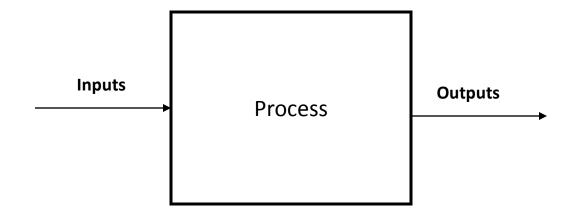
# ASQ North Jersey Section 304 Education Committee Quality Management Systems (QMS) NJIT

# ASQ Agenda

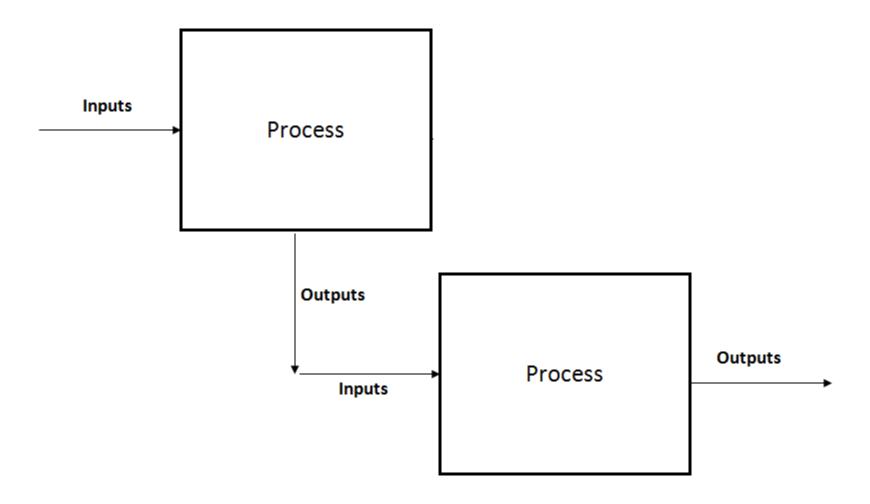
- Process defined & example
- Distributions
- Quality, Management, & Systems defined
- QMS elements
- ISO 9001
- ASQ Certifications & SQC

# Process defined?

# Process defined



#### Process defined



Interaction: the outputs from one process become the inputs to the next process.

# Process example

• Pea plant: Pisum sativum

inputs: seed / water / sunlight / soil

outputs: stem / root / leaf /flower / pod / pea

Process example



Pea plant

# Process example



Pea plant

#### **Process information**

 routine processes over time produces a huge number of individual outputs



ASQ Section 304

#### **Process information**

large number of individual peas



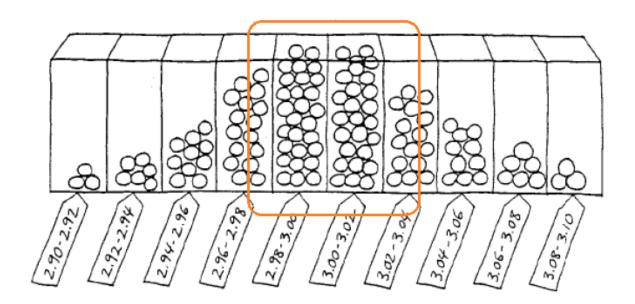
ASQ Section 304

# **Process Output**

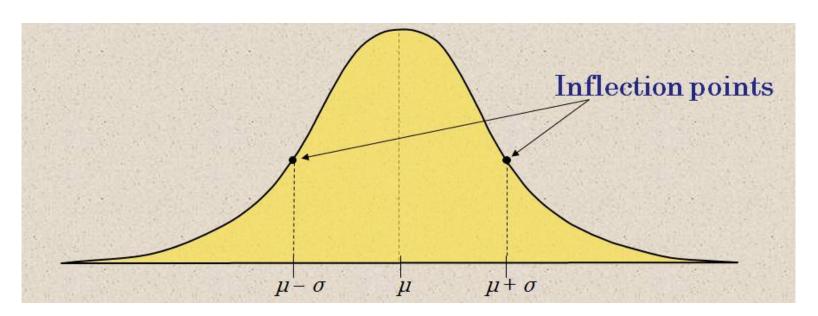
• **DISTRIBUTIONS** 

#### Central tendency

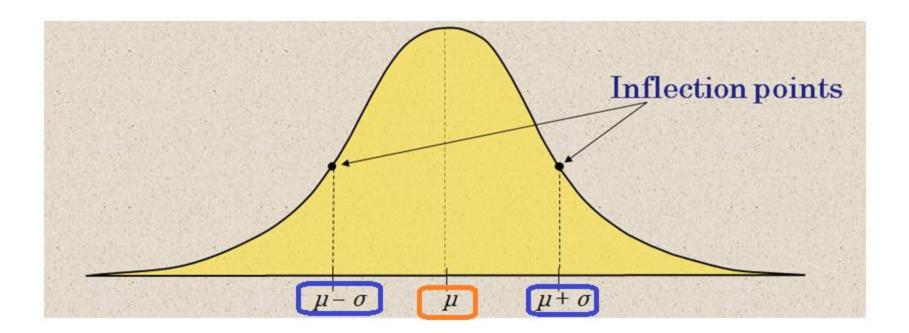
- mean (average) μ
- median (middle)
- mode (most frequent)



- Dispersion (variation)
  - range (maximum minus minimum)
  - standard deviation  $\sigma$
  - variance  $\sigma^2$



- Central tendency accuracy
- Dispersion precision

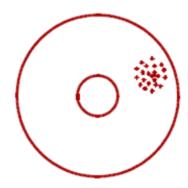


- Dispersion precision
- Central tendency accuracy

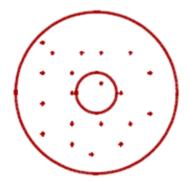


Precise, but not accurate

- Dispersion precision
- Central tendency accuracy

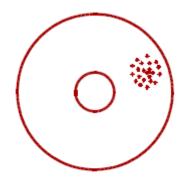


Precise, but not accurate

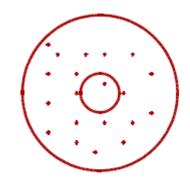


Accurate, but not precise

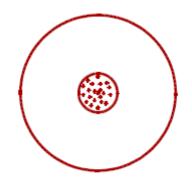
- Dispersion precision
- Central tendency accuracy



Precise, but not accurate



Accurate, but not precise



Accurate and precise

## **QMS**

Quality Management Systems

#### QMS

- Quality Management Systems
  - Quality

Management

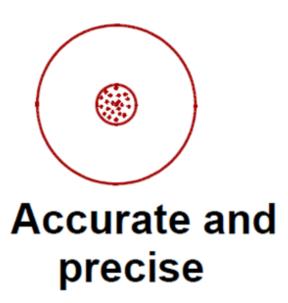
Systems

### Definition

• Quality: ?

#### Definition

Quality: On-target with minimum variation



#### Definition

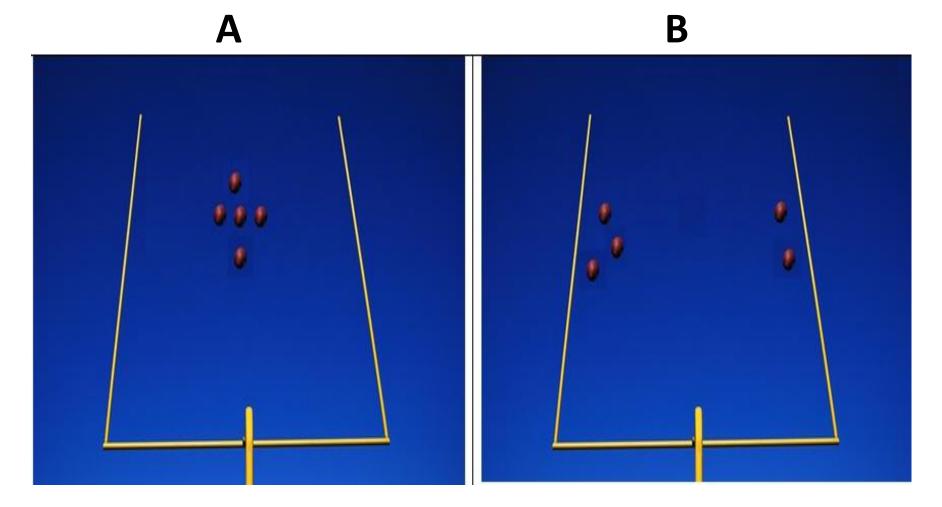
Common alternative:

'Conformance to requirements'



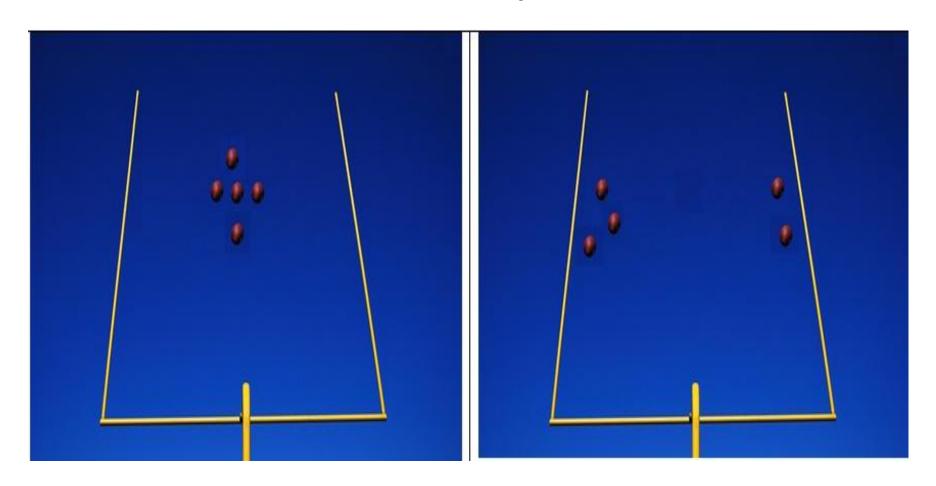


# Quality defined

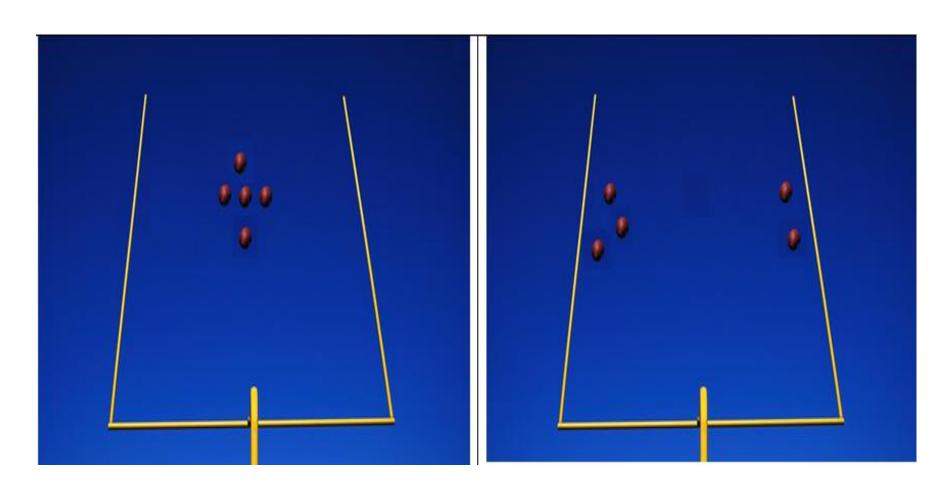


### Quality defined:

On-target with minimum variation - best vs. conformance to requirements - weak



# Quality: On-target with minimum variation



#### **QMS**

- Quality Management Systems
  - Quality

Management

Systems

# Management

- Organizational legacy
- Throughout organization
- Clear communication
- Available resources & information
- Intelligent, efficient, adaptable
- Discipline & desire to challenge status-quo
- Constancy of purpose
- Accomplishment enjoyment

# Management

- Organizational legacy
- Throughout organization
- Clear communication
- Available resources & information
- Intelligent, efficient, adaptable
- Discipline & desire to challenge status-quo
- Constancy of purpose
- Accomplishment enjoyment

# Management

Conventional wisdom:
 "There's no reason for individuals to have a computer in their home."

 Kenneth Olsen, president & founder of Digital Equipment Corp. 1977

#### **QMS**

- Quality Management Systems
  - Quality

Management

Systems

• A set of processes all working together to achieve a common objective.

What is the opposite of a system?

What is the opposite of a system?

-Chaos?

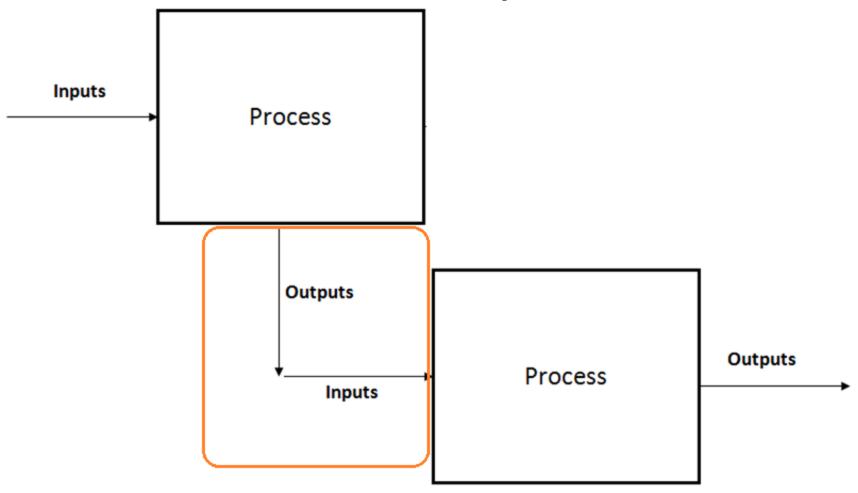
-Anarchy?

What is the opposite of a system?

-An individual

no interactions & no legacy

# Processes in a System



Interaction: the outputs from one process become the inputs to the next process.

## Systems

- vegetable farm
  - -processes ex. pea plant
  - human resource laborer/driver/clerical
  - equipment irrigation/harvest/transportation
  - materials fertilizer/lime/mulch/wood/brick
  - documentation instruction/invoice/receipt

### Common QMS Elements

- Leadership
- Customer Focus
- Quality Objectives and Planning to Achieve Them
- Operational Planning and Control
- Control of Documented Information
- Support: People & Competence Awareness
- Internal Audits
- Corrective Action & Actions to Address Risk
- Performance Evaluation
- Improvement

### Common QMS Elements

#### Football metaphor –

- Competent people camp, preseason, weekly
- Documentation the playbook
- Planning—scouting, film, new plays
- Operational planning draft, trades, free agency
- Quality objective winning team

# QMS Excellence



ASQ Section 304

# INTERNATIONAL STANDARD

ISO 9001

Fourth edition 2008-11-15

# Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

#### AMERICAN NATIONAL STANDARD

ASQ/ANSI/ISO 9001:2015

# Quality management systems — Requirements

This standard is an identical adoption of ISO 9001:2015



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The Global Voice of Quality'



#### CERTIFICATE SCHEDULE

#### Ashland Specialty Ingredients North America & Europe

#### Locations:

#### Aqualon Company 500 Hercules Road Wilmington, Delaware 19808, USA

#### Aqualon Company 500 Hercules Road, Building 8159 Wilmington, Delaware 19808, USA

#### Aqualon Company 50 South Minnisink Avenue Parlin, New Jersey 08859, USA

Aqualon Company 1111 Hercules Road Hopewell, Virginia 23860, USA

#### Activities:

Management of Ashland Specialty Ingredients Division North American and European Quality Management System Operations and Processes Including Logistics/Supply Chain, Procurement, Sales/Marketing and Design and Development.

Manufacture of Excipients for Tablet Coating used in Pharmaceutical and Neutraceutical Industries.

Manufacture of Hydroxyethyl Cellulose.

Manufacture of Sodium Carboxymethyl Cellulose, Hydroxyethyl Cellulose, Hydroxypropyl Cellulose, Ethyl Cellulose, and Various Fluidized Polymer Systems.

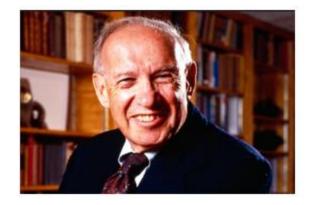
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This document is subject to the provision on the reverse
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This approval is carried out in accordance with the USA assessment and certification procedure, and monitored by USA.

### QMS Essential

Peter F. Drucker



Peter Drucker 19-Nov-1909 to 11-Nov-2005

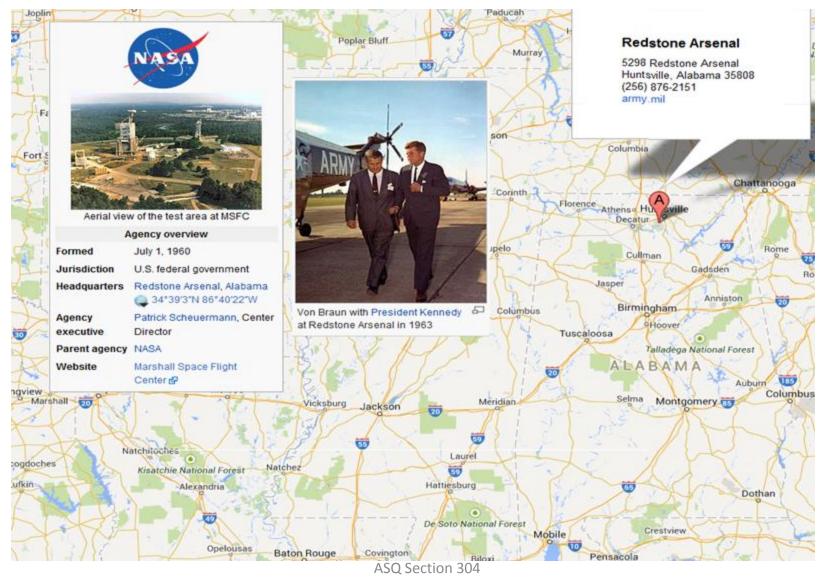
"The only things that evolve by themselves in an organization are:

disorder, friction, & malperformance!"

# Entropy alone at work!



# Case Study – ASI Plant



### Huntsville, Alabama



Size: 10 acres Employees: 25

Operating since: 1949

#### Key capabilities:

- Complex iron processing
- · Powder formulation and blending

#### Primary products:

- Nutritional iron supplements
- Ferronyl™iron supplement
- Micropowder<sup>™</sup> iron supplement
- Iron pentacarbonyl

# Case Study – ASI product



8145 Blazer Drive, Wilmington, DE 19808 Tel: (302) 594-5000

#### Sales Specifications

Report Id: WH0294

#### Ferronyl Iron

#### Chemical Description:

Iron Powder

#### Specifications:

Appearance @ 25 deg. C (Test 01) - Uniform Powder	Pass
Color (Test 01) - Grey	Pass
Identification Test (FTA0003)	Pass
Apparent Density (g/cm3, FTW1092)	>=1.5 - <=2.5
% On 200 Mesh (FTW1080)	<=0.0
% On 325Mesh (FTW1080)	<=5.0
Median Particle Diameter (microns) (FTW448)	<=8.5
%Iron (mass balance, Test 10)	>=98.0
% Iron Assay (FTW1095)	>=98.0
% Acid Insoluble (FTW1087)	<=0.2
ppm Lead (GLI ME-30) PASS equals <=4	Pass
ppm Arsenic (GLI ME-30) PASS equals <=3.0	Pass
ppm Mercury (GLI E80-3) PASS equals <=2	Pass
ppm Ammonia (GLI E7-7)	<=120
827825	
7/31/2014	

# Case Study – ASI Tolling process



### Freetown, Massachusetts



Size: 70 acres Employees: 65

Operating since: 1964

#### Key capabilities:

- Polymerization
- Esterification
- Fine chemicals
- Controlled substances
- Pilot plant

#### **Primary products:**

- Aquastyle<sup>™</sup> polymers
- Aquaflex<sup>™</sup> copolymers
- Styleze<sup>™</sup> polymers
- Cerasynt™ emulsifiers
- Ceraphyl™ emollients
- Peroxydone™ polymer complex
- Ganex<sup>™</sup> copolymers

### **ASQ**

- HQ Milwaukee WI
- Founded 1946
- The Global Voice of Quality
- Geographic Regions & Sections
- Region 3 CT / NY / NJ
- Section 304 North Jersey
- Division discipline focused ~ 22 ex. FD&C

### **ASQ Certifications**

- ca 1965 -> Certified Quality Engineer
- Based on ASQ BOK Body-of-Knowledge
- ASQ exam: 100 150 questions / open book
- 17 different certifications
- Popular: CQA / CQE / CSSGB / CPGP
- Available: CSS BB & YB / CQI / CQT / CMQ-OE
- Local exam prep available

# **ASQ Training**

Process Behavior Analysis

Taguchi Design of Experiments

New!
 Business Process Management Introduction:
 An aid to understanding the Process Approach
 Requirements in ISO 9001:2015

#### SAVE THE DATE

39th Spring Quality Conference

Thursday 13-April-2017

Hanover Marriott, Whippany NJ

# **ASQ North Jersey**

Education Committee

Our Mission is to help Knowledge Workers increase their Productivity!