

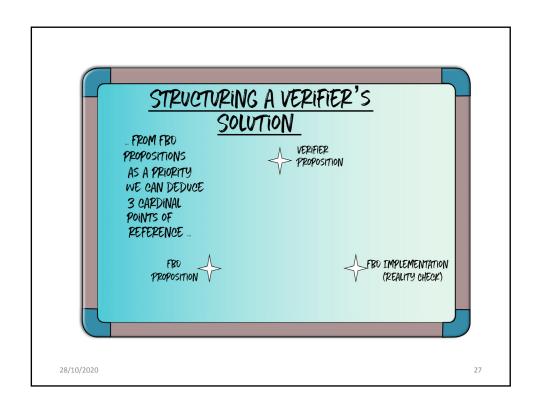


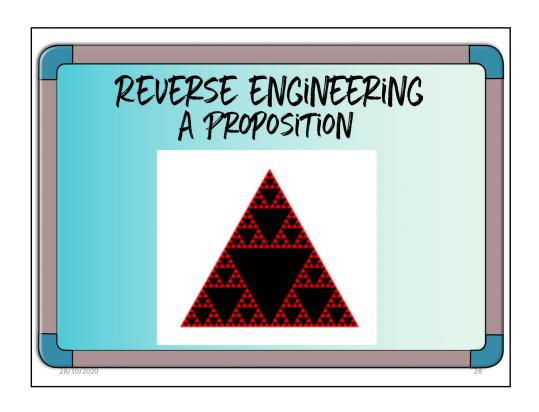






... BY SIMPLE DEDUCTION
OUR APPROACH TO
VERIFICATION CAN THEREFORE BE
DEDUCED. I.E VERIFY
'1. DOES THE FBO INTEND TO DO
THE RIGHT THINGS AND
2. IS THE FBO DOING THOSE THINGS?





# Exercise – Reverse Engineering the FBO's Proposition

# REVERSE ENGINEERING A PROPOSITION

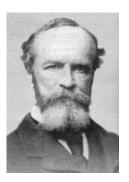
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# PA(168

"Objective evidence and certitude are doubtless very fine ideals to play with, but where on this moonlit and dream-visited planet are they found?"

- William James 1842 –1910 (considered to be one of the greatest philosophers of the pragmatic school)



"Information that can be proved true, based upon facts obtained through observation, measurement test or other means"

- First defined BS EN 8402/1995
- Referred Regulation (EC) 178/2004 but not defined

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### PA(170

# **Attributes of Objective Evidence**

✓Scientific — Can the data be evaluated by independent observers to reach the same conclusions?

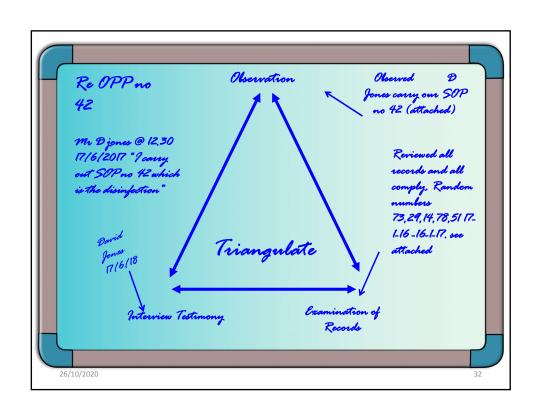
- ✓ Scientific Are the data documented in a manner to allow re-creation of the data or the events described?
- ✓Scientific Does the documented evidence provide sufficient data to prove what happened, when, by whom, how, and why?
- $\checkmark$ Legal Was the documentation completed concurrent with the tasks?
- √Legal Is the documentation attributable?

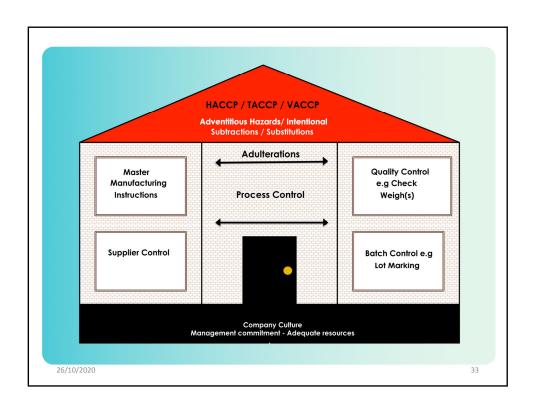


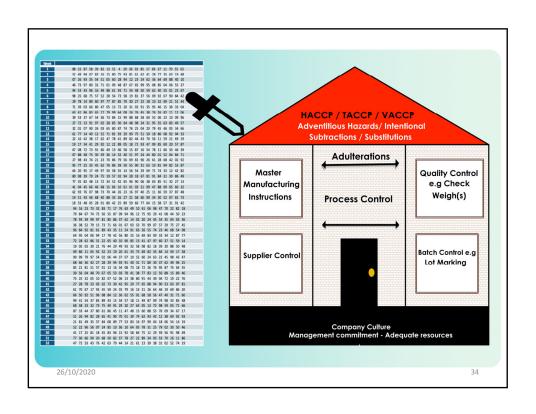


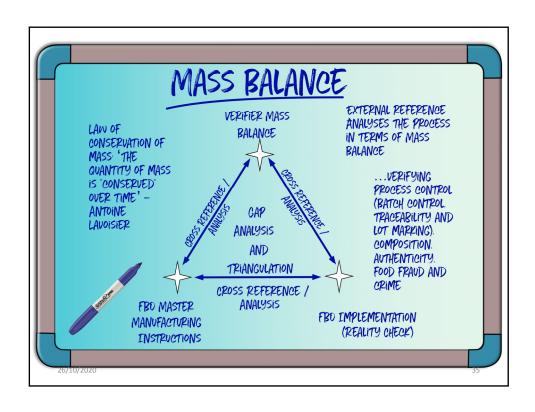


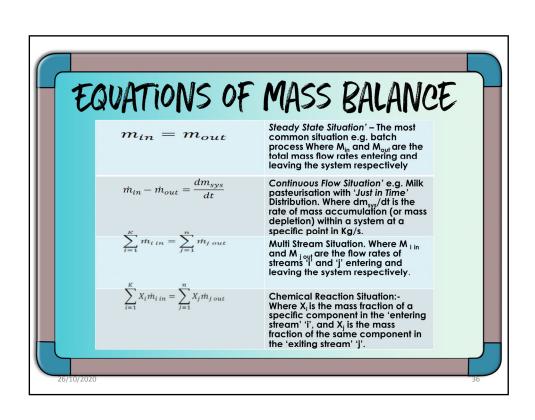
Denise Dion USA FDA Office of Regulatory Affairs Primary Editor of the FDA Investigations Operations manual



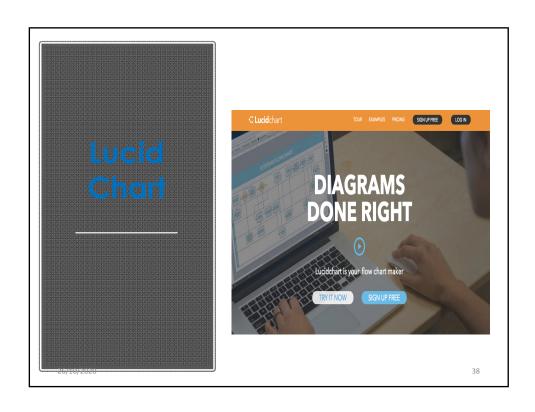


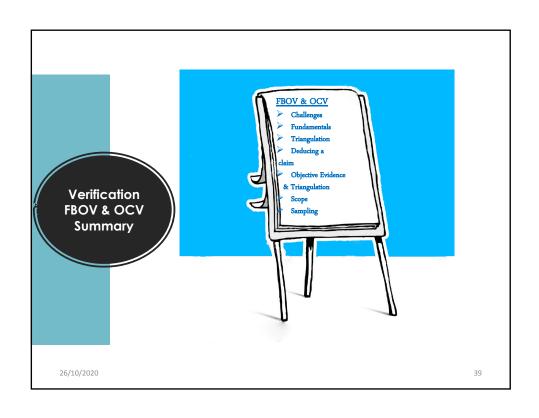


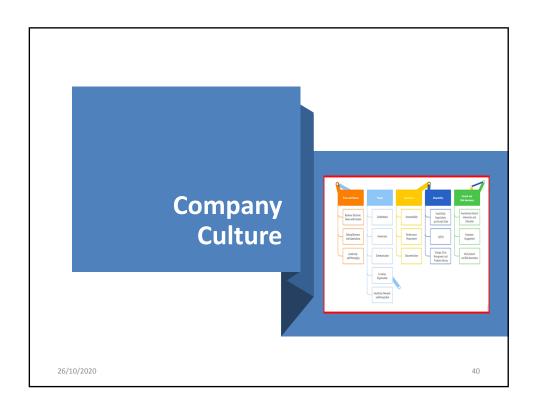


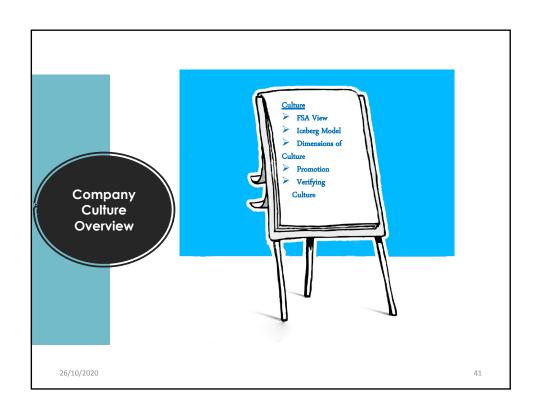


# Exercise – A mass Balance



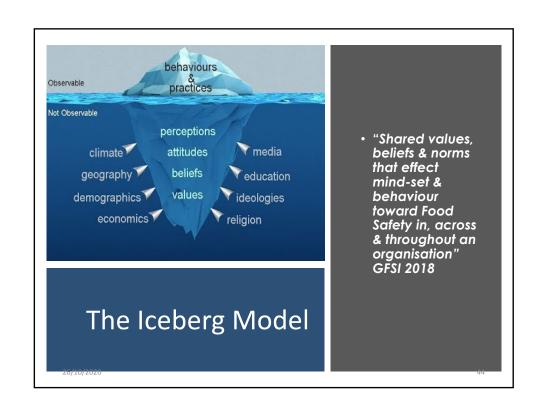


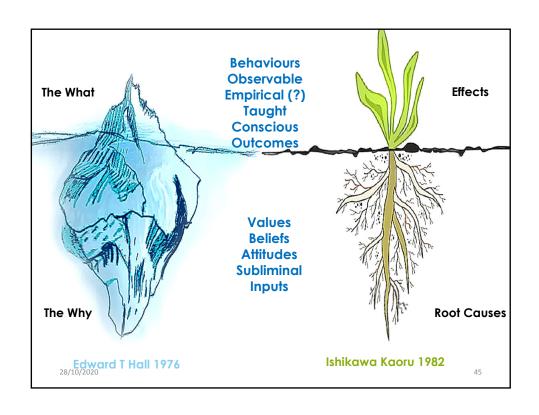


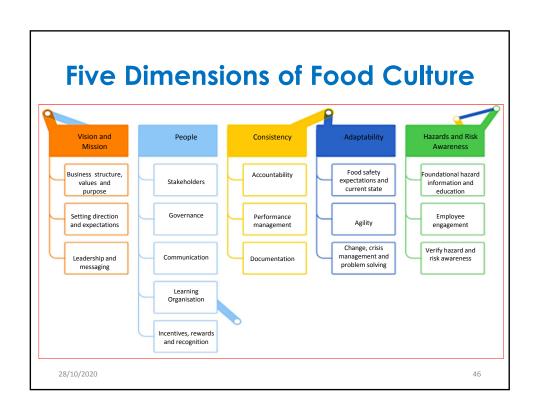












# Verifying FBO Culture





Food safety culture diagnostic toolkit for inspectors

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This is a draft toolkit developed as part of an ongoing research project. The views expressed in this document are those of Greenstreet Berman Ltd and its contractors and not necessarily those of the Food Standards Agency.

Greenstreet Berman Ltd, 10 Fitzroy Square, Fitzrovia, London W1T 5HP, T: 020 3102 2110. W: www.greenstreet.co.uk

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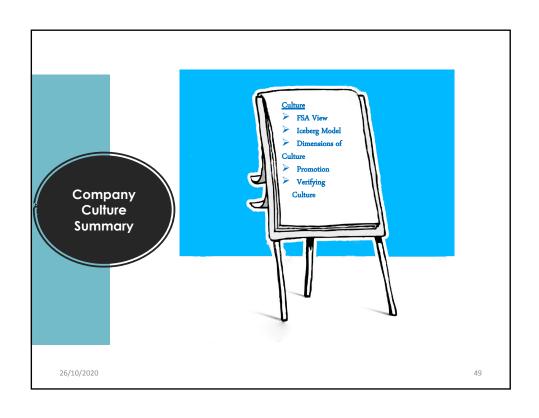
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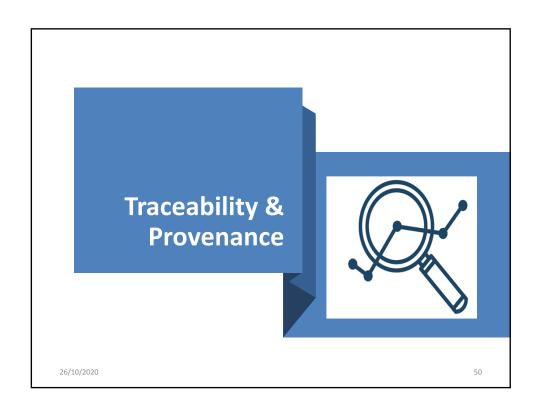
26/10/2020 4

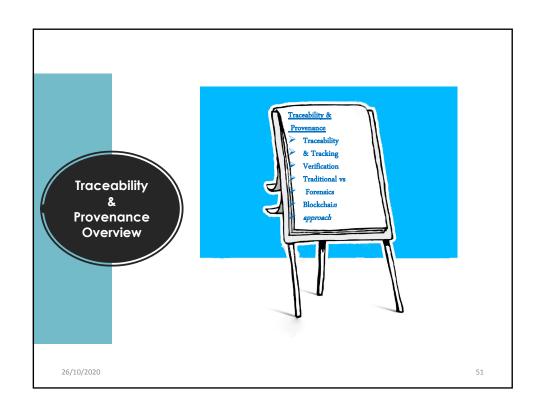
# Exercise - Promoting & Verifying FBO Food Culture



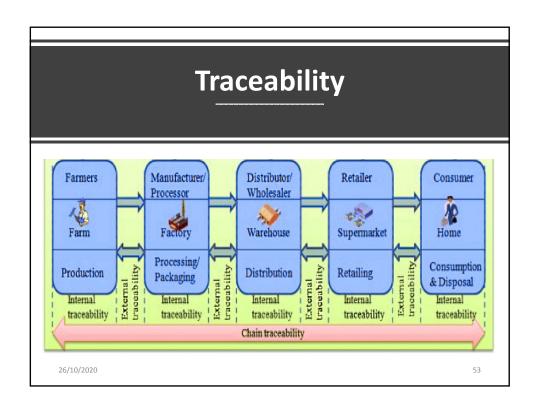
26/10/2020 48

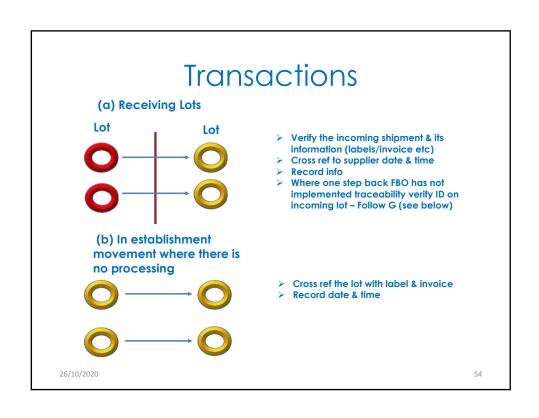




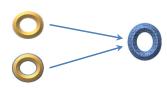




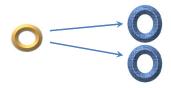








(d) Division of a lot



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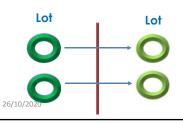
- Verify data re pre-combined lots, refer SOP & record
- > Assign new ID to combined lot
- Link data before & after combination & record
- Record info re combination work needed for ID if any (eg date, quantity before & after combination)
- Prepare label & invoice with the new ID & attach.
- Verify pre-divided lot data & record
- Assign new lot ID to divided lots
- Record the ID linkages
- Record division data, e.g quantities before & after division, date & time.
- Prepare label & invoice with 55 the new ID & attach

# **Transactions**

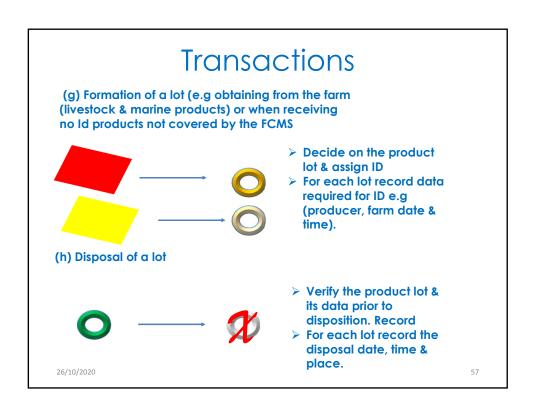
(e) Processing Not Involving Combination of Lots e.g Heating, freezing drying etc

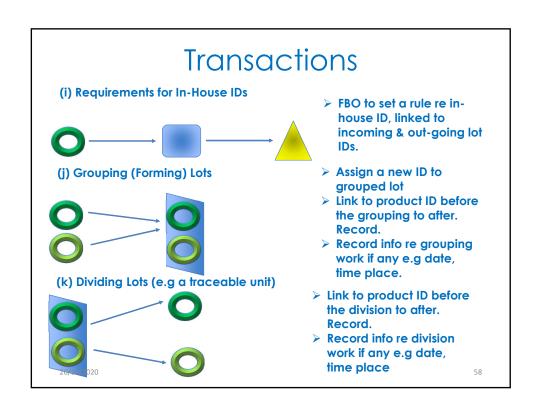


- - (f) Shipment of a Lot

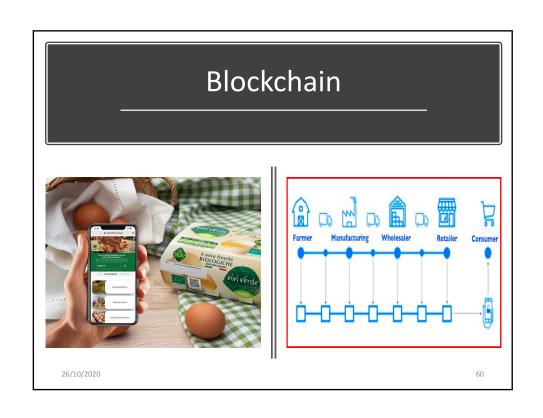


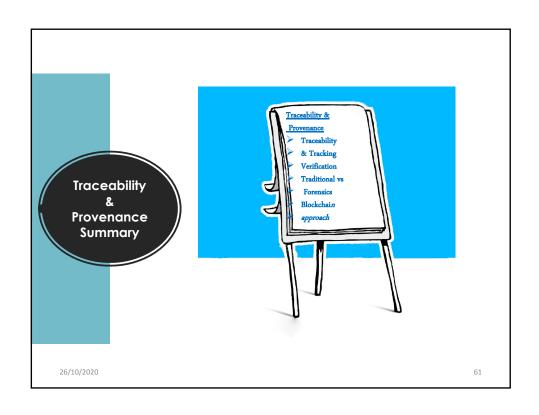
- Verify pre-processing lots data & record
- Record info re processing work required fo ID - If any e.g date & time of processing, quantities before & after processing.
- Prepare label & invoice with ID of processed lot and attach.
  - Verify lot to be shipped & its data.
    Record
  - Cross ref & link ID of shipped lot to buyer date & time. Record.

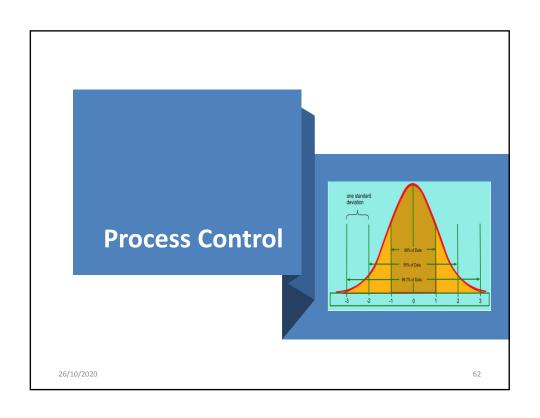


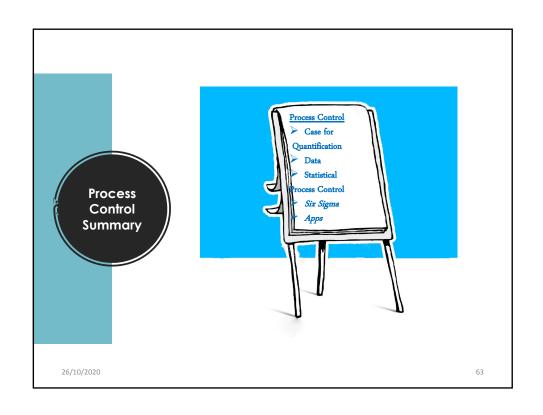


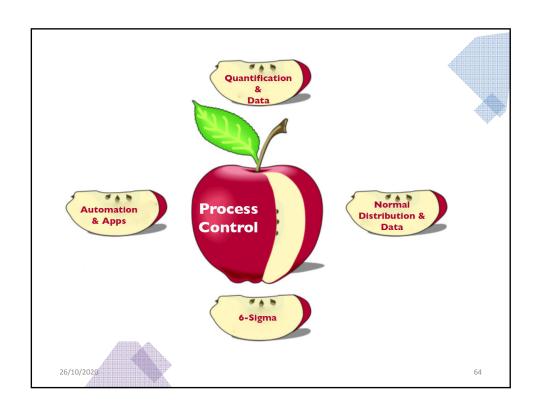
Traditional vs Forensics		
	Traditional	Forensics
Speed	x Can be slow relies on checking data & each point in the supply chain	✓ Fast 1 to 5 days
Accuracy	xReliant on packaging - Fails when packaging lost or counterfeit	<ul> <li>✓ Traces product not packaging</li> <li>✓ Science &amp; algorithmic methods</li> <li>Can't be counterfeited without detection</li> </ul>
Farm to Fork	x Reliant on packaging –  Does not reach critical point of consumption	✓ Actual product assayed Trace from consumer to farm
Scientific 6/10/2020	x Paper based – Prone to error	Peer reviewed scientific     literature     Accepted as evidence in     court



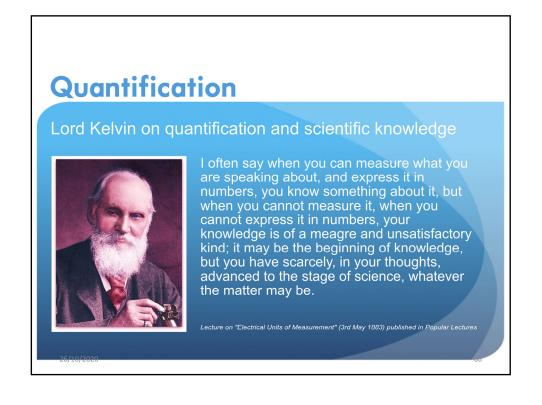


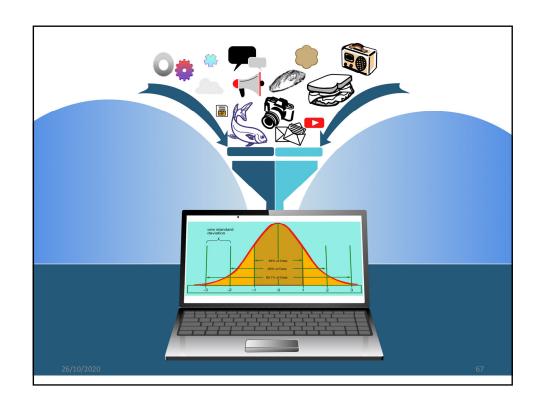


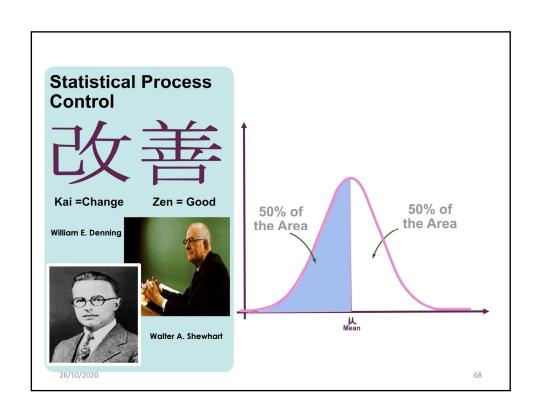












# Common Cause & Special Cause Variation

### **Common Cause Variation**

A source of variation
caused by unknown factors
that result in a steady but
random distribution of output
around the mean/average of
the data. Common cause
variation is a measure of the
process's potential, or how
well the process can perform
when special cause
variation is removed.

# Special Cause Variation

Special cause variability is a shift in output caused by a specific known factors such as environmental conditions or processing errors. It is insidious but can be accounted for directly and potentially removed. It is a measure of process control. Also referred to as "exceptional" or "assignable" variation



26/10/2020

