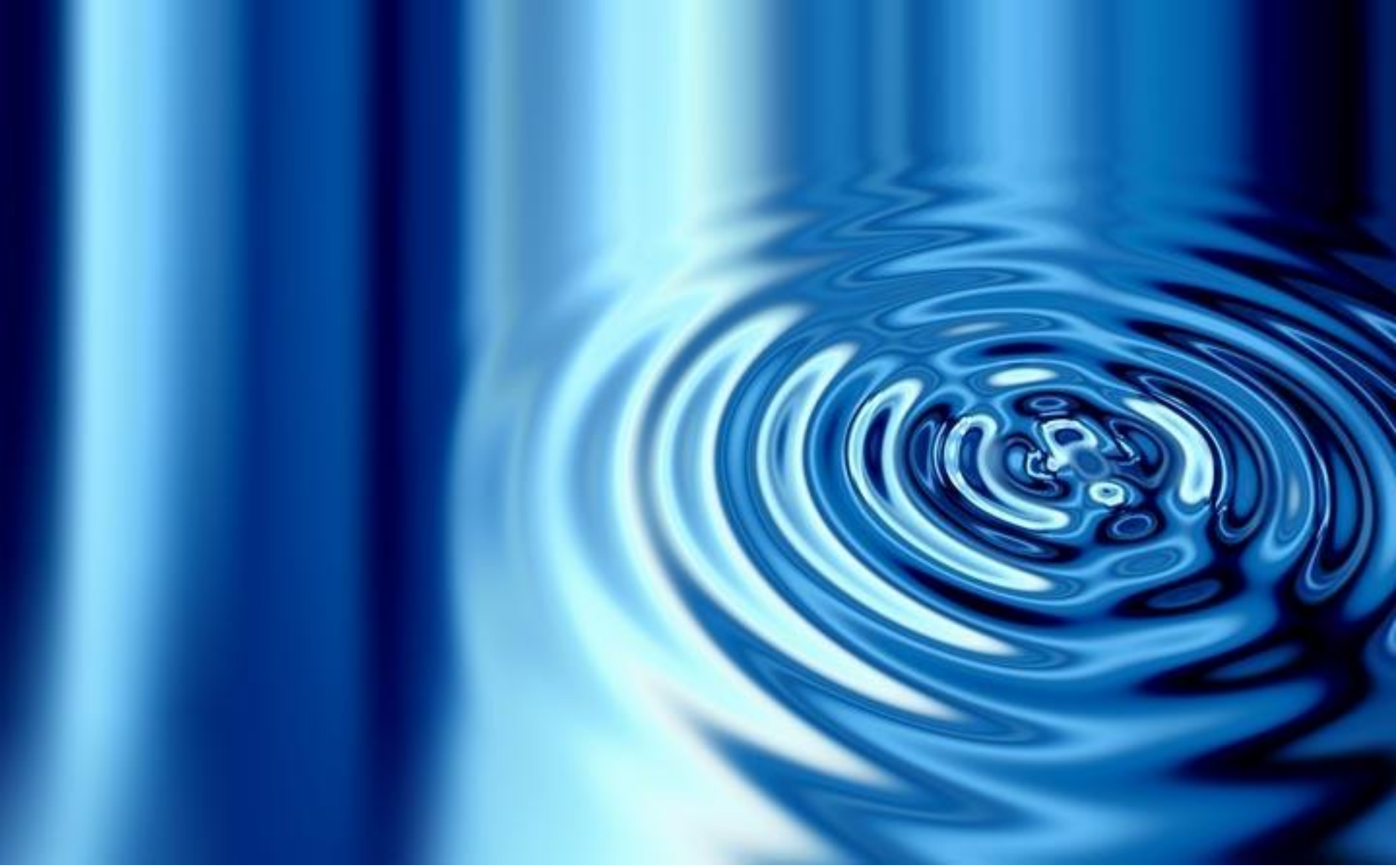

It All Starts With Water

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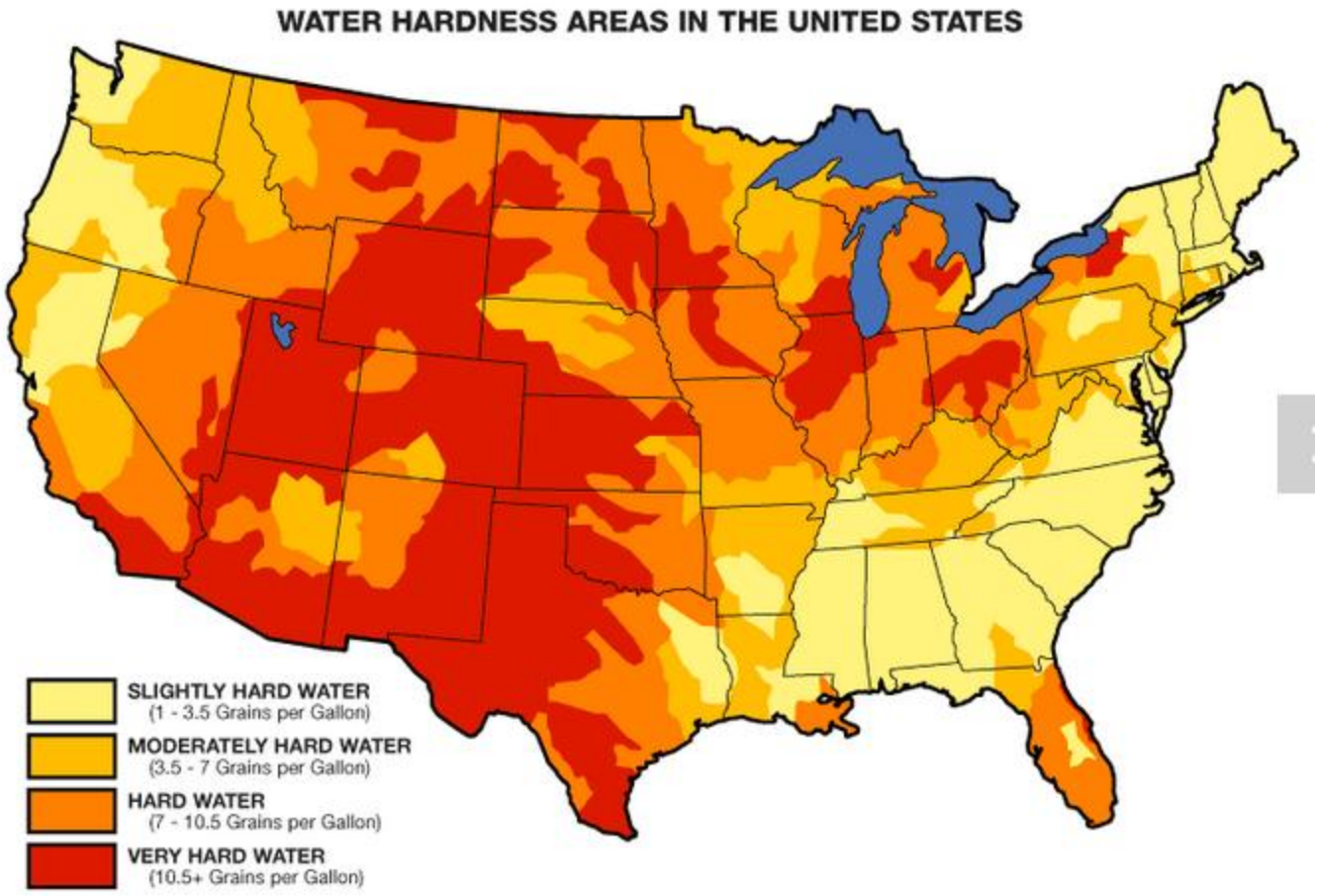
Water Hardness – USA Map



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Water Quality Across The USA

Sample Name	Source	Condition	Water Hardness	Total PPM	Total Dissolved Solids	PH	Total Alk	Iron	Manganese	Chloride	Silica	Barium
MN Water	Unknown	Unknown	31.3	535.2	965	8.1	426	0.12	0.09	35	34.10	0.02
Cold Water	Municipal	Unsoftened	19.7	336.9	672	7.9	225	0.27	0.00	84	21.03	0.07
Cold Water	**Well**	**Unsoftened**	**18.4**	**314.6**	**476**	**8.0**	**251**	**0.88**	**0.17**	**41**	**11.08**	**0.10**
Cold Water	**Well**	**Unsoftened**	**18.2**	**311.2**	**478**	**7.8**	**250**	**0.87**	**0.17**	**40**	**10.99**	**0.10**
Water	Unknown	Unknown	16.0	273.6	381	7.9	264	0.67	0.04	11	11.83	0.09
Cold Water	**Well**	**Unsoftened**	**15.3**	**261.6**	**493**	**8.0**	**284**	**0.76**	**0.05**	**60**	**16.34**	**0.24**
Cold Water	Well	Unsoftened	13.3	227.4	320	8.1	237	0.00	0.00	6	9.60	0.03
Cold Water	Municipal	Unsoftened	11.1	189.8	335	8.2	192	0.00	0.00	28	7.06	0.06
Missouri Water	Municipal	Unsoftened	9.2	157.3	242	7.8	152	0.00	0.00	8	11.21	0.03
Cold Water	**Well**	**Unsoftened**	**8.2**	**140.2**	**243**	**8.1**	**128**	**0.12**	**0.13**	**15**	**8.98**	**0.33**
Chem Storage Area	Municipal	Unknown	8.0	136.8	271	7.7	90	0.00	0.00	44	8.02	0.04
CIP Room	Municipal	Unknown	7.5	128.3	266	7.9	89	0.00	0.00	43	7.66	0.03
Filler Room	Municipal	Unknown	7.5	128.3	271	7.8	89	0.04	0.00	44	6.95	0.03
Well & City	Well/City	Unknown	7.5	128.3	367	8.2	188	0.00	0.00	16	57.11	0.12
Cold Water	**Municipal**	**Unsoftened**	**7.3**	**124.8**	**336**	**7.0**	**40**	**0.00**	**0.00**	**39**	**7.29**	**0.02**
PA 2 Water	Municipal	Unknown	6.8	116.3	552	8.3	195	0.00	0.00	102	11.98	0.00
Municipal Water	**Municipal**	**Unsoftened**	**6.1**	**104.3**	**171**	**7.9**	**99**	**0.00**	**0.00**	**11**	**44.06**	**0.00**
West Middlesex, PA	Well	Unsoftened	5.2	88.9	225	7.6	53	0.00	0.00	48	4.38	0.02
City Water	Municipal	Unsoftened	5.0	85.5	245	7.6	50	0.00	0.00	45	5.48	0.00
California Water	Municipal	Unknown	4.8	82.1	187	8.3	102	0.02	0.00	12	49.84	0.09

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Initial Startup Validation Process

- System supply water quality (Calcium Carbonate Concentration) can easily impact ability to validate extended run times.
  - Citric Acid (food grade) can be added to combat hardness precipitation
  - Nano or RO water filtered water will reduce carbonate soiling.

- Rarely are there problems with an aseptic processing system during the initial startup phase of the validation…..providing that:
  - The thermal lethality is designed to provide the needed F_0 value.
  - Any extraneous materials utilized during the installation process are removed. (tape, gaskets…etc.;
  - Steam barrier settings are set at the proper temperatures.
  - Employees are properly trained.
  - The programmers are properly trained on the needed actions so that all valves are in the programming structure.

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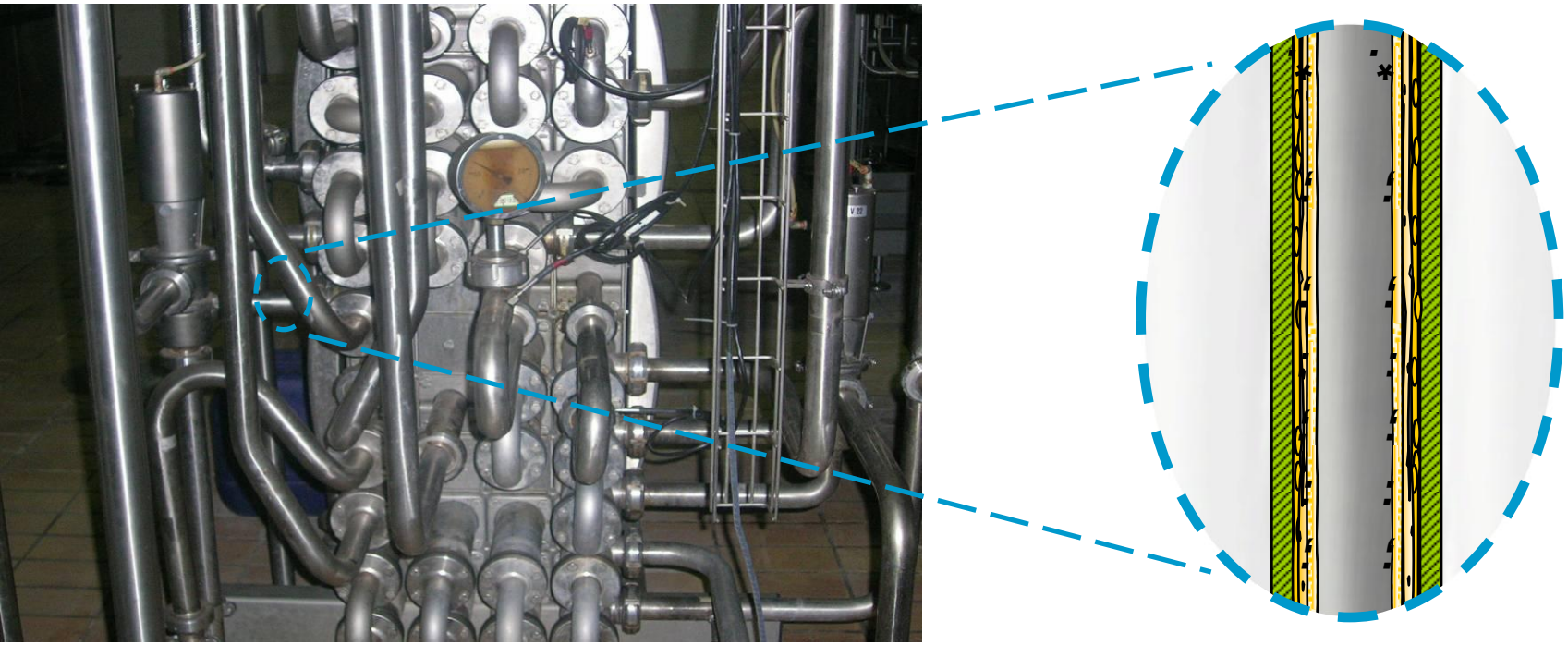
Click to Start

Click to Continue

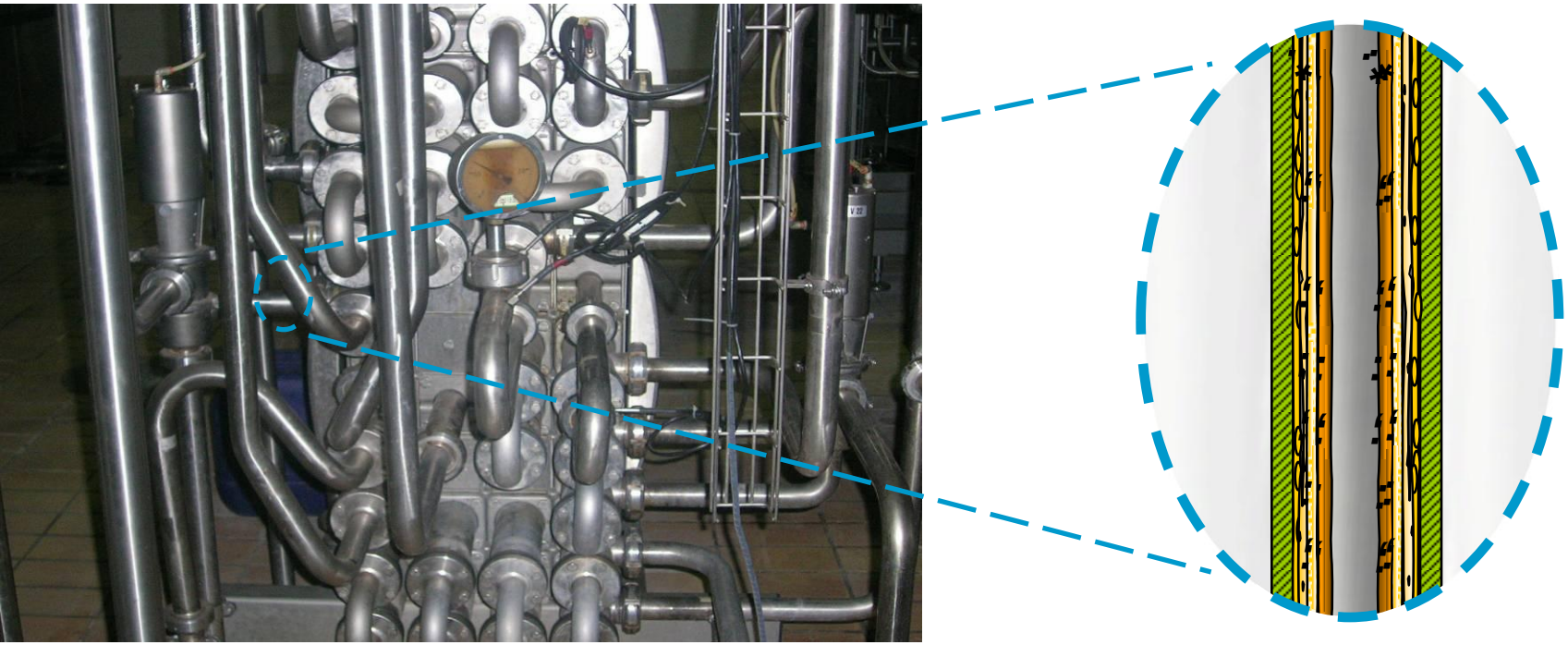
Application Overview
UHT Fouling Illustration



Fouling:

- Dense layer of mineral deposit formed on stainless
- 2nd layer formed consisting of matrix of proteins, fat, and/or carbohydrate depending on process stream

Application Overview
Traditional Cleaning Chemistry Illustration



- High caustic concentrations can cause fouling layer to swell leading to the formation of a rubber-like top layer (protein), thus preventing further penetration of the alkaline cleaning solution into the soil layer.
- Acid rinse required to remove remaining mineral soil.

UHT Soil Removal Guide

Process Fluid	Thermally Degraded Soil Composition	Best Choice Chemistry
Milk	Protein, fat, sugar mineral $CaPO_4$	Caustic, chelate, EX-HS Acid cycle
Soya	Protein, mineral	Caustic, chelate, EX-HS Acid cycle
Ice Cream Mix	Protein, cocoa, sugar, gum	Caustic, EDTA chelate, CL2, EX-HS, Acid cycle
Vegetable Juice	Pulp fiber, carotene wax, oxalate (tartrate from grape juice)	Caustic, EX-HS, EDTA chelate Acid cycle
Fruit Juice	Pulp fiber, hesperidin's, mineral	Caustic, EX-HS Acid cycle
Desert Puddings	Starch, protein, cocoa, TiO_2, mineral	Caustic, chelate, EX-HS Acid cycle
Formulated Dairy	Protein, fat, sugar, gum	Caustic, chelate, EX-HS
Non-Dairy Creamer	Protein, TiO_2	Caustic, EX-HS Acid cycle

When are UHT's Cleaned?

- Every 24 – 48 hrs. depending on process stream and quality requirements and filing.
- Any longer and thermophile survival becomes a high risk.
- When the operator observes steam flow pressure increase to maintain temp range and process flow rate.
- Usually a minimum of 2 AIC (aseptic intermediate cleans) during a production cycle.

Whole Milk UHT Soil Example

Thermally degraded milk protein, fat and sugars and milk minerals

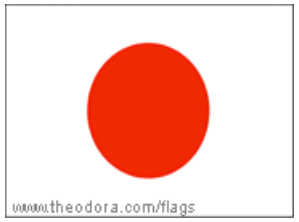
Remaining mineral Calcium Phosphate

Hold Tube Before CIP

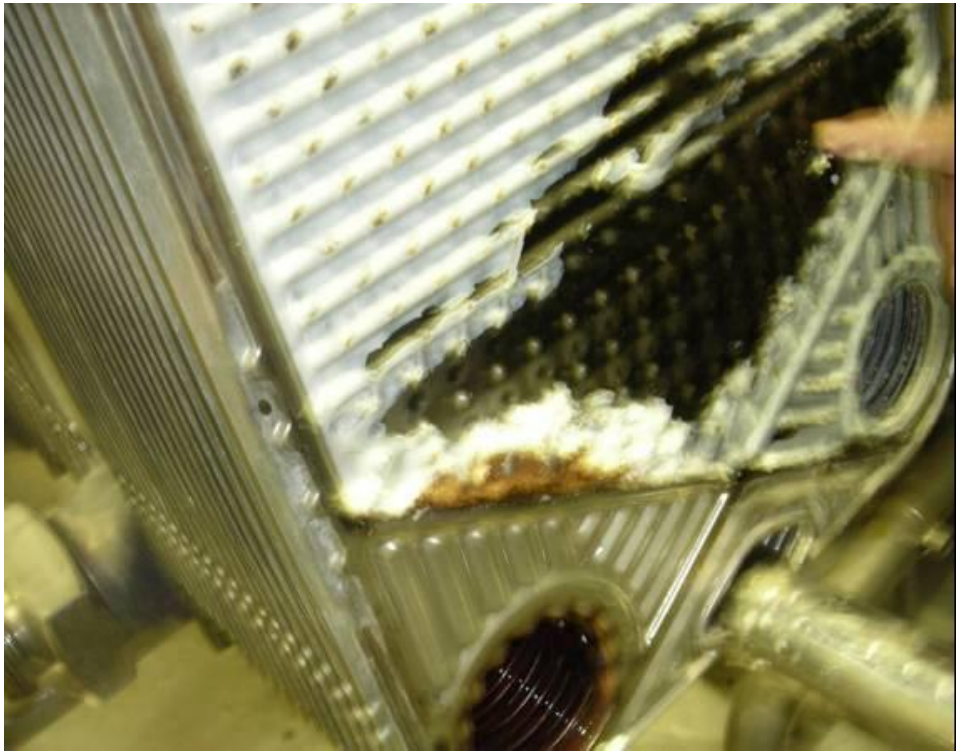
After Alkaline Additive Before Acid Step

Clean Hold Tube After Acid CIP Step

Dairy UHT Fouling Example

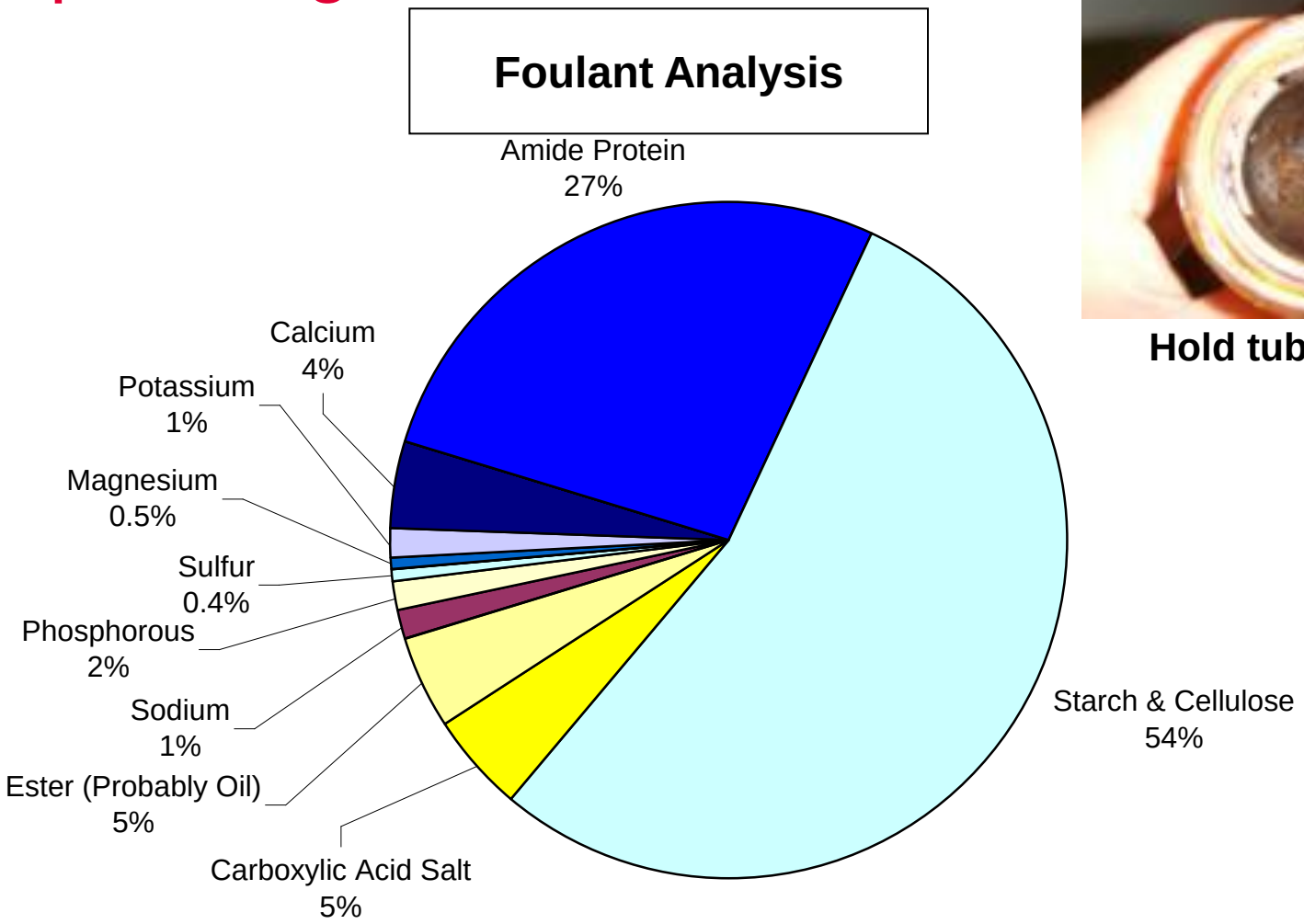


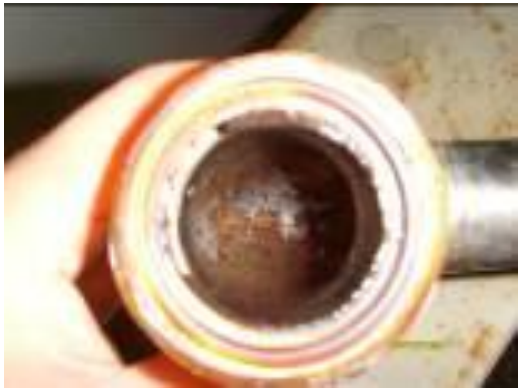
Typical fouling for Dairy plate UHT heating section



Hokyoso Dairy

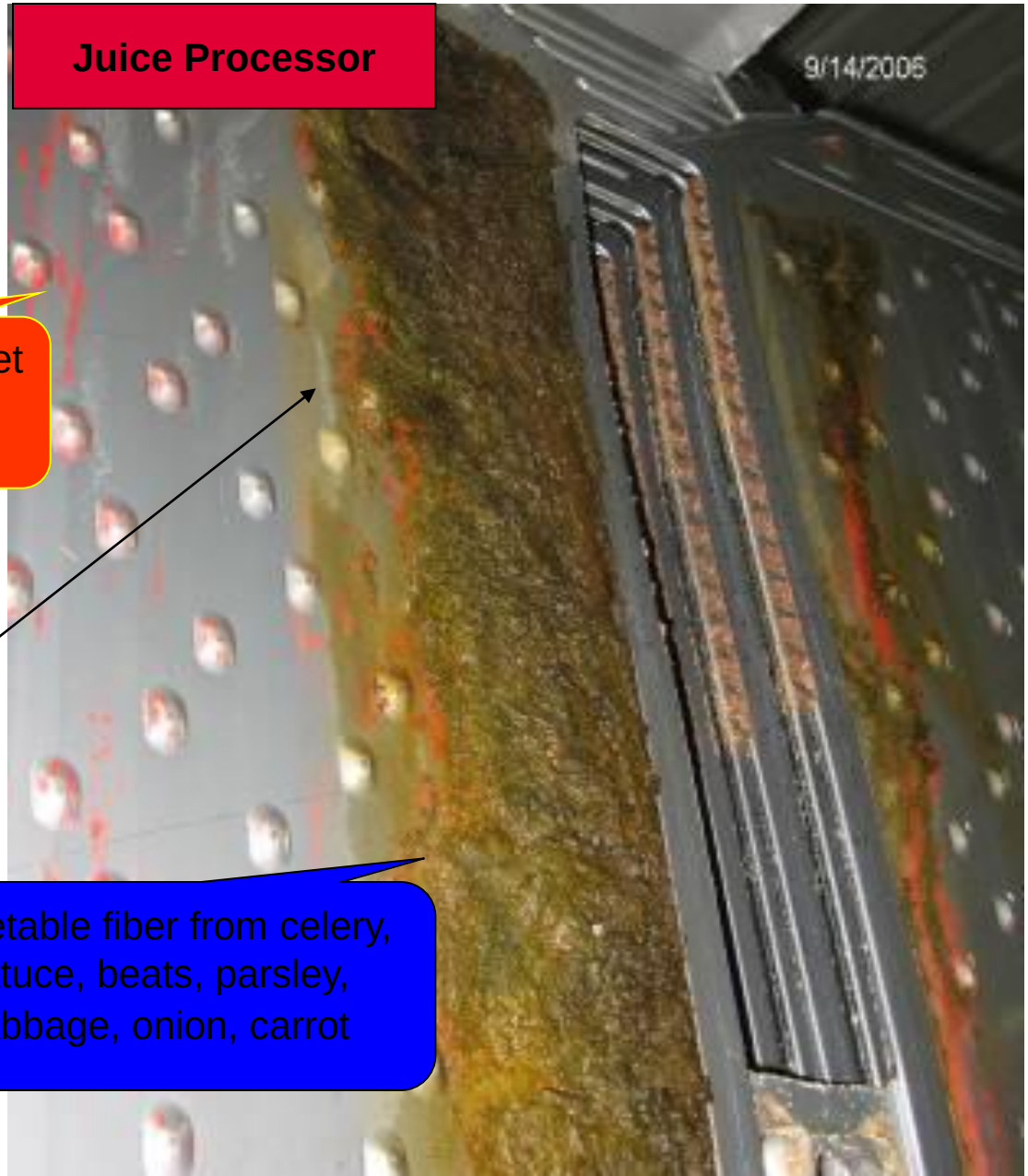
Complex Vegetable Juice Soil



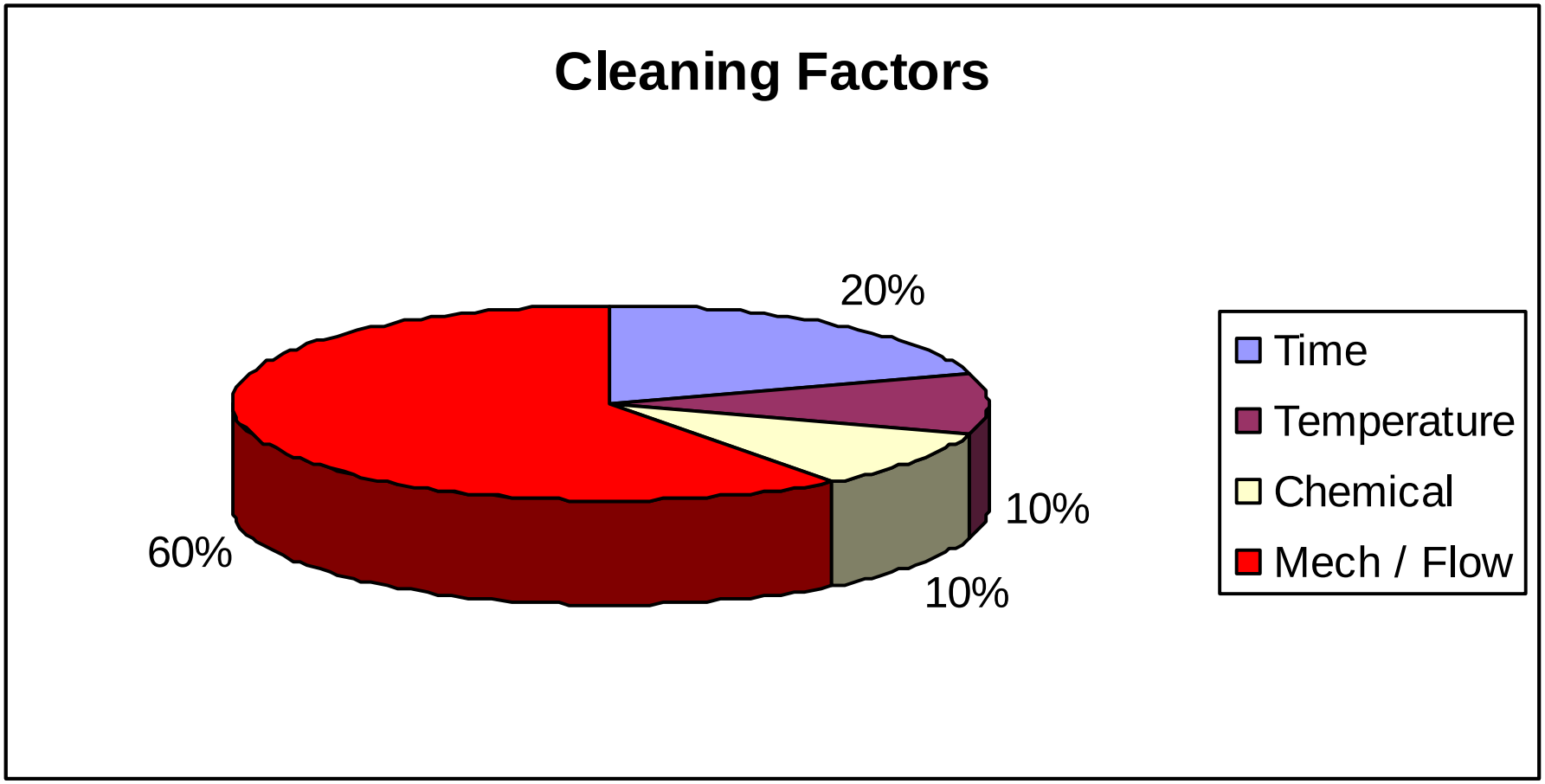


Hold tube fouling

Juice Processor Fouling Example



UHT Cause of Hygienic Problems



Tetra Pak
protects what's good

"The vast majority of UHT hygienic problems are traced back to poor flow rate during CIP and resulting poor cleaning of the tubes, plate press, aseptic valves, or vapor separator"

Problem Solving – Gap Analysis

The SIX RULES Of TROUBLE SHOOTING

1. Take nothing for granted and **believe no one**. Check it for yourself.
2. Rely only on verifiable facts, not on others' memories.
3. Eliminate one possible cause of the problem at a time to narrow the problem down.
4. Change nothing until you have the problem narrowed down as much as possible. Any change made before this point is reached, will only lead to confusion.
5. When changes are made, make only one change at a time.
6. When the problem is solved, take positive steps to see that it can never repeat itself. This usually means continuing communication with the people who make or who are responsible for the daily operation.

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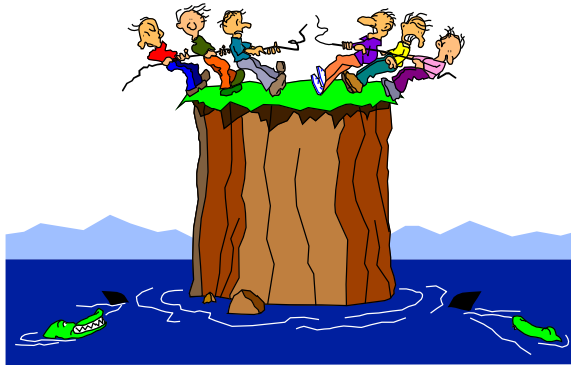
COMMON SENSE

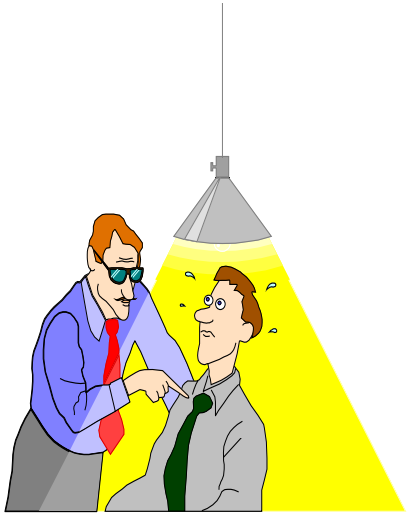
There is nothing common about Common Sense!

Reality Sense:

Is the knack of seeing things as they are, and doing things, as they ought to be done.

Problem - Emotional Phases





- Panic
- Defensive
- Blame
- Want it to go away - Hope for miracle

- Look For Causes and Find Solutions

Organized Problem Solving

Is this a TRUE statement ?

I don’t understand why we are having a problem. We are doing things the same way that we have always done them.

The True Definition Of……

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- **Line Sampling Identified Focus Area**
- **Detective Work Identified Source**

Contaminated Product Air Blow

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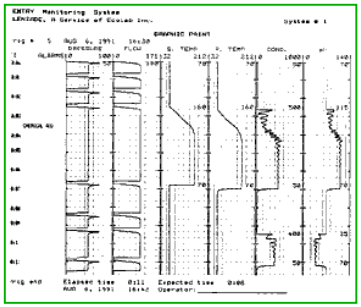
Debris found inside a plate heat exchanger

Organized Problem Solving

SANITATION

- **Review program & practices**
  - **CIP**
  - **COP**
  - **Manual cleaning**
  - **Four Factors (Time, Temp., Concentration, Mechanical Force)**



- **Review monitoring programs**
  - **Visual inspection**
  - **ATP monitoring**
  - **Chemical**
  - **Microbiological**

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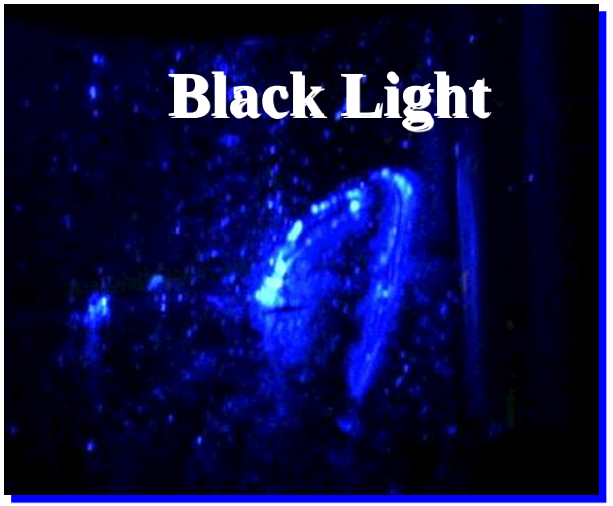
Routine Inspection & Maintenance Neglected

Spray Ball Maintenance

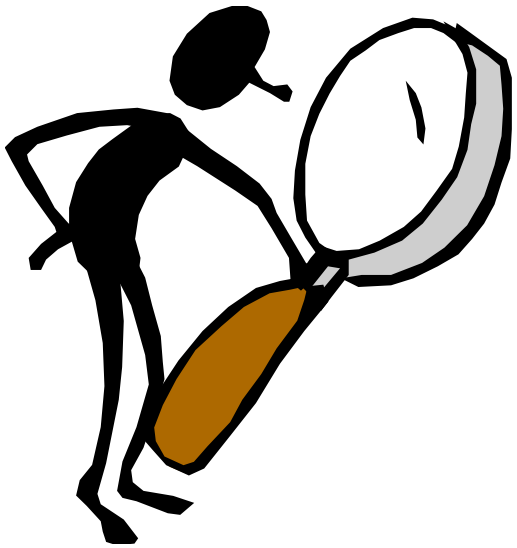
ECOLAB

Visual / Sensory Inspection

- **Immediate**
- **Often Over Looked**
- **Tools Needed**
  - **Flashlights**
  - **Spot Lights**
  - **Black Lights**
  - **Soil ID Test Kit**



“There Is More To Cleanliness Than Meets The Eye”



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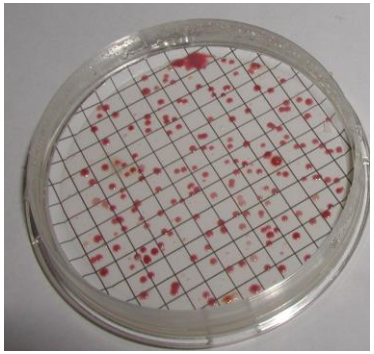
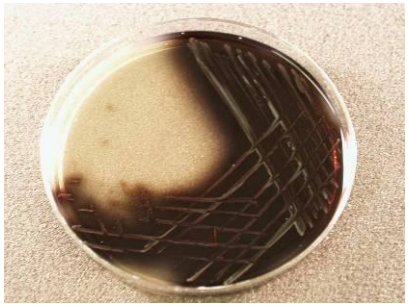
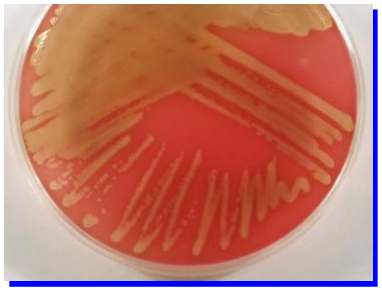
ENVIRONMENT

- **Air quality**
- **Water quality**
- **Specific Microorganism Testing**







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YouTube Video……

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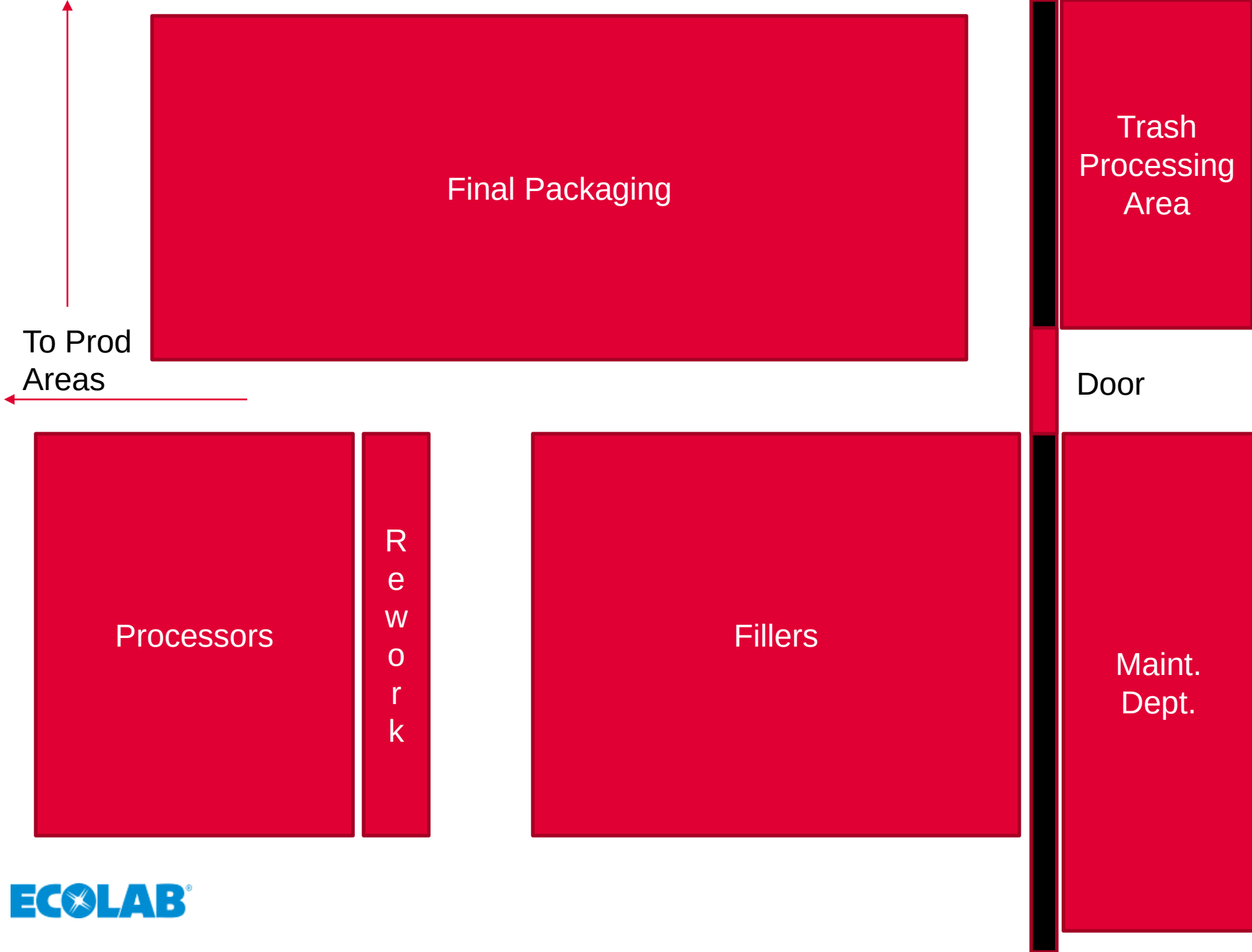
Example Client Production Layout

They were having an “opportunity”

That was exploding on “social media”


Final Packaging
Trash Processing Area
To Prod Areas
Door
Processors
Rework
Fillers
Maint. Dept.

Air Sampling Agar Strip Results

1 - Aerobic Plate Count

2 – Coliform/ Gram Negative Count

3 – Yeast & Mold Count

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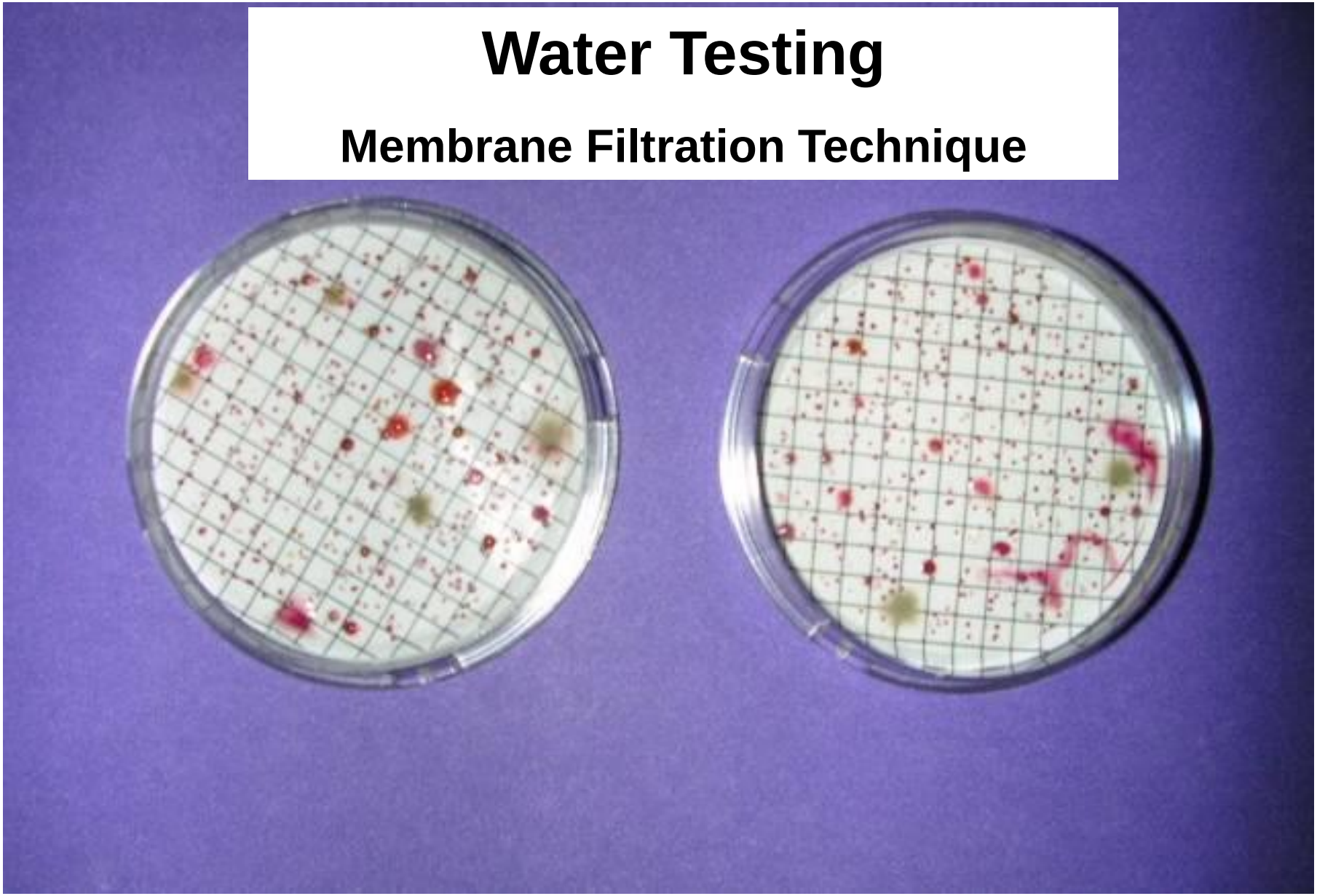
Water Testing

Membrane Filtration Technique



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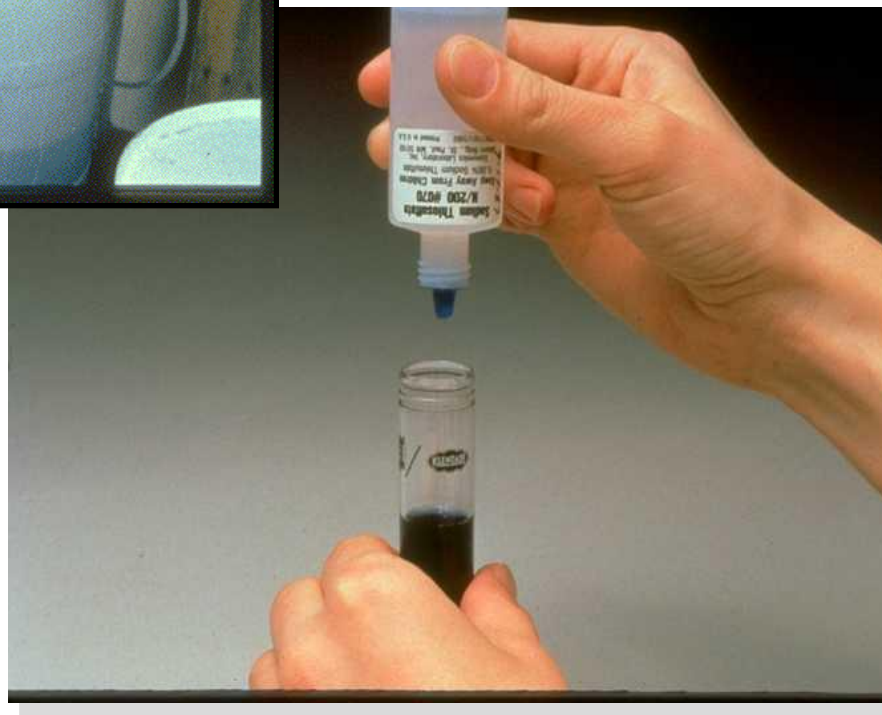
Document & Record Results



Ensure Proper Chemical Concentration !

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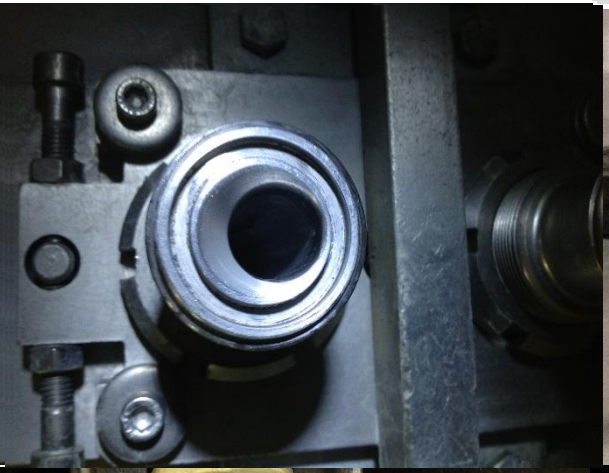
A065 1280x1024 2012/06/12 17:36:13

A080 1280x1024 2012/06/13 14:06:54



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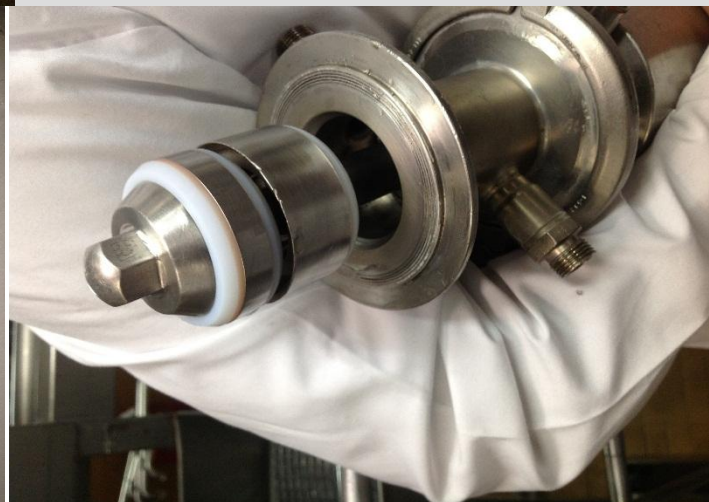
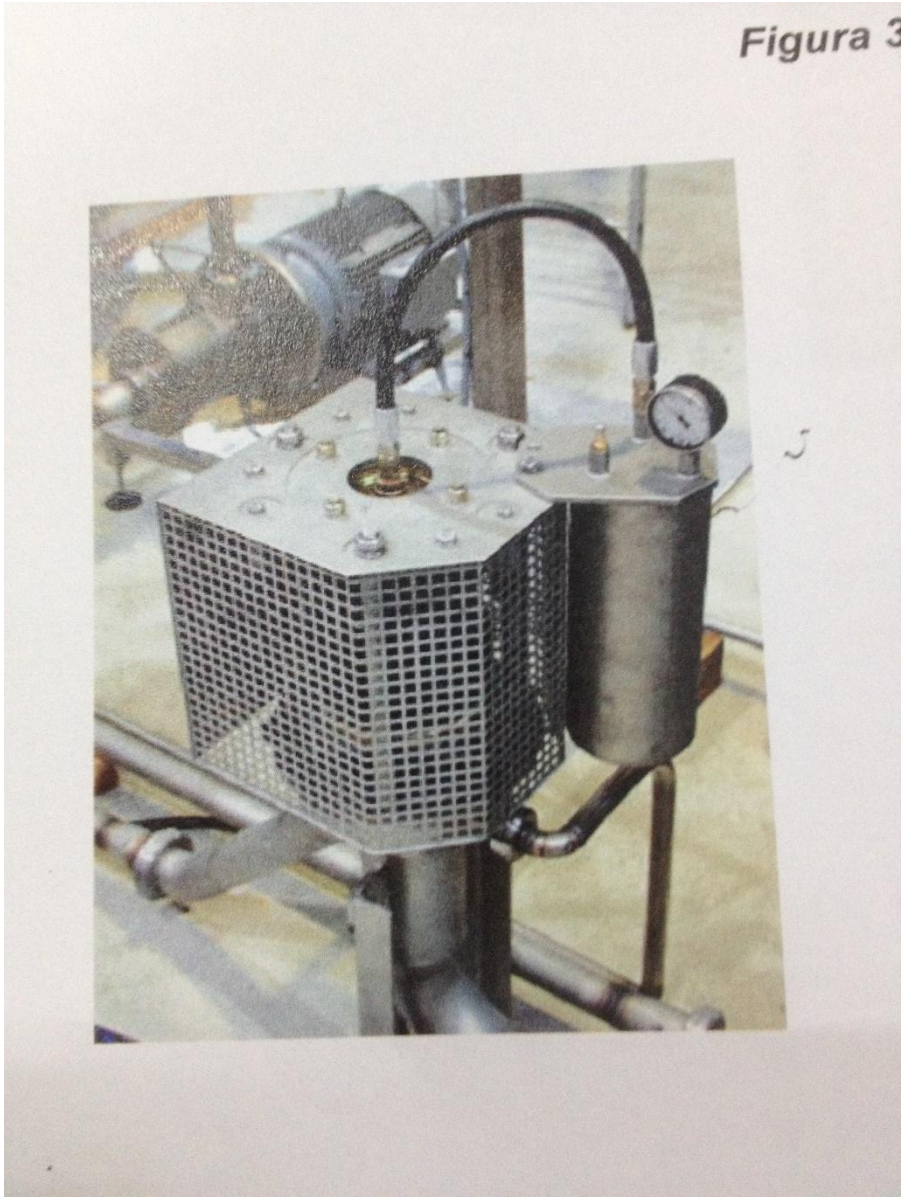


“Aseptic Homogenizer Dampener” – Root Cause Item



From the client…It come’s apart???

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Items That Are Missing

- Documentation of actions/repairs…
- Failure to complete corrective action items.
- Gasket Type/Application Matching

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FMEA – Failure Mode & Effect Analysis

Failure Mode & Effects Analysis
(Process FMEA)

Page ____ of ____
Product Brand(s) or SKUs: _____
Revision No: _____

Factory: _____
Process Owner(s): _____
Key Dates: _____

FMEA Number: _____
Prepared By: _____
Date (orig.): _____

Team Members: _____

Facilitated By: _____

Date (revised): _____

Occurrence Scale

Detection Scale

Process Function / Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)	Occur	Current Process Control(s)	Detect.	R.P.N.	Recommended Action	Responsibility & Target Completion Date	Action Results**					
												Action taken	Sev**	Occur**	Detect**	O.R.P.N	R.P.N.
									0							0	0
									0							0	0

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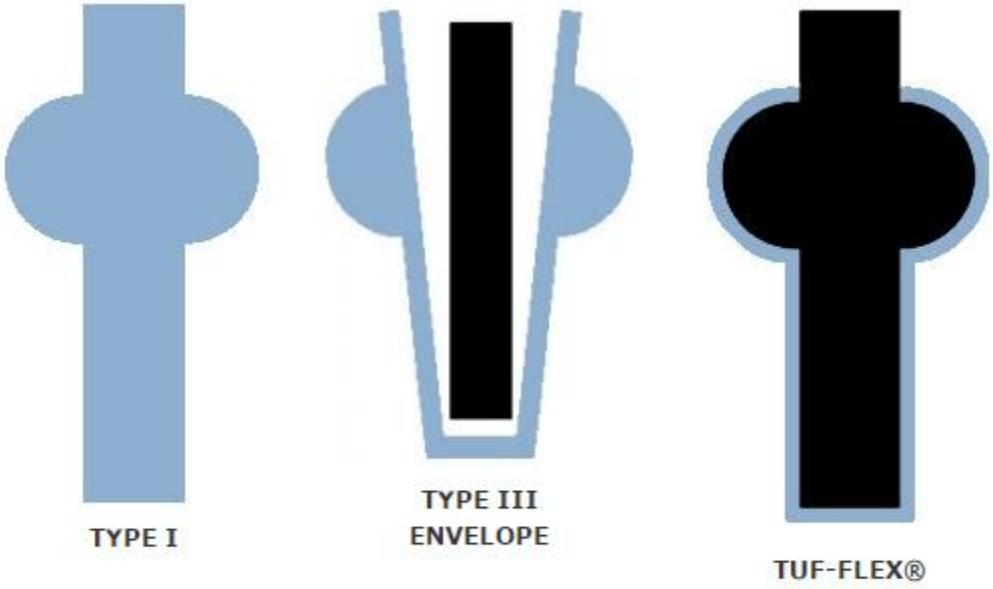
http://www.rubberfab.com/products/sanitary-gaskets/specialty-gaskets/tuf-flex

TUF-FLEX® GASKET COMPARISON



TYPE I

A Solid PTFE Type I Gasket is guaranteed to fail in SIP conditions. They will creep, cold flow and leak at delta T.

TYPE III ENVELOPE

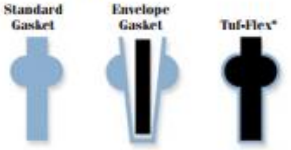
The Envelope Gasket construction provides inconsistent results between the two materials. It will also creep, cold flow and leak over time.

TUF-FLEX®

The PTFE grafted elastomer in a TUF-FLEX sanitary gasket will maintain I.D. without re-torquing or leaking.

Tuf-Flex®

Tuf-Flex®, **the ultimate pharmaceutical sanitary gasket**, is setting new standards for **purity, performance, flexibility** and is the world's first **unitized gasket**. A Tuf-Flex® gasket's contact surface is PTFE unitized to an EPDM rubber inner core. **This totally bonded construction provides the inert, non-stick benefits of PTFE with the memory of an elastomeric gasket without fear or risk of pigmentation or spalling.** Designed to meet critical requirements in biopharmaceutical, ultra-pure water, WFI (water for injection) and **difficult aseptic processing applications.** Tuf-Flex's® extended service life **increases up-time by out performing other gaskets by eliminating costly process interruptions.** Achieve higher performance under SIP/CIP conditions.



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Tapered Diaphragm Valve – Aseptic Homo Sealing System

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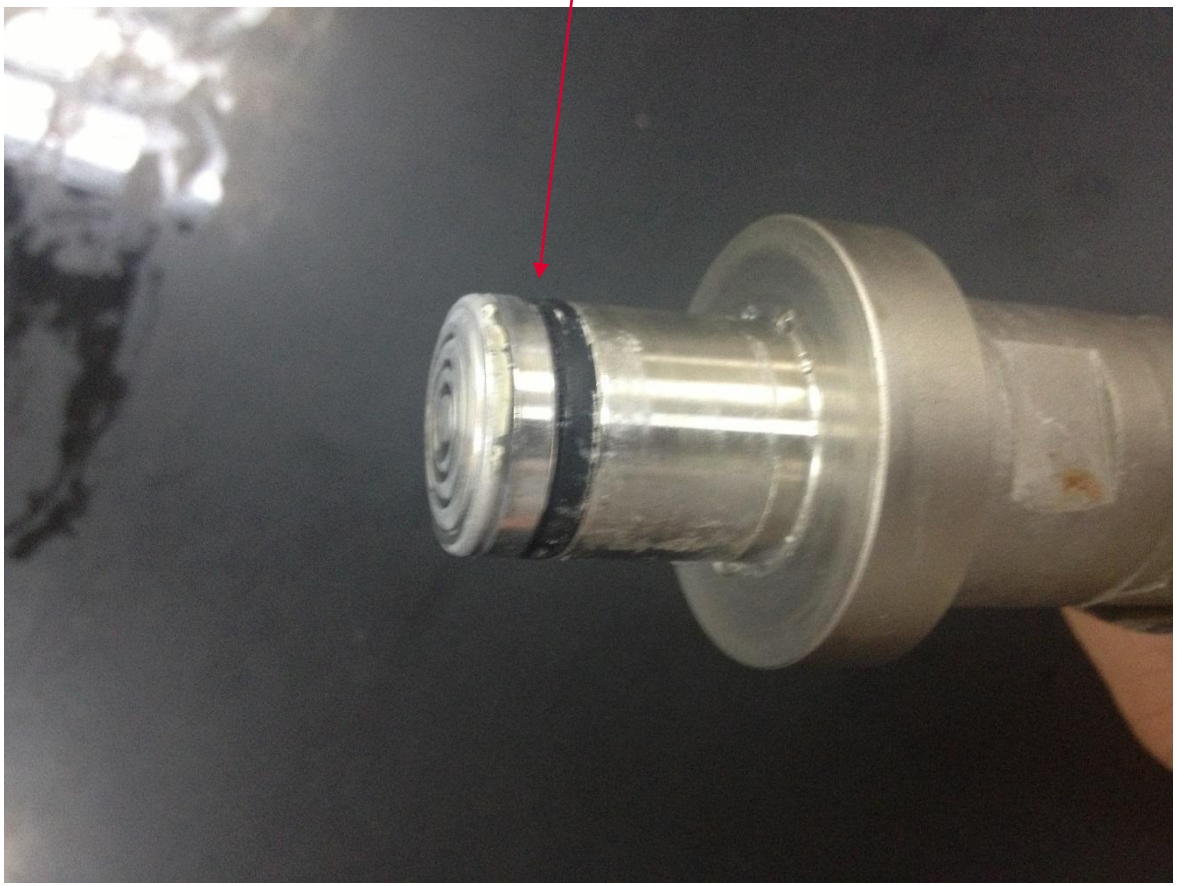
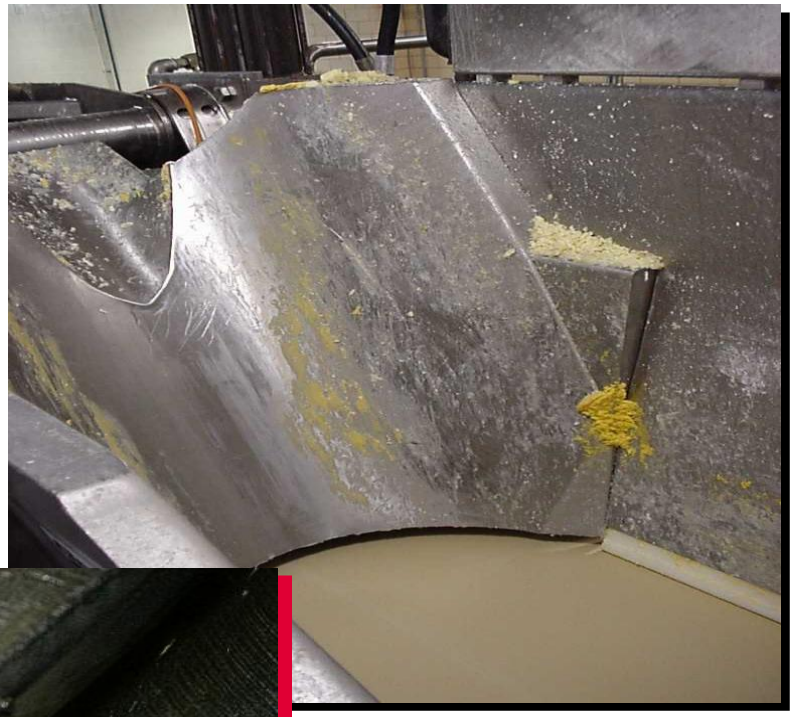
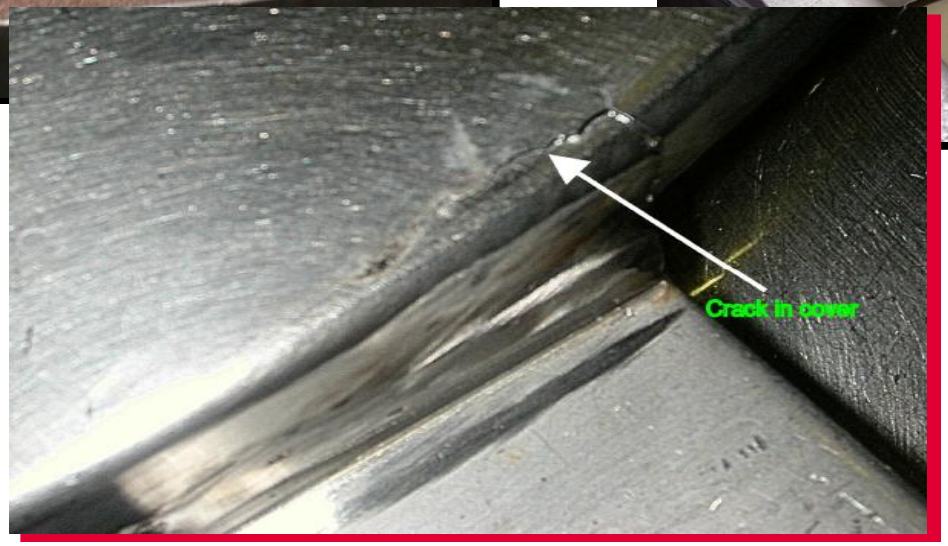
Level Transmitter O-Ring Failure



Poor sanitary design and maintenance will negate the best cleaning program!





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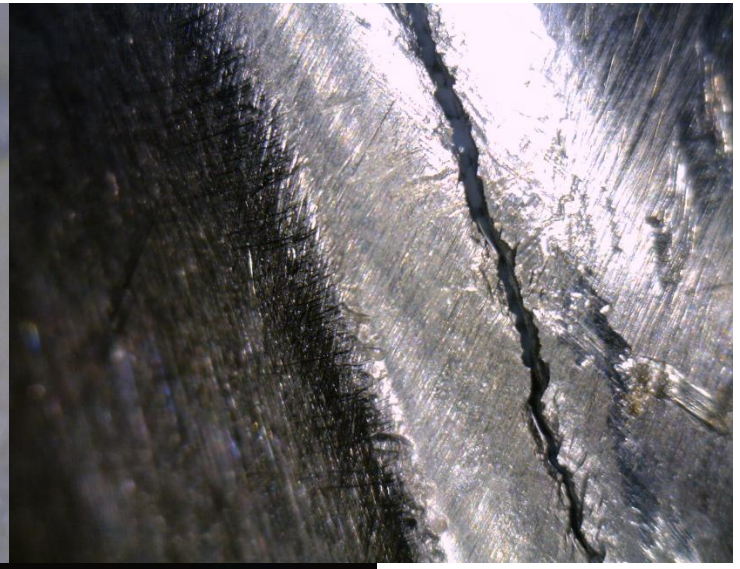
“Hidden” Fitting……..

Rubber Goods – Stainless Steel Failure – Aseptic Sampler Fitting



Examined with portable microscope

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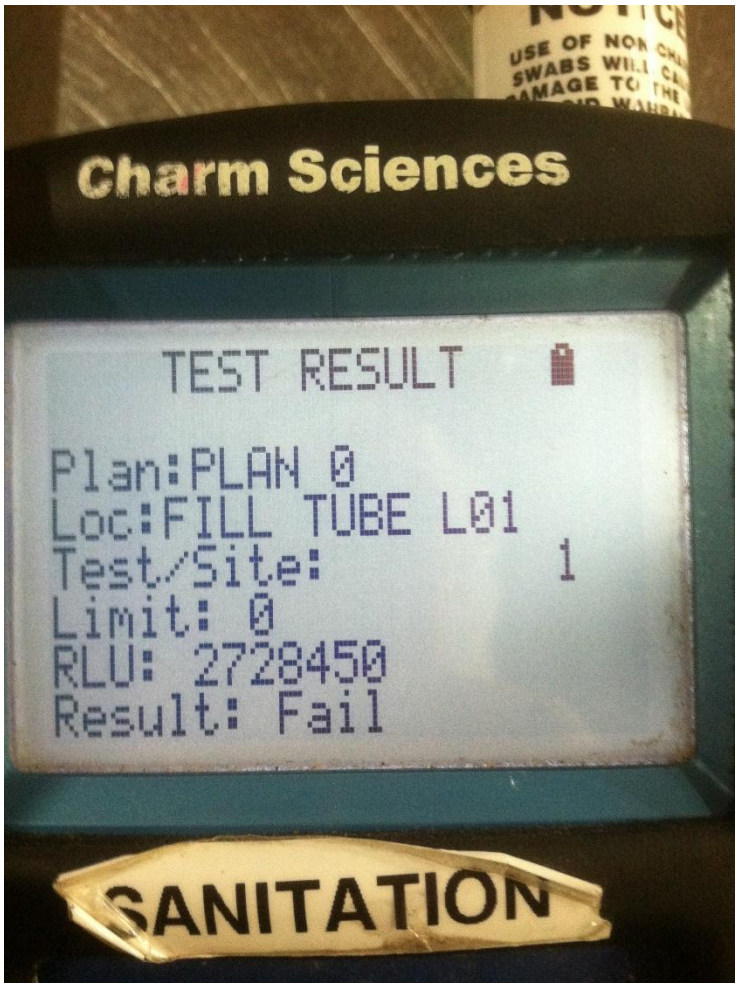
Product Air Blow – To Aseptic Processor



ATP Testing Sites Must Match Areas Sampled

Blending Transfer Pump Seal To UHT Processor – Swabbed For Spore Formers – High G+ Growth

Static Mixer After “Value Added” Production Run – End Of CIP

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Rare Earth Magnet…….Problem??

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Items Discovered This Week!!

we make it easier
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Aseptic Processing Equipment Does Not Stay **New** Forever

Thank You – Questions??

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