



Visual Inspection of Injectable Products: Inspection Technologies

John G. Shabushnig, Ph.D.
Insight Pharma Consulting, LLC



johnshabushnig@aol.com
March 2018



“I see no more than you,
but I have trained myself
to notice what I see.”

Sherlock Holmes
in *The Adventure of the Blanched Soldier*





Agenda

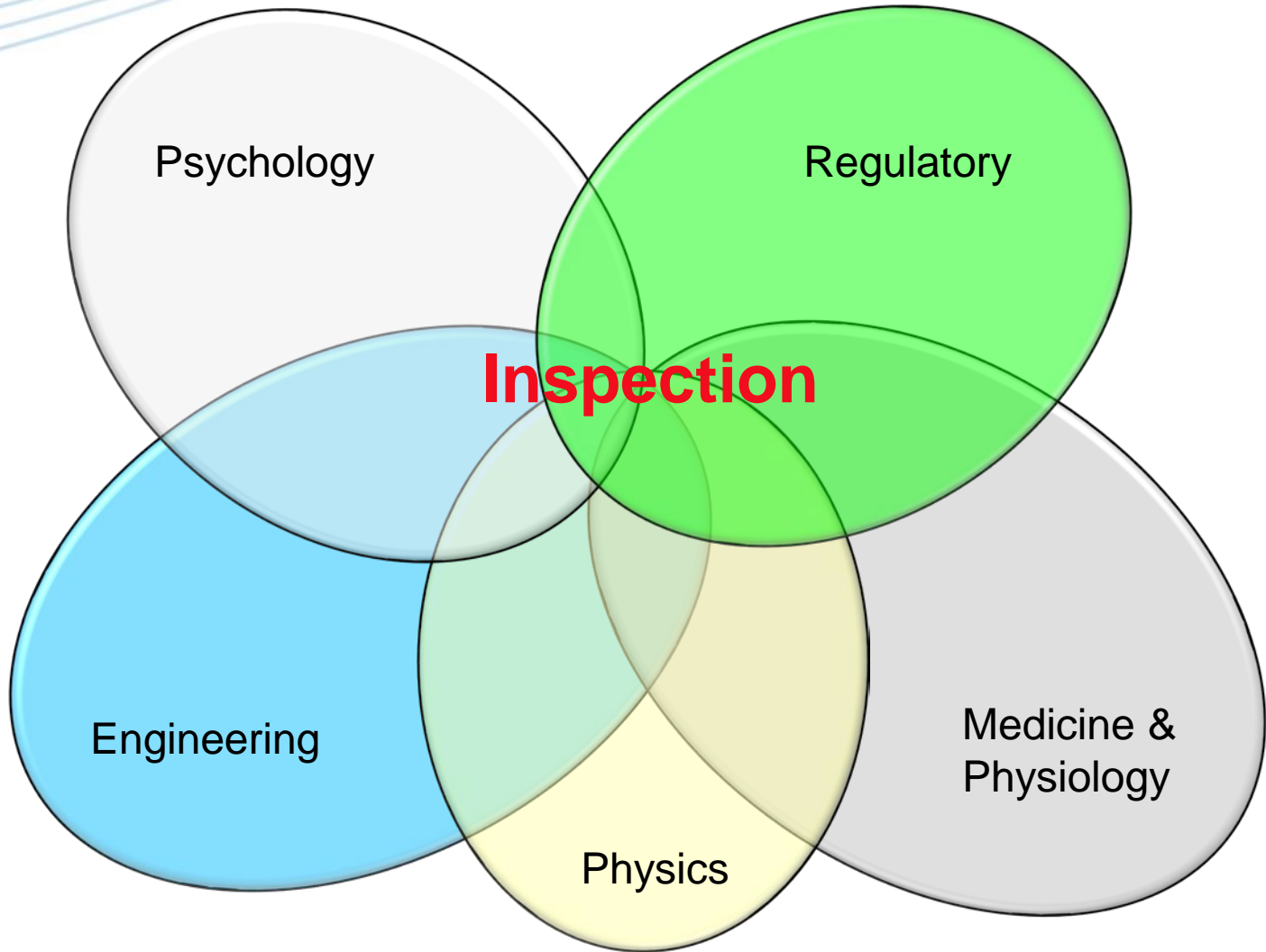
- Manual Inspection
- Semi-Automated Inspection
- Automated Inspection



Manual Inspection

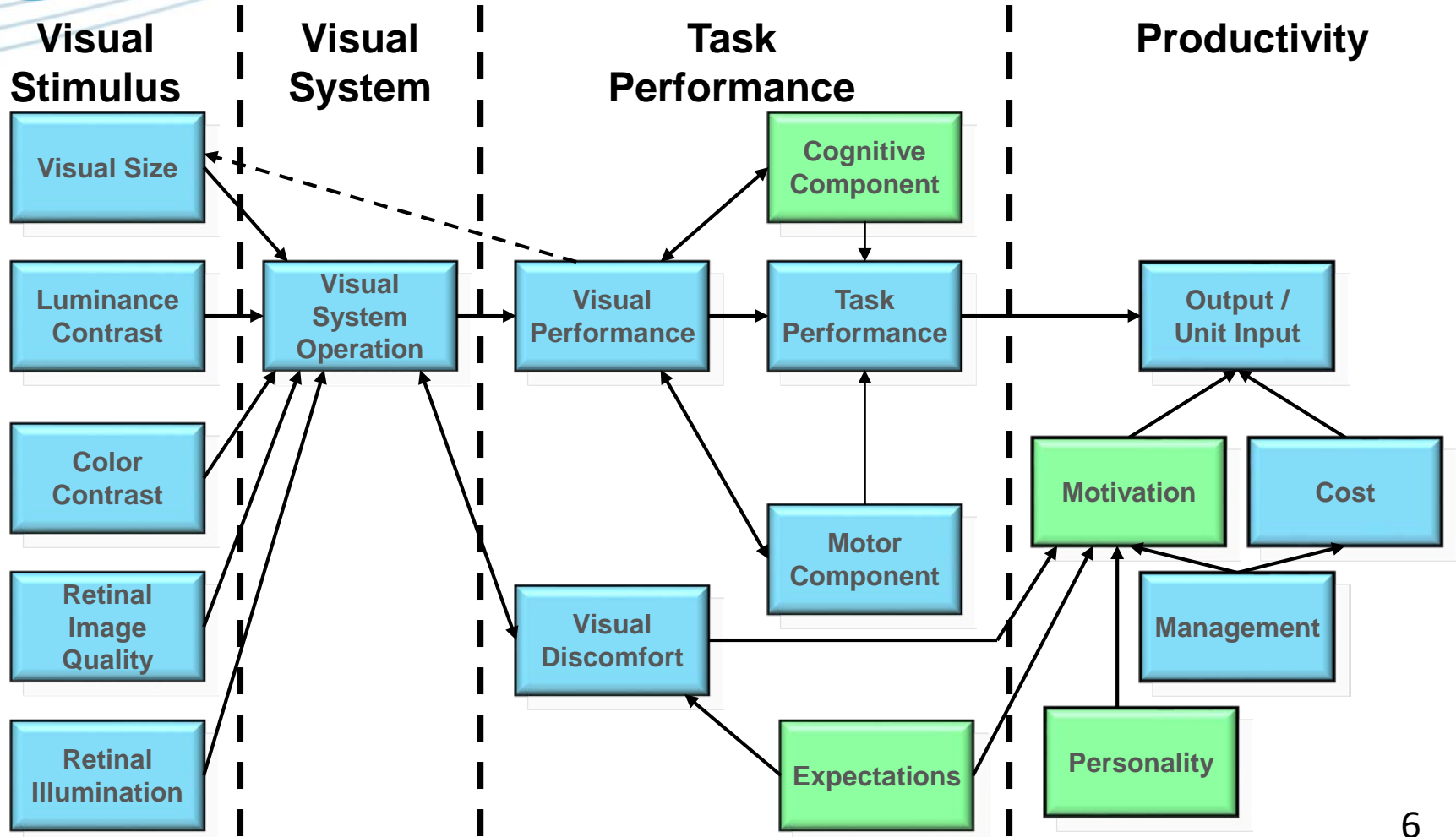


Inspection Influences





Inspection



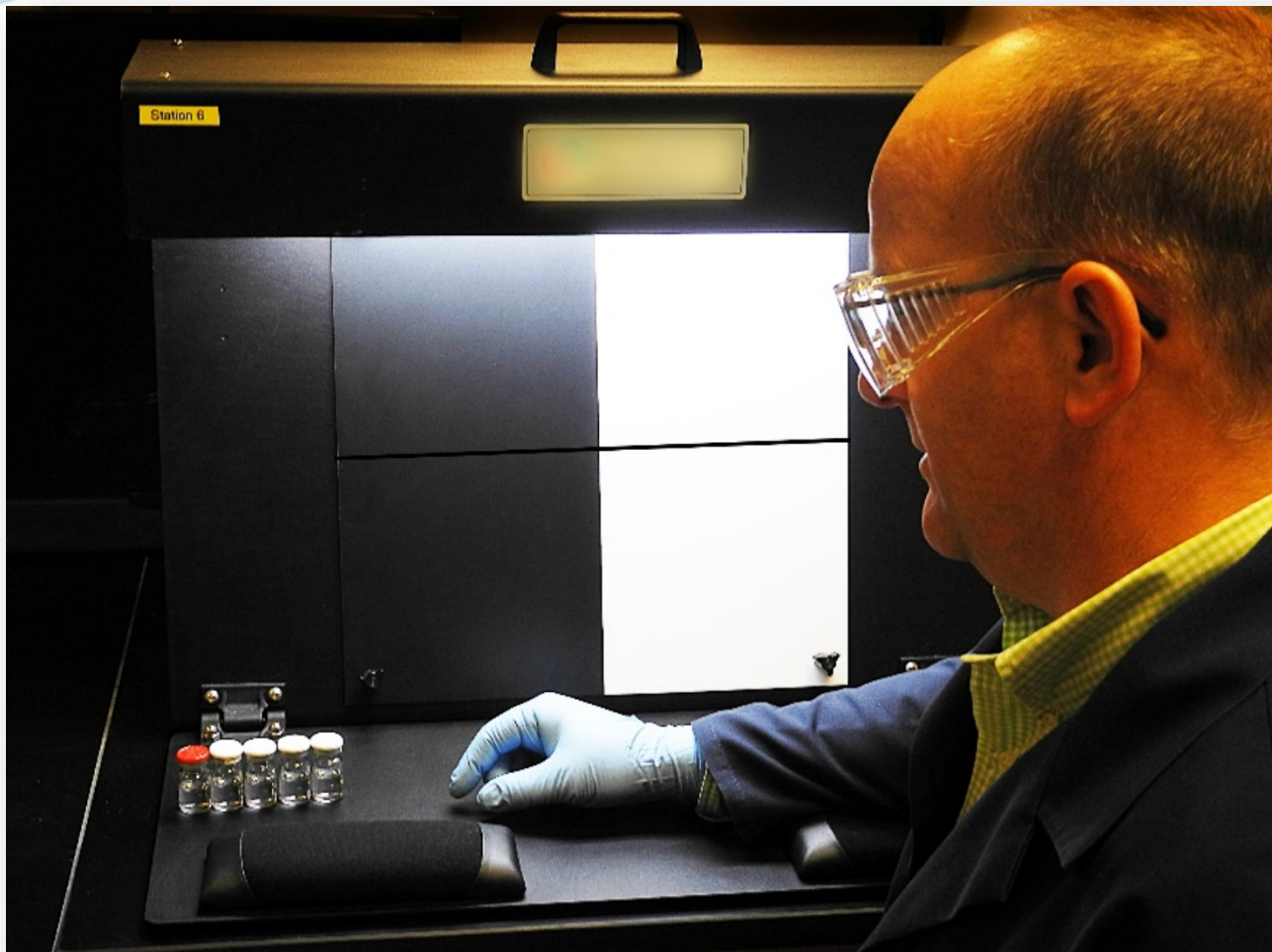
From G. Salvendy, Handbook of Human Factors and Ergonomics, 2nd Edition

An Introduction to Visual Inspection

© 2018 John G. Shabushnig



Manual Inspection





Manual Inspection



Phoenix Imaging MIB-100



Manual Inspection





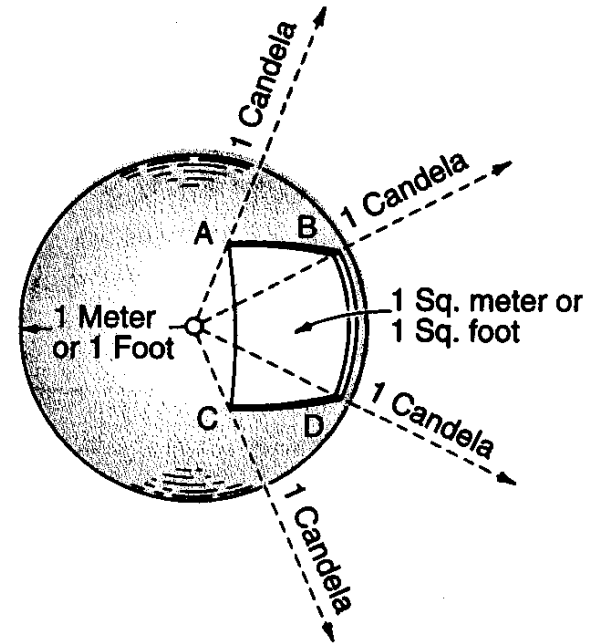
Critical Inspection Parameters

- Lighting
 - Illumination Intensity
 - Uniform, Flicker-free
 - Fluorescent, Incandescent, LED
 - Tyndall (dark-field)
- Background
 - Black / White
- Presentation and Manipulation
 - Swirl and/or invert
- Pace
 - 10 sec / container reference



Illuminance

- Luminous Intensity
 - 1 candela = 1/638 W/sr
 - formerly candlepower
- Illuminance
 - 1 lux = 1 lumen/m²
 - 1 foot-candle = 1 lumen/ft²
 - 1 fc = 10.75 lux
- Inverse Square Law
 - illumination = luminous intensity/d²



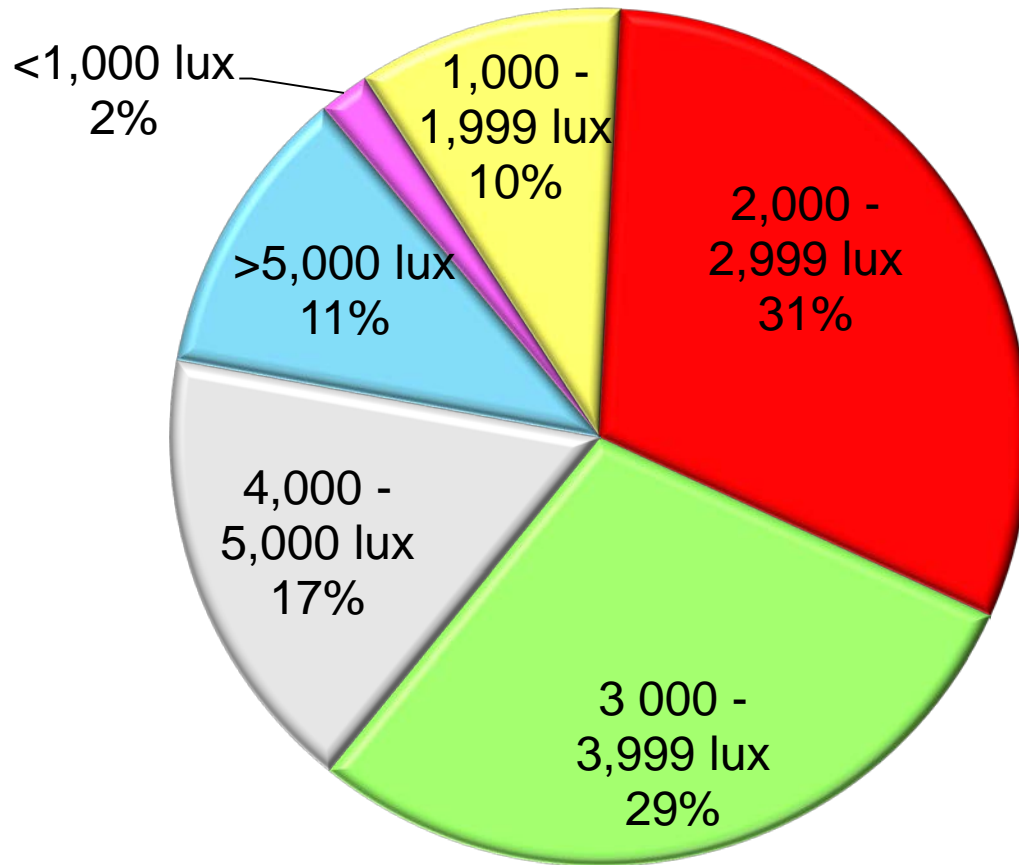


Illumination Intensity

- USP, EP, JP and WHO
 - 2,000-3,750 lux, Higher (e.g., 8,000-10,000 lux for difficult to inspect containers and products)
- ChP
 - 1,000-1,500 lux (clear solutions), 2,000-3,000 lux (colored solutions and glass, plastic containers)
 - 4,000 lux (suspensions, emulsions)
- IESNA
 - “Difficult Inspection”, visual tasks of low contrast and small size. 1,000 lux
 - “Exacting Inspection”, visual tasks near threshold. 3,000-10,000 lux

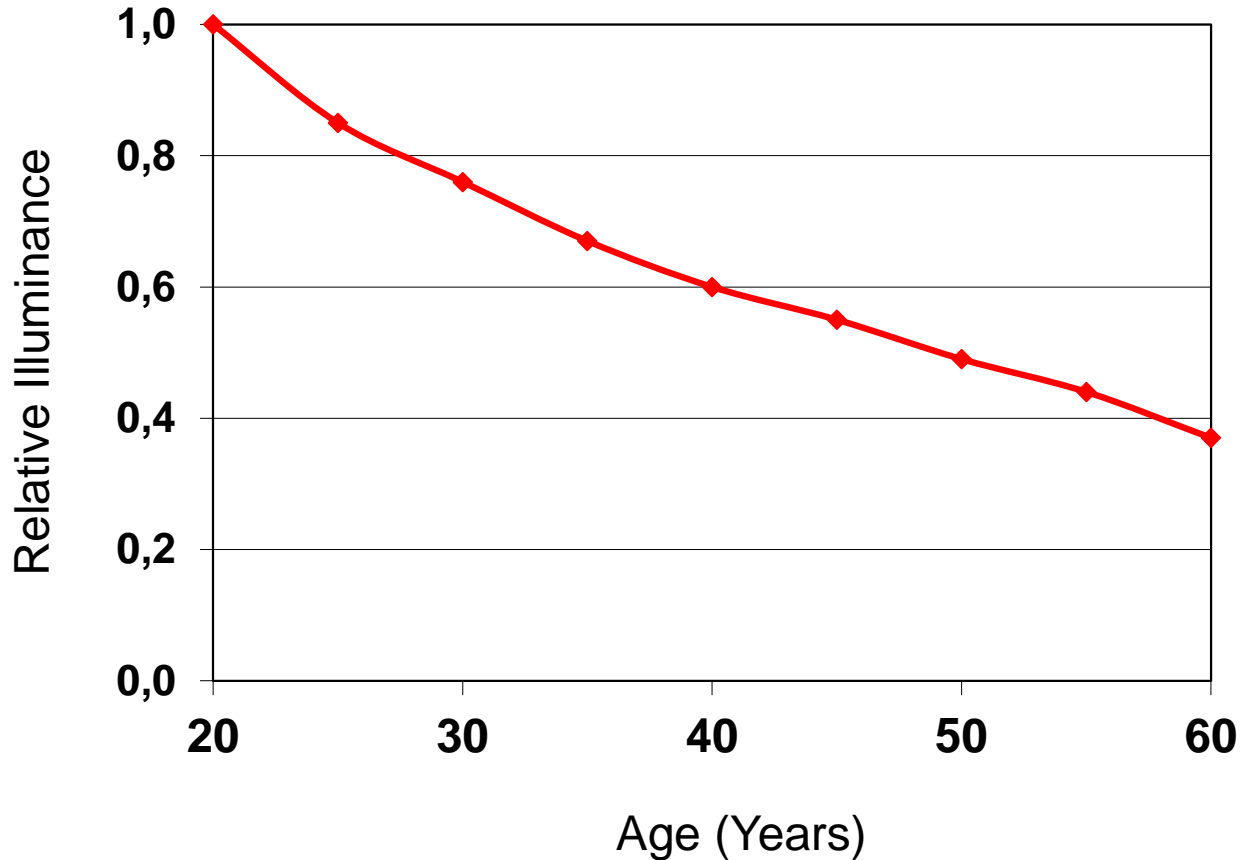


What is the average illumination intensity at the container during manual inspection?





Aging and Relative Illuminance



From IESNA Lighting Handbook, 9th Edition

An Introduction to Visual Inspection

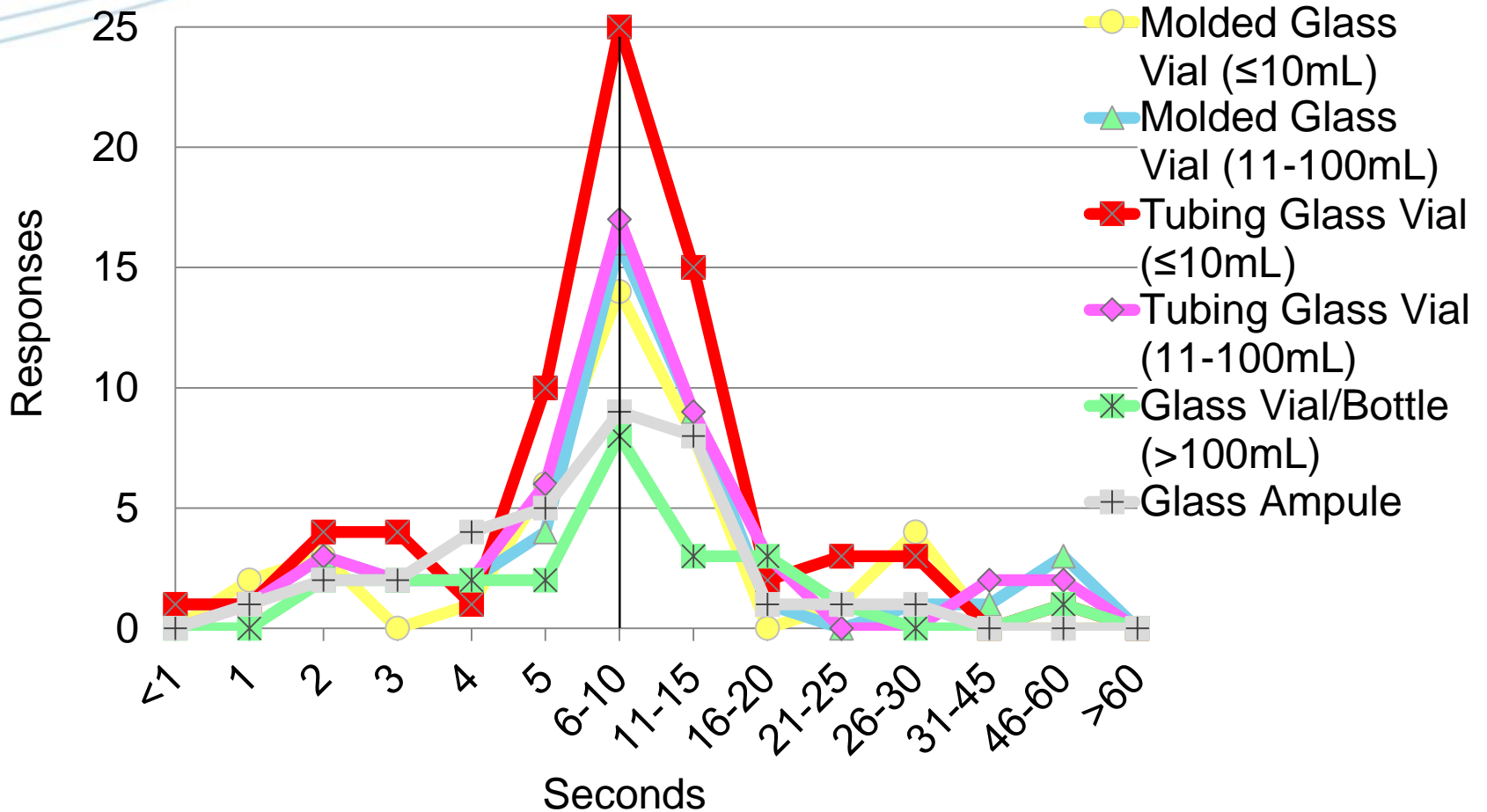


Manual Inspection Conditions

- 73% control inspection time or the pace of inspection.
 - 46% with Timer
 - 29% by SOP
 - 24% with Conveyor
- 26% use a magnifier.
 - 44% 2X, 25% 3X, 8% 4X, 8% 5X, 14% >5X
- 6% use a polarizer.
- Light Source used:
 - 73% Fluorescent, 19% LED, 18% Incandescent,

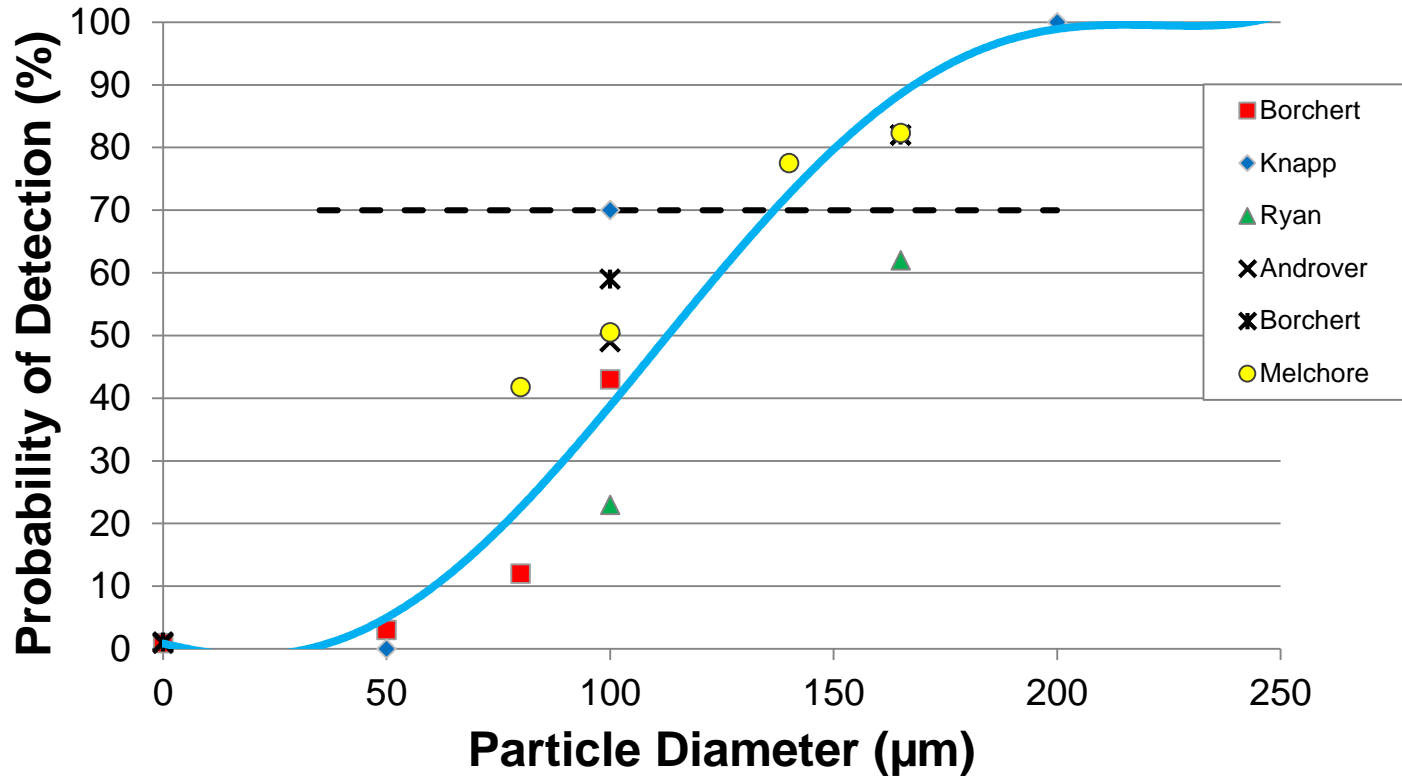


What is the average inspection time for this container type?





Human Inspection Performance



From Shabushnig, Melchore, Geiger, Chrai and Gerger, PDA Annual Meeting 1995

An Introduction to Visual Inspection

© 2018 John G. Shabushnig



Inspection Performance

- Human Inspection
 - Visual acuity
 - Fatigue
 - Flexibility
- Probabilistic
 - Especially true for particulate matter due to continuously changing presentation.



Semi-Automated Inspection



Semi-Automated Inspection

- Machine Material Handling
 - Transport, Spin/Rotation, Traying
 - Consistent lighting and presentation
 - Manual or Machine Rejection
- Human Inspection
 - Quality Decision



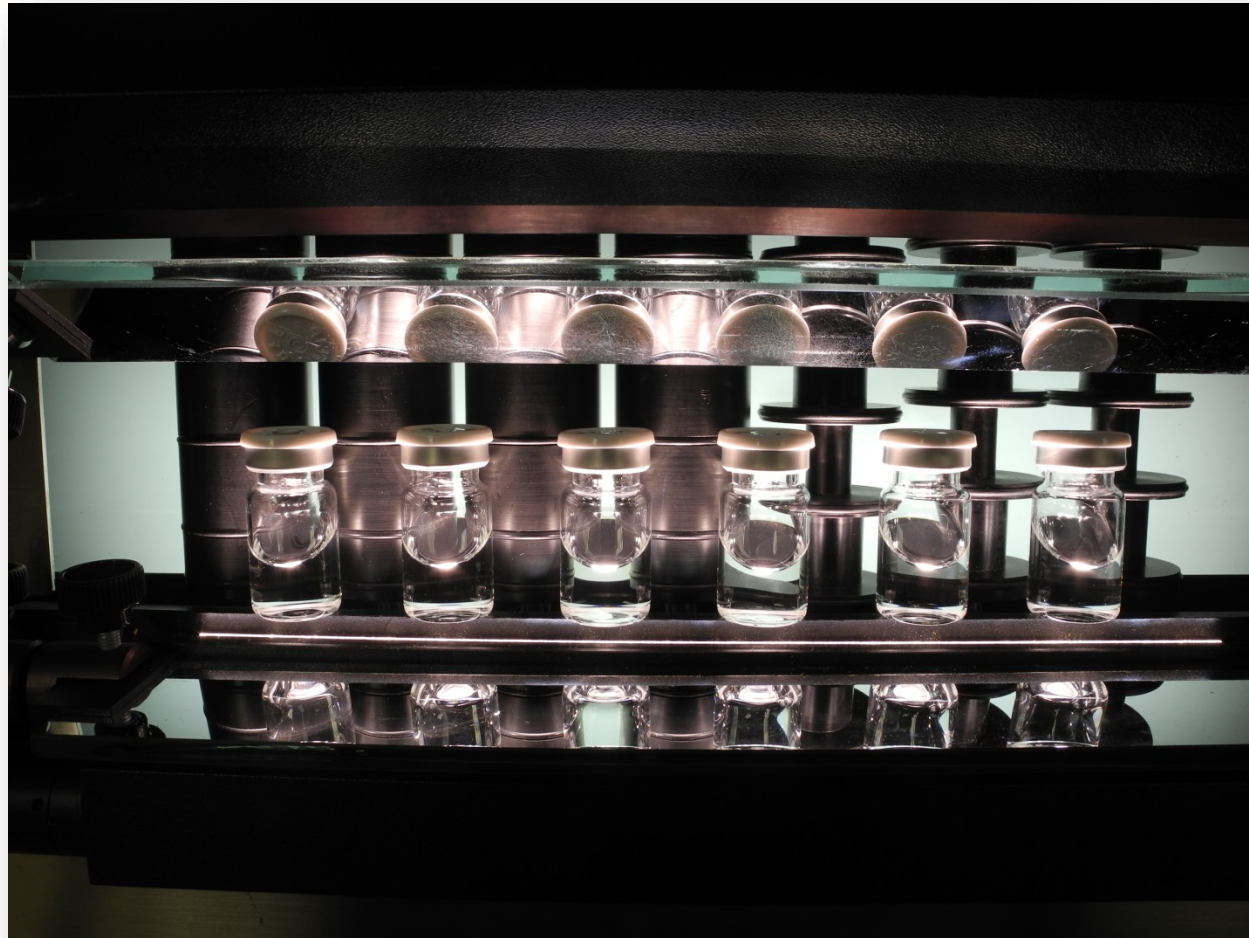
Semi-Automated Inspection



Seidenader



Semi-Automated Inspection



Seidenader



Inspection Performance

- Semi-Automated
 - Similar to manual
 - May have poor sensitivity for heavy particles
 - Particles stop moving before inspection
 - Improved ergonomics
 - Improved throughput



Automated Inspection



Automated Particle Inspection

Light Source

Product

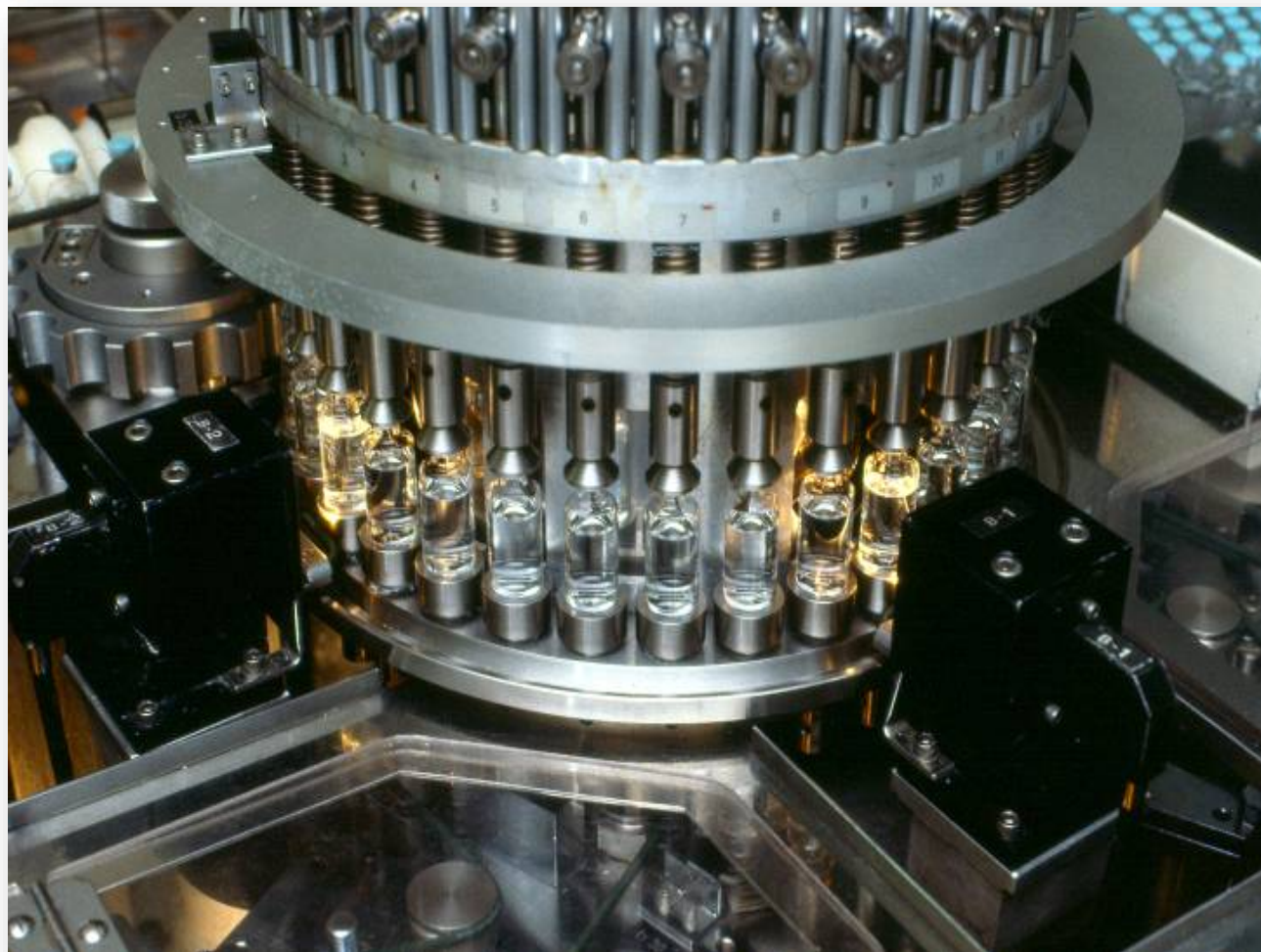
Linear Detector



Bosch Static Detection (SD)



Automated Particle Inspection



Eisai AIM-288

An Introduction to Visual Inspection

© 2018 John G. Shabushnig



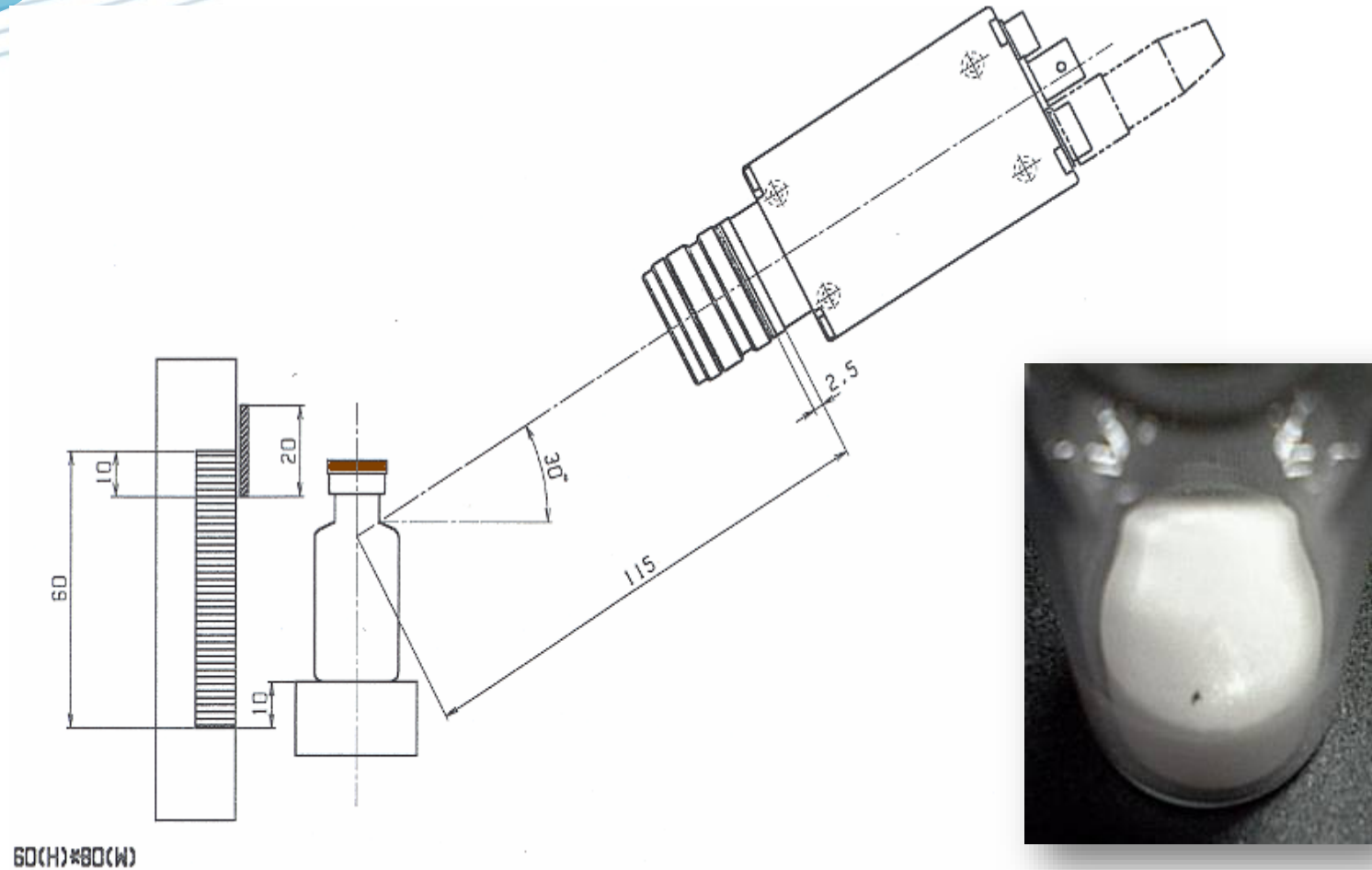
Automated Inspection



Eisai EIS-596



Automated Inspection



An Introduction to Visual Inspection

© 2018 John G. Shabushnig



Inspection Performance

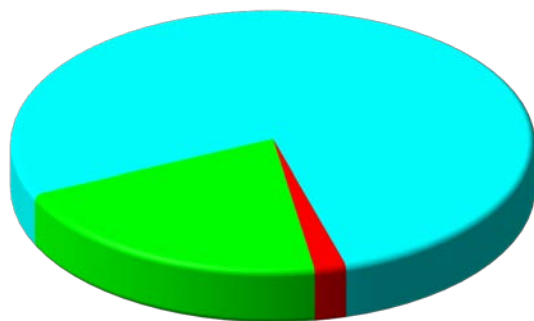
- Machine Inspection
 - Adjustable Sensitivity
 - Increased sensitivity must be balanced with increased false rejection rates.
 - Often product dependent
 - viscosity, surface tension, container design and variability
- Improved Reproducibility
- Improved Throughput
- High Initial Investment



Machine Inspection Performance

Human

Inconclusive

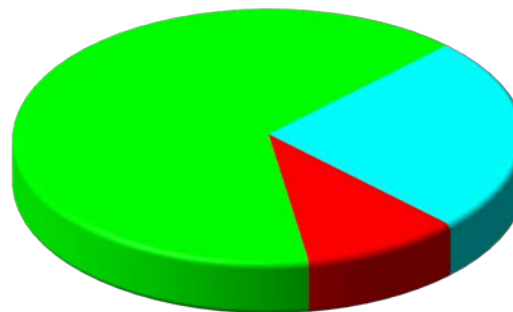


Good

Reject

Machine

Good



Inconclusive

Reject

A set of 250 vials was inspected 20 times by each method. Any vial not classified consistently 20 of 20 times was classified inconclusive.



What technique is used for inspection for / of ...

	2014	2008	2003	1996
Particles				
Manual	49%	33%	46%	33%
Semi-Automated	17%	24%	19%	20%
Automated	33%	43%	35%	42%
Container/Closure				
Manual	54%	36%	63%	48%
Semi-Automated	18%	26%	15%	42%
Automated	28%	39%	20%	5%



Does your firm have plans to replace manual inspection with automated inspection?

	2014	2008	2003	1996
Shift to Automated Inspection	50%	67%	50%	68%
Justification				
Quality	85%	75%	92%	92%
Productivity	87%	92%	92%	100%
Other	5%	0%	8%	17%



Inspection Standards





How frequently do you challenge or retest automated inspection equipment?

	2014	2008	2003	1996
Never	1%	0%	0%	15%
Each Shift	1%	8%	13%	8%
Start of Lot	46%	42%	75%	38%
Start and End of Lot	8%	ND	ND	ND
Daily	15%	25%	19%	23%
Weekly	2%	0%	0%	8%
Monthly	2%	ND	ND	ND
Quarterly	1%	ND	ND	ND
Annually	19%	ND	ND	ND

ND = No Data, question not asked in survey from this year

An Introduction to Visual Inspection



Questions?

**BEAUTIFUL,
BUT OBSOLETE.**

