



Finished Product Testing  
(isn't the answer?)

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# Is it Red Light or Green Light?

...FPT ensures product is safe to consume.

To be 100%, we'd have to test 100% of the product...

...FPT helps the manufacturer target, identify and rectify defects.

The focus is on the COA in hand rather than application to the system...

...FPT increases brand awareness and provides assurance to the customer and consumer.

Product safety responsibility is broad spectrum...

...FPT provides a historical measure of safety and quality.

Sampling and lab analysis should and must change so how can you compare over time...



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# Or Caution?



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# Feedlot to Fork

BEEF CARCASS



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# Does 'de facto' adoption of the N60 strategy make sense????

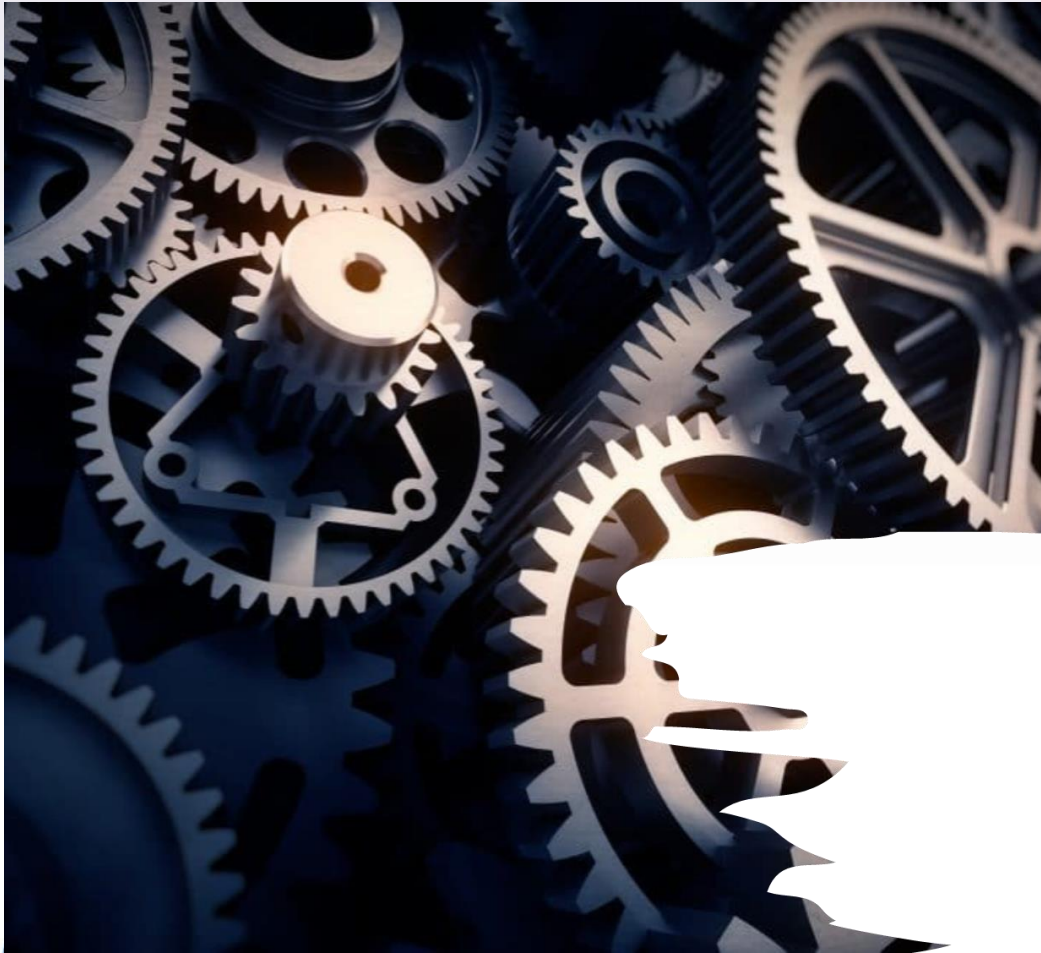


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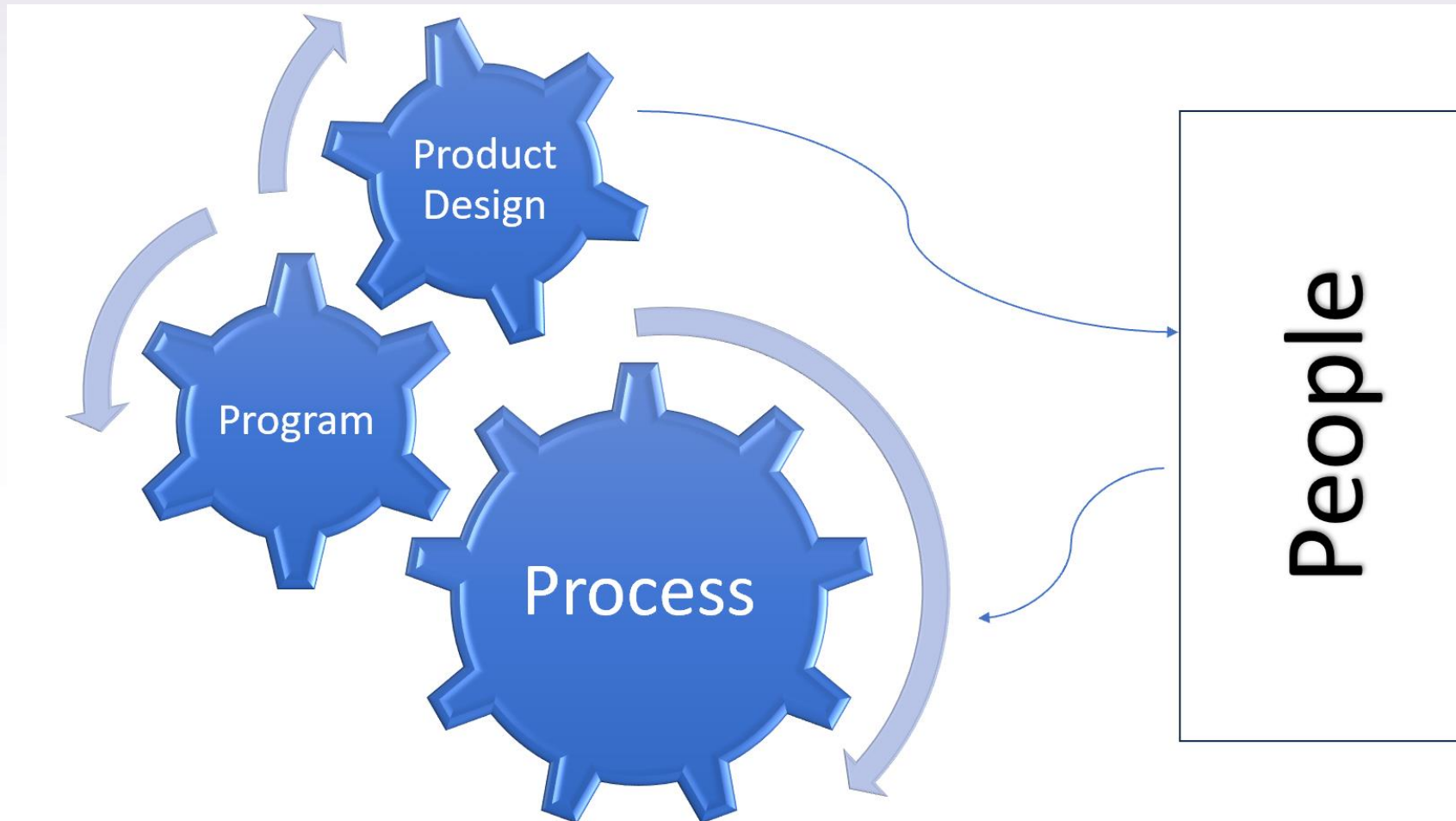
# Beyond the COA...Let's Get Into the Gears



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# The Food Safety System

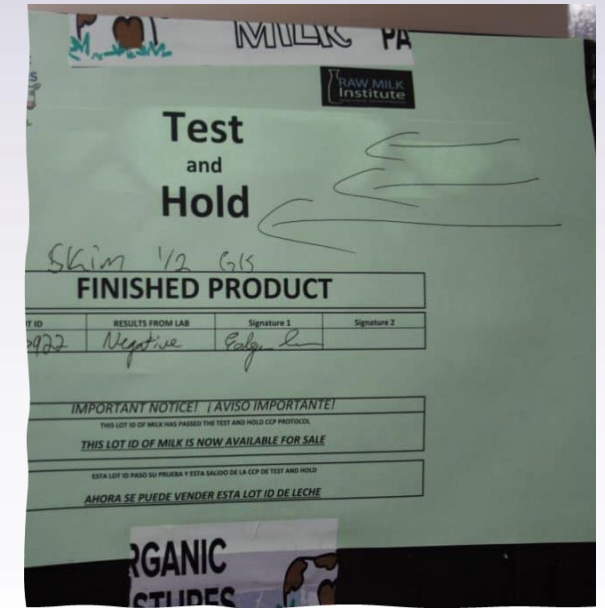
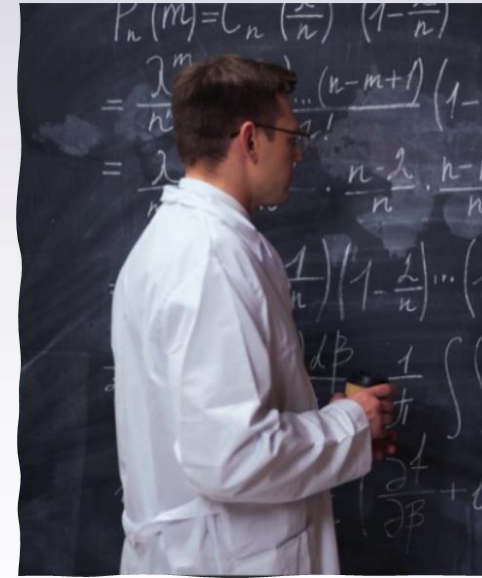


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# People- The Right Stuff

- The Scientists
- The Samplers
- The Laboratory Staff
- The FSQ Team
- The Supply Chain
- The Customers



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# A plug on the FPT Operation

→ Careful design of the system, alignment of resources, actions on the result and long-trend activities.

**Once Design is complete, implementation must be militant. This level of execution requires:**

1. Time Study of Each Piece of the Process [might mean more cost]
2. Confident Personnel [think Back-ups]
3. Robot-like Consistency

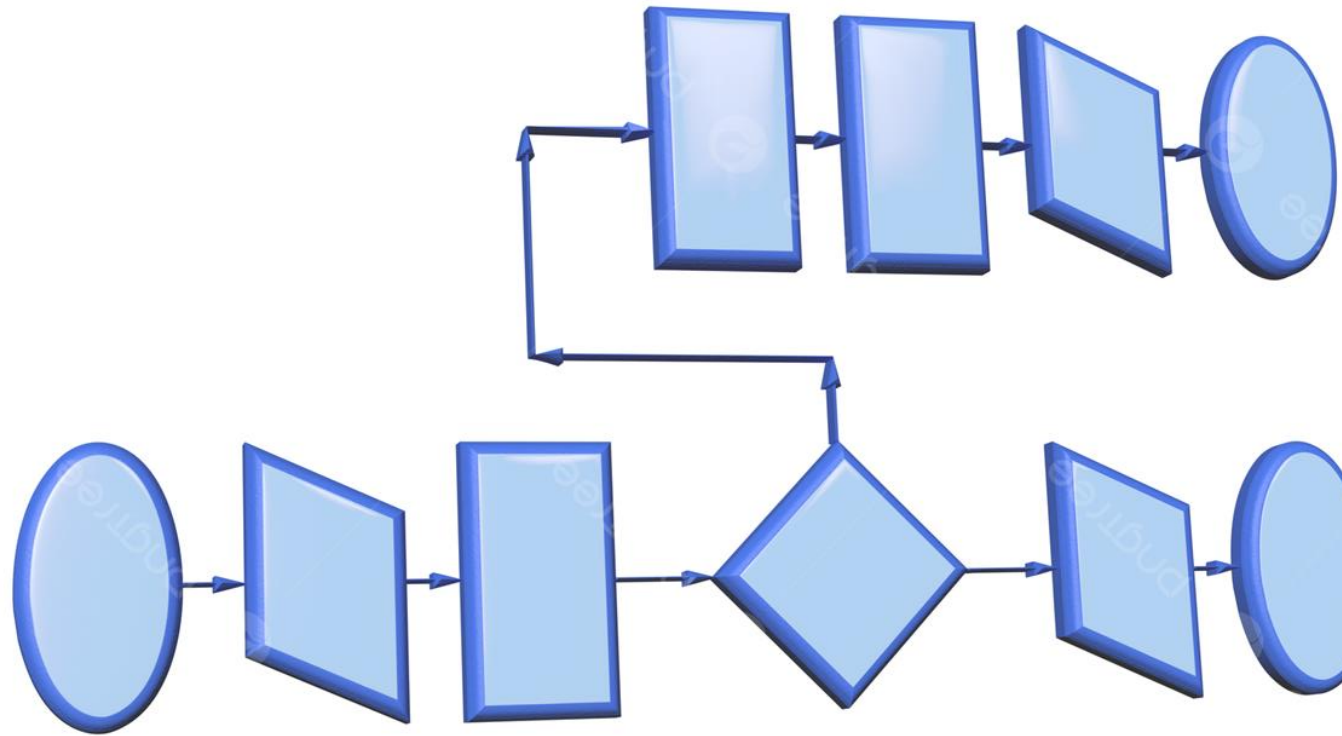
**Zero** amount of free-will should reside with sampling personnel. Decision-making from results should be pre-determined by designated people. This is not a spin zone.

**Food Safety Culture and Engagement is directly linked to the commitment 'leadership' has to people.**



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# Manufacturing Process and FPT Process



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# Process Considerations

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Identification of the Targeted Sample Collection

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Ability to safely and effectively sample

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Aseptic collection

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Identification of Sample

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Storage and Conveyance of the Sample

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Timing to Laboratory Operation

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Result Communication

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Actions After Result

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# Program and Procedure is Critical

As simple as possible

**Must, shall** vs may, should

Written, well-maintained system

Verifiable

No Spin, No Interpretation- Explain the  
Why to the People



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# Put Product Sampling in Perspective

One lot on hold of 100,000 1lbs  
packages = 45,359 kg



Ten 25g samples = 250 g = 0.250 kg, or  
0.00055% of the food is actually tested



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# Statistically-Based Sampling

- If 10% of lot was the contaminated, and you test 10 samples:
  - 65% chance you would detect the contamination
  - 35% chance that a contaminated lot is released
  - You would have to test 30 units to reach 95% confidence of rejection
- If 0.5% contaminated
  - 5% chance you would detect the contaminant
  - 95% chance that a contaminated lot is released
  - You would have to test 600 units to reach 95% confidence of rejection

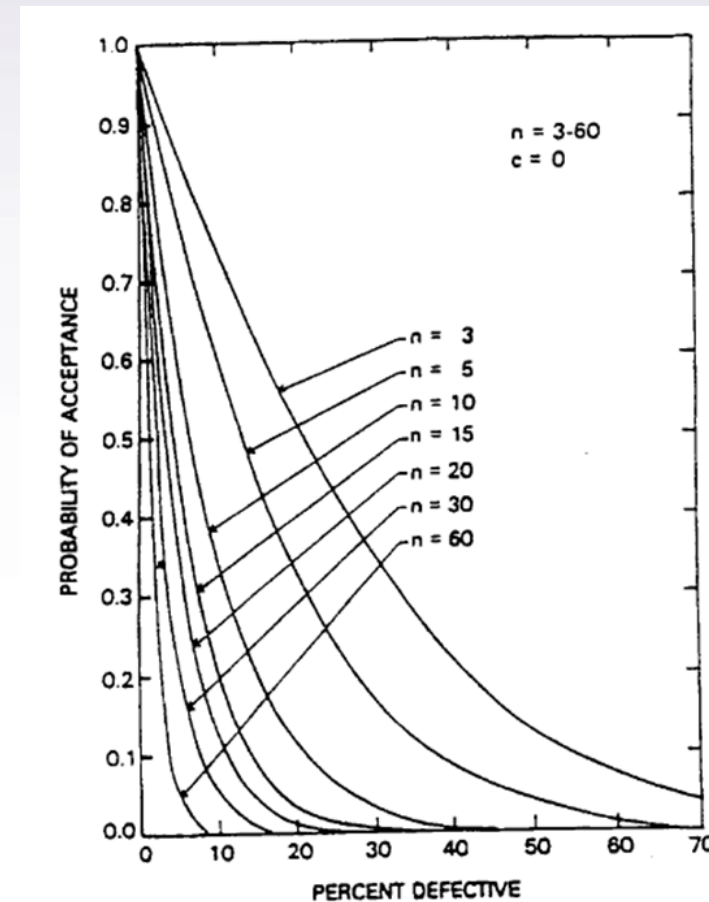


Figure 1. Single sampling (two-class) attribute plans for sample sizes  $n = 3, 5, 10, 15, 20, 30, 60$ , and  $c = 0$ .



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# Statistical Limitations of End Product Testing

## Sampling Probability

*Probability of Missing Sporadic Contamination by Product Sampling*

Number of Samples Tested	% Contamination in Lot			
	10%	2%	1%	0.5%
3	73%	94%	97%	99%
10	35%	82%	90%	95%
60	<0.5%	30%	55%	74%
120	<0.5%	8.5%	30%	55%
180	<0.5%	2.6%	16%	41%
240	<0.5%	0.8%	9%	30%



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# How is the lot defined?

## **IMPERATIVE to know how you define a "lot" for sample testing**

- For purposes of a recall, you **MUST** have a full breakdown of all equipment and it must be cleaned using a chemical, to count as "separation of lots"
  - No "water rinse" or "product push" allowed!
- When you agree to do micro testing for a customer, are you completely isolating that "lot" of product from product going to other customers?
  - Did you allow extra time and personnel and COST for full breakdown & cleaning both before and after this "lot" of product that will be tested?



# Lot Segregation

- You MUST be sure that no other customer's product is implicated as part of the same "lot" tested, unless that product is still in YOUR control (still on your premises).
  - If other product is tied-to the tested lot, such as coming from a continuous-use flow-through silo or going through the same fry-line with no "break in production" in-between... a pathogen positive or out-of-spec result for the one customer can cause you to be in a public recall of all the other product that was already released out of your control!
- Are you including the extra TIME, paperwork, personnel, cleaning chemicals, and refrigerated shipping or pick-up of samples in the cost that you assign to micro testing of product samples per each customer request?



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# More “hidden” costs

**Especially for small to medium size companies...**

- If multiple customers ask for finished product testing, you can easily find yourself spending more time breaking-down and cleaning equipment than actually producing product...
  - If you fail to account for all expenses involved, and price accordingly, you can easily be in a situation where it costs you more than you are profiting for this product.
  - Part of the "cost" involved is hiring competent people to do the cleaning, the documentation of sanitation activities, and to do the actual sampling, etc.
  - And don't forget that you need someone knowledgeable about food microbiology on your staff (or consulting for you) who is reading and interpreting the results from the micro testing, and recording all of the proper paperwork for any actions needed regarding the outcome of the testing.



# What Do Customers Want?

- Customers want confidence that the products you supply will uphold their standards of safety and quality.
- It's always worth having a discussion of specification requirements, whether it's during the onboarding process with a new customer or during the commercialization process of a new product.
- Full alignment between customer and supplier ON finished product specs can save time and money for both parties!

So...how do we (suppliers) talk to our customers about finished product testing requirements?



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# Customer Required Testing - Scenarios

## Scenario 1:

You Produce The Same/Similar Product, You Will Be Sole Supplier

Make your historical data work for you!

- Challenge studies
- Finished product testing on similar items
- Current testing frequencies
- Environmental monitoring data
- Walk them through your process: you are the expert!

## Scenario 2:

You Are The Developing Supplier Of A New Product

What levers can you pull in product development?

- Packaging
- Formulation
- Interventions
- Intended use
- Discuss a validation/data collection period

## Scenario 3:

You Are A New Supplier Of An Existing Item For The Customer

You don't have leverage, but let's still have a conversation.

- What is the capability of your process and your staff (and your lab)?
- Go through customer specs in detail. If something is unclear - ASK.



# Talking to Customers: The Do's

**DO:** Get involved early in the development process.

**DO:** Have the right people in the room - Technical Experts, R&D, Quality, Procurement/Sales for visibility (but they should not be leading the discussion).

**DO:** Read customer requirements carefully! Dig into required frequencies, approved testing methods, actions required for out of spec product.

**DO:** Ensure any testing costs are reflected in the product pricing.



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# Talking to Customers: The Do Nots

**DON'T:** Have this conversation via email.

**DON'T:** Expect to get away with no finished product testing at all.

**DON'T:** Wait until the specification is signed and pricing is set.

**DON'T:** Agree to specifications you are not confident your process can deliver.

**DON'T:** Produce before you and the customer agree on the specification.



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# Connect with the Panel

Donna Schaffner



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Thanks!

# Questions?



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