



Visual Inspection of Injectable Products: Inspection Technologies

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



johnshabushnig@aol.com
September 2023



“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

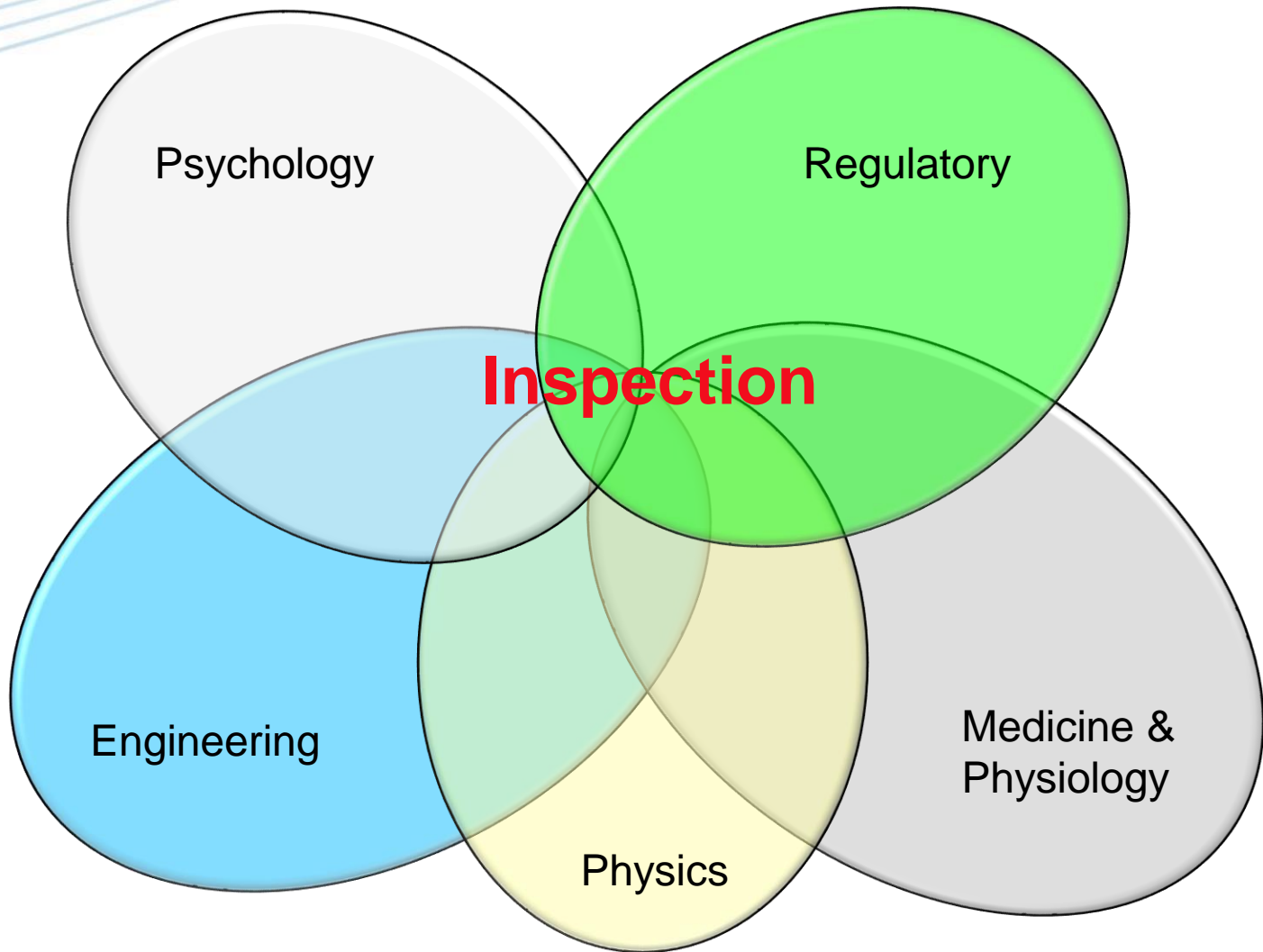
- Manual Inspection
- Semi-Automated Inspection
- Automated Inspection



Manual Inspection

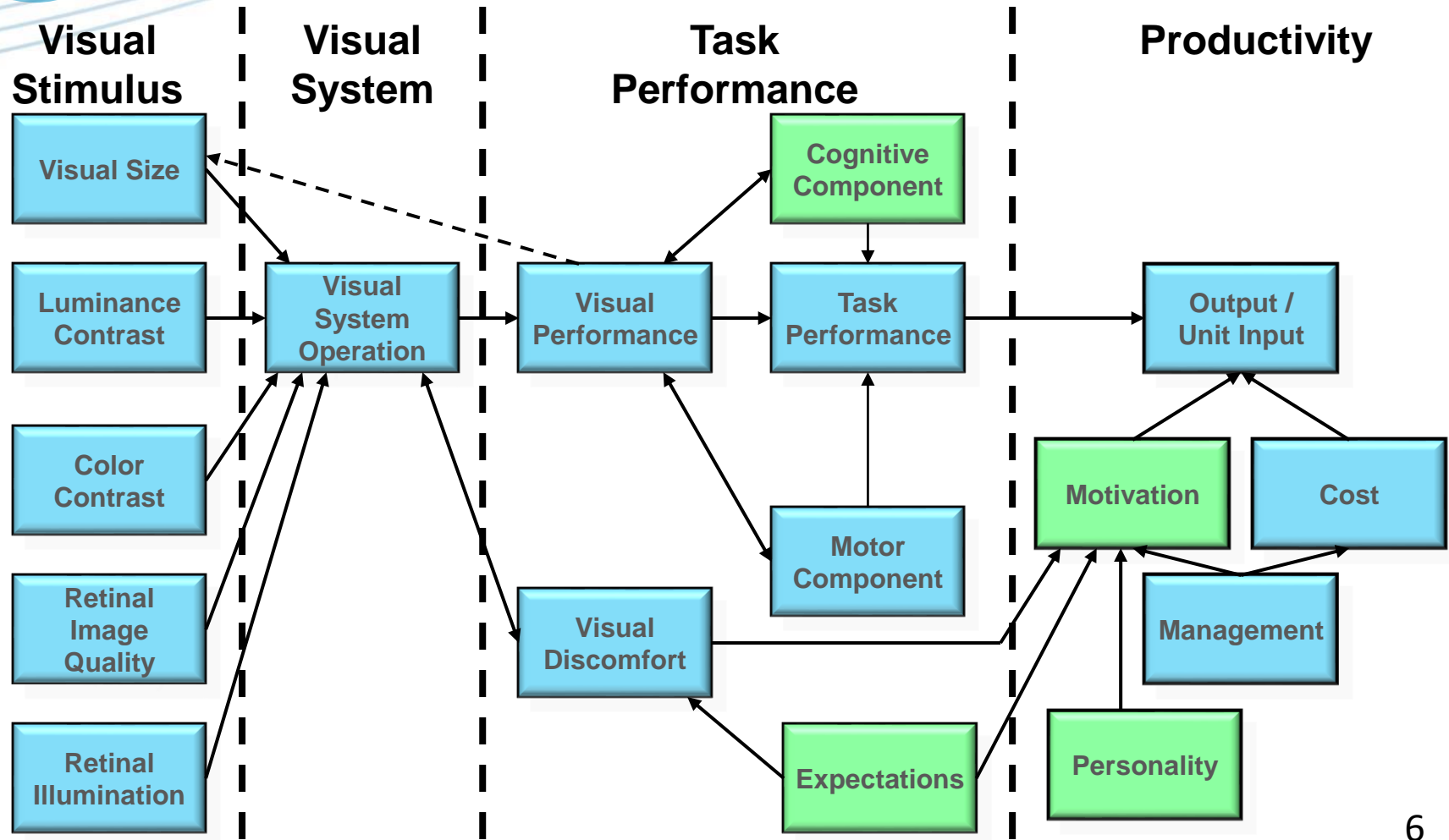


Inspection Influences





Inspection



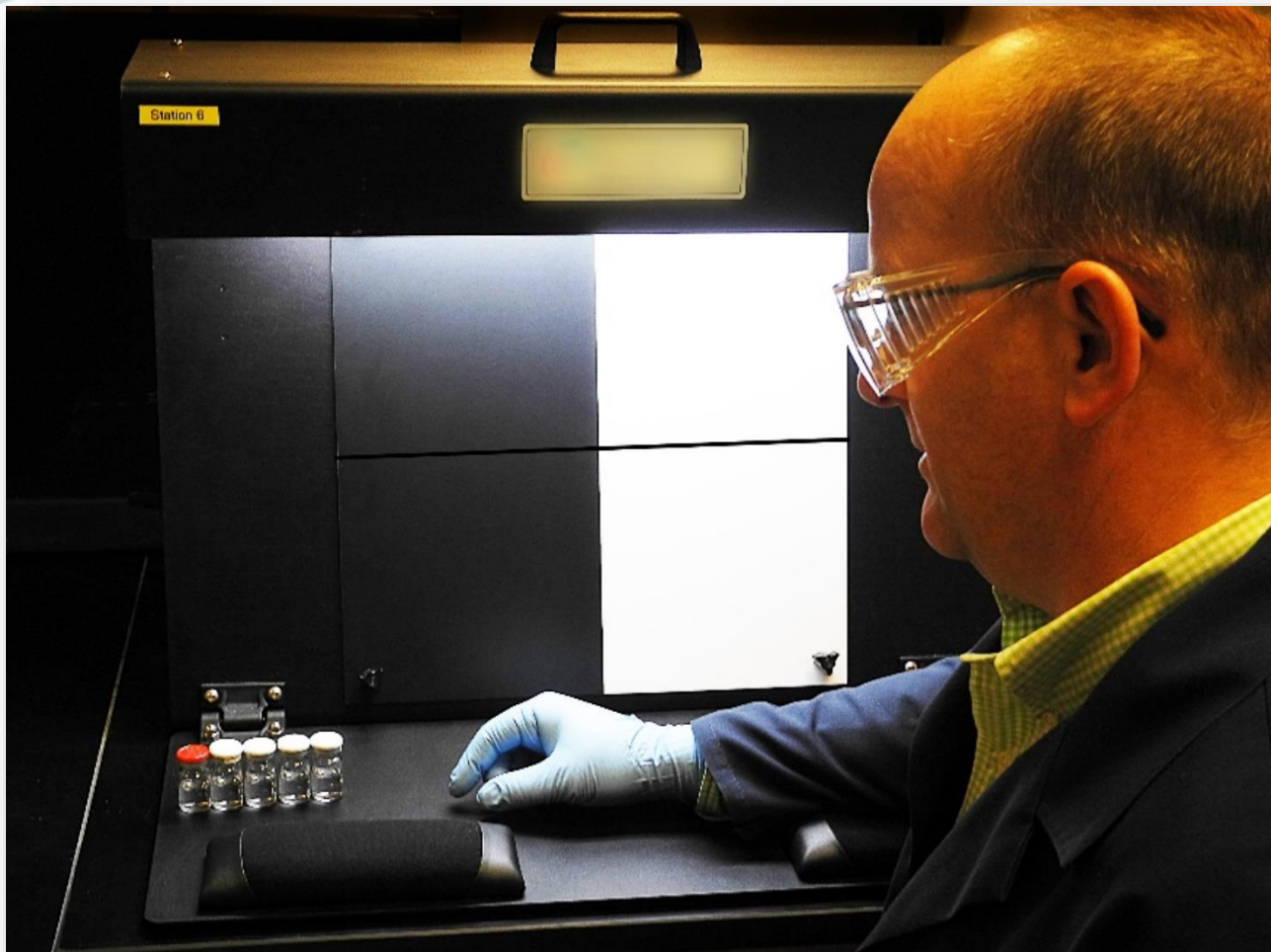
From G. Salvendy, Handbook of Human Factors and Ergonomics, 2nd Edition

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Manual Inspection





Manual Inspection



Phoenix Imaging MIB-100



Manual Inspection





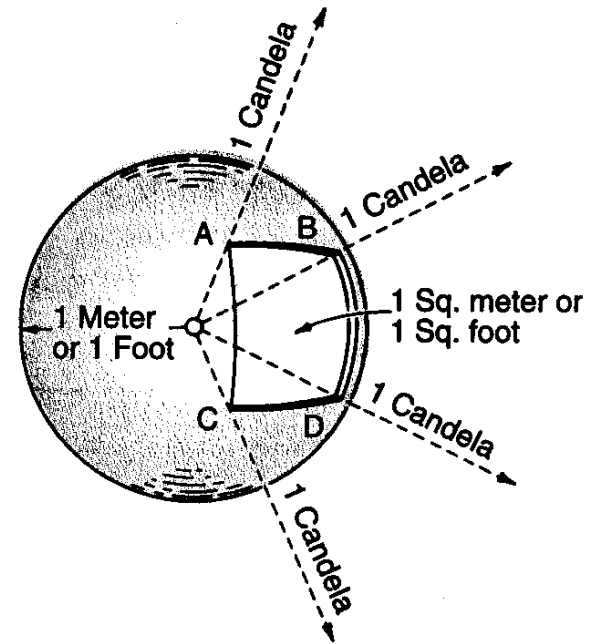
Critical Inspection Parameters

- Lighting
 - Illumination Intensity (2,000-3,750 lux)
 - Uniform, Flicker-free
 - Fluorescent, Incandescent, LED
 - Tyndall (dark-field)
- Background
 - Black / White
- Presentation and Manipulation
 - Swirl and/or invert
- Pace
 - 10 sec / container (per pharmacopeias)



Illuminance

- Luminous Intensity (output)
 - 1 candela = 1/638 W/sr
 - 1 lumen = 1 candela in all directions
 - 1 candela formerly 1 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





Common Light Levels

- Bright sunny day, 100,000 lux
- Full daylight, 10,000 lux
- **Visual Inspection, 1,000-10,000 lux**
- Typical office lighting, 300-500 lux
- Typical stairway, 50-100 lux
- Twilight, 10 lux
- Full moon, <1 lux

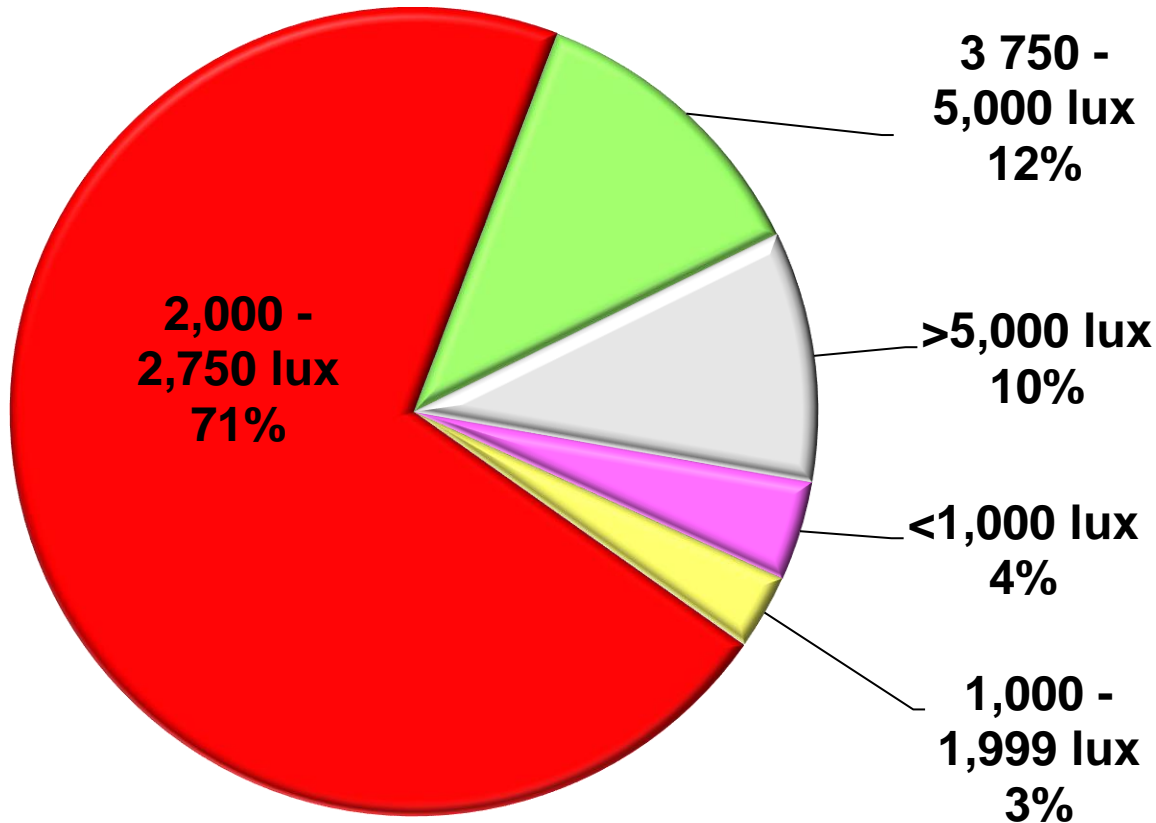


Illumination Intensity

- 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



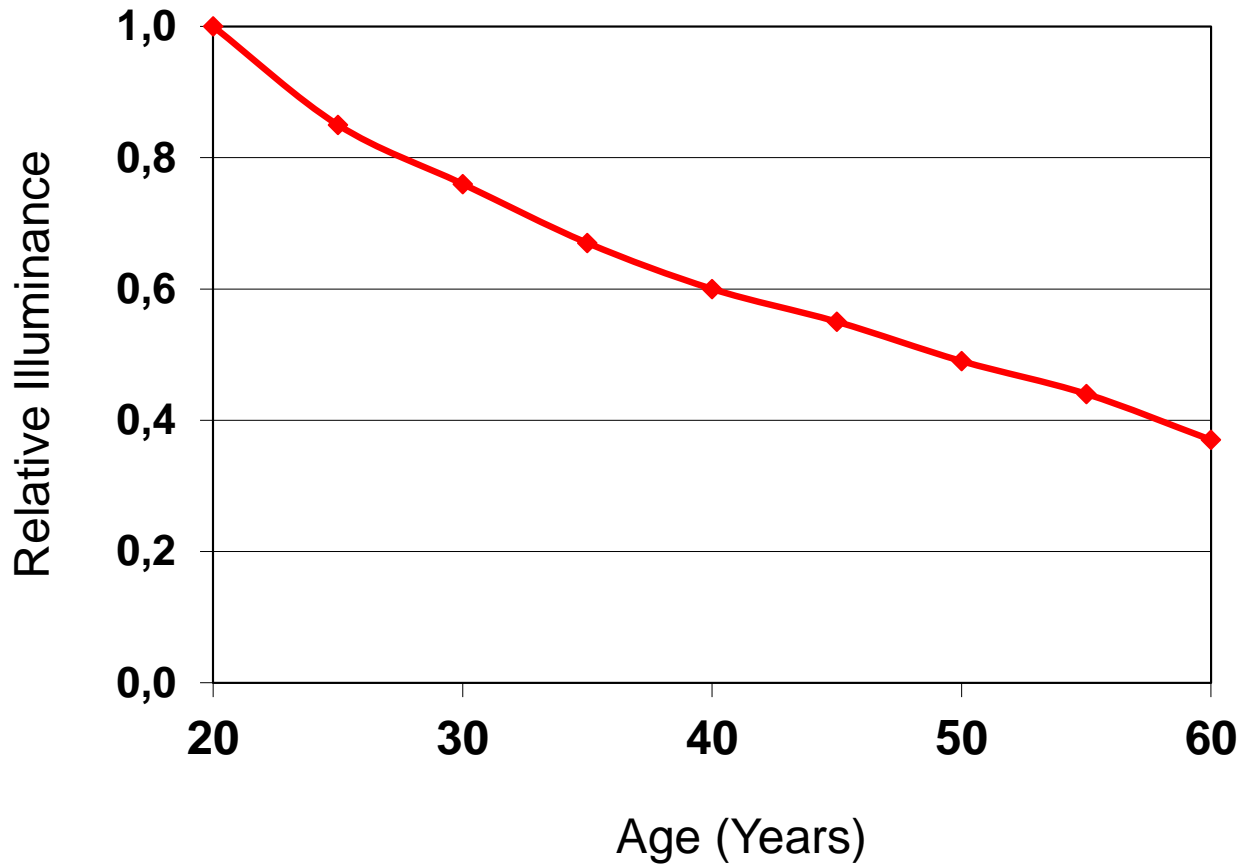
What is the average illumination intensity at the container during manual inspection?



From 2023 PDA Visual Inspection Survey



Aging and Relative Illuminance



From IESNA Lighting Handbook, 9th Edition

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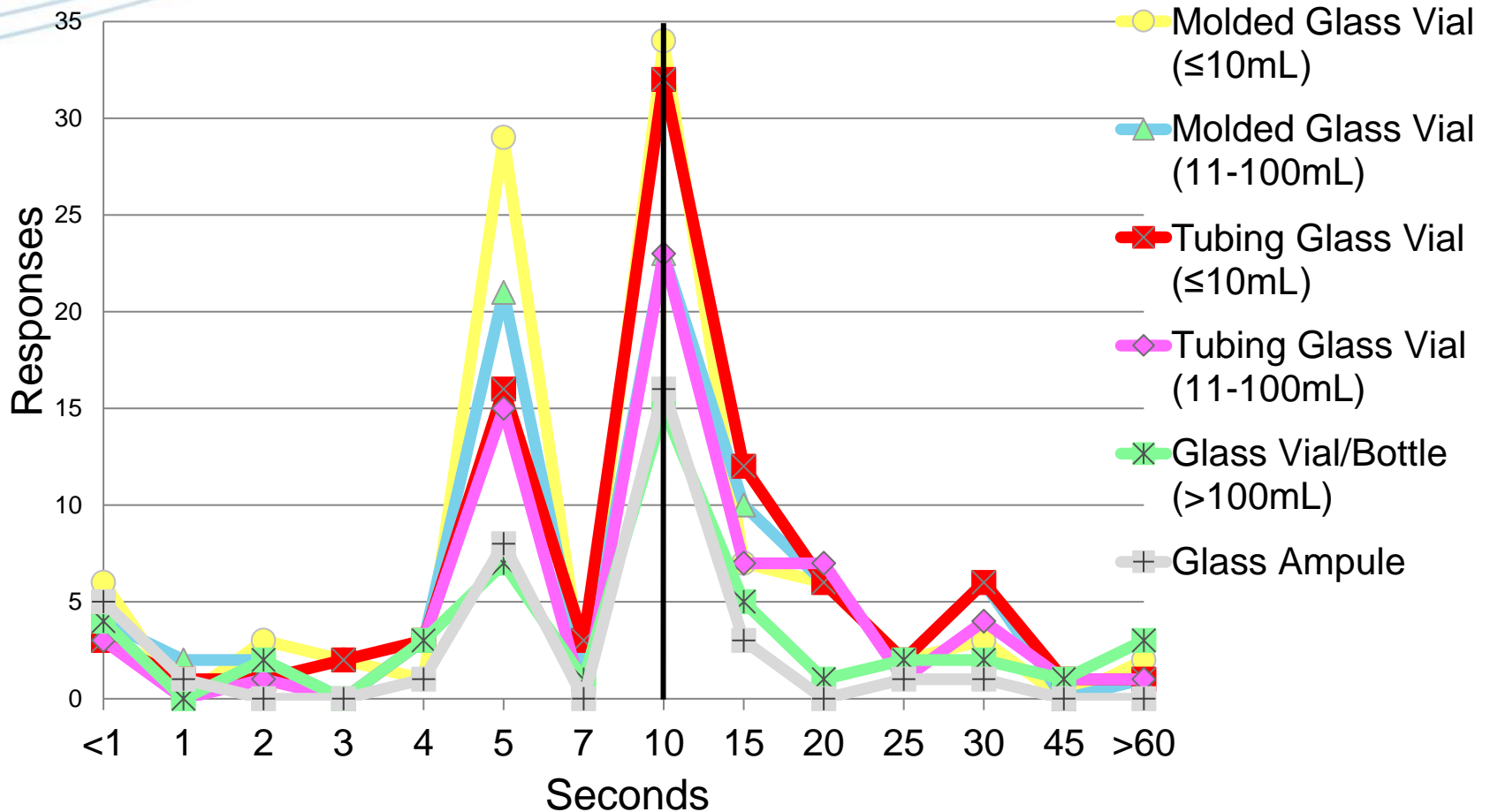
Manual Inspection Conditions

- 73% control inspection time or the pace of inspection.
 - 80% by SOP
 - 33% with Timer
 - 19% with Conveyor
- 15% use a magnifier.
 - 29% 2X, 24% 3X, 10% 4X, 24% 5X, 14% >5X
- Light Source used:
 - 62% LED, 44% Fluorescent, 12% Incandescent,

From 2023 PDA Visual Inspection Survey



What is the average inspection time for this container type?

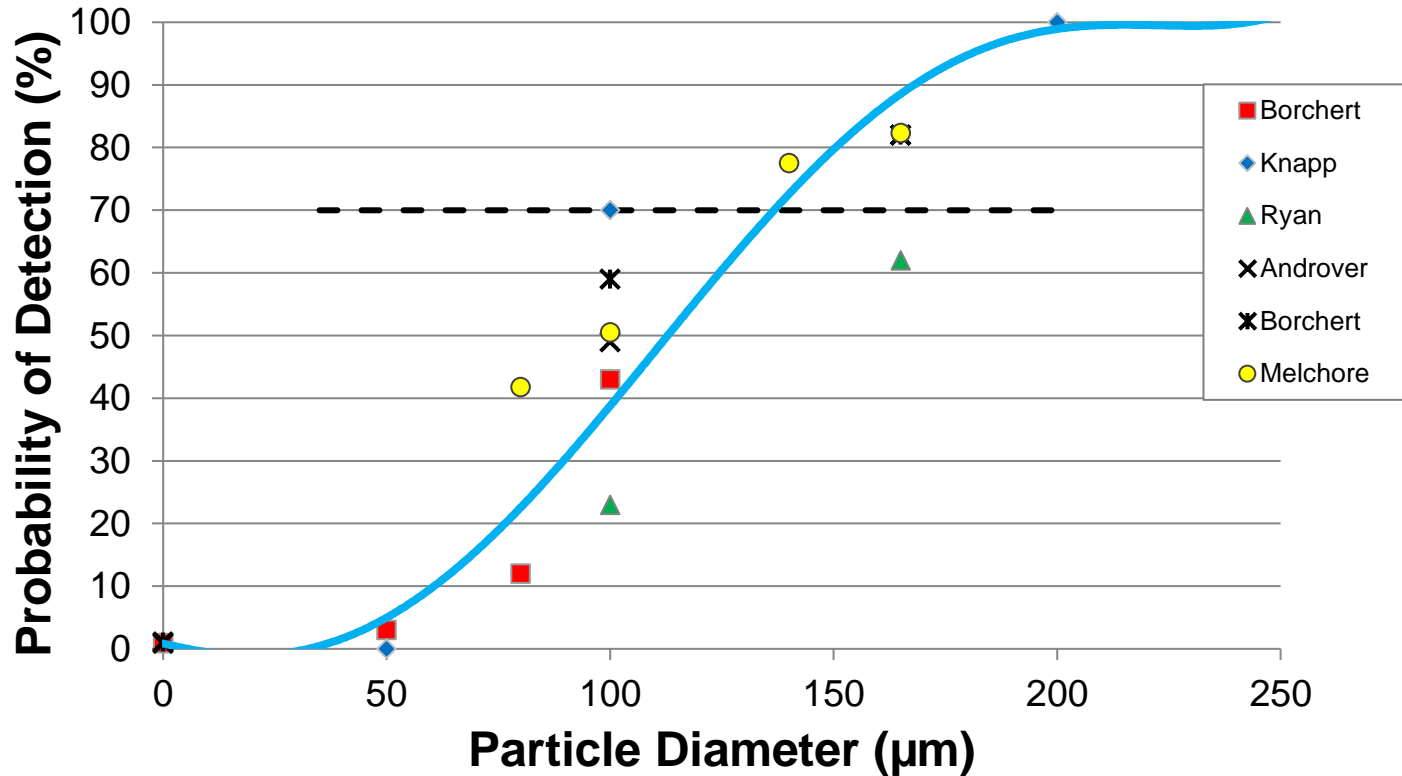


From 2023 PDA Visual Inspection Survey

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Human Inspection Performance



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

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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



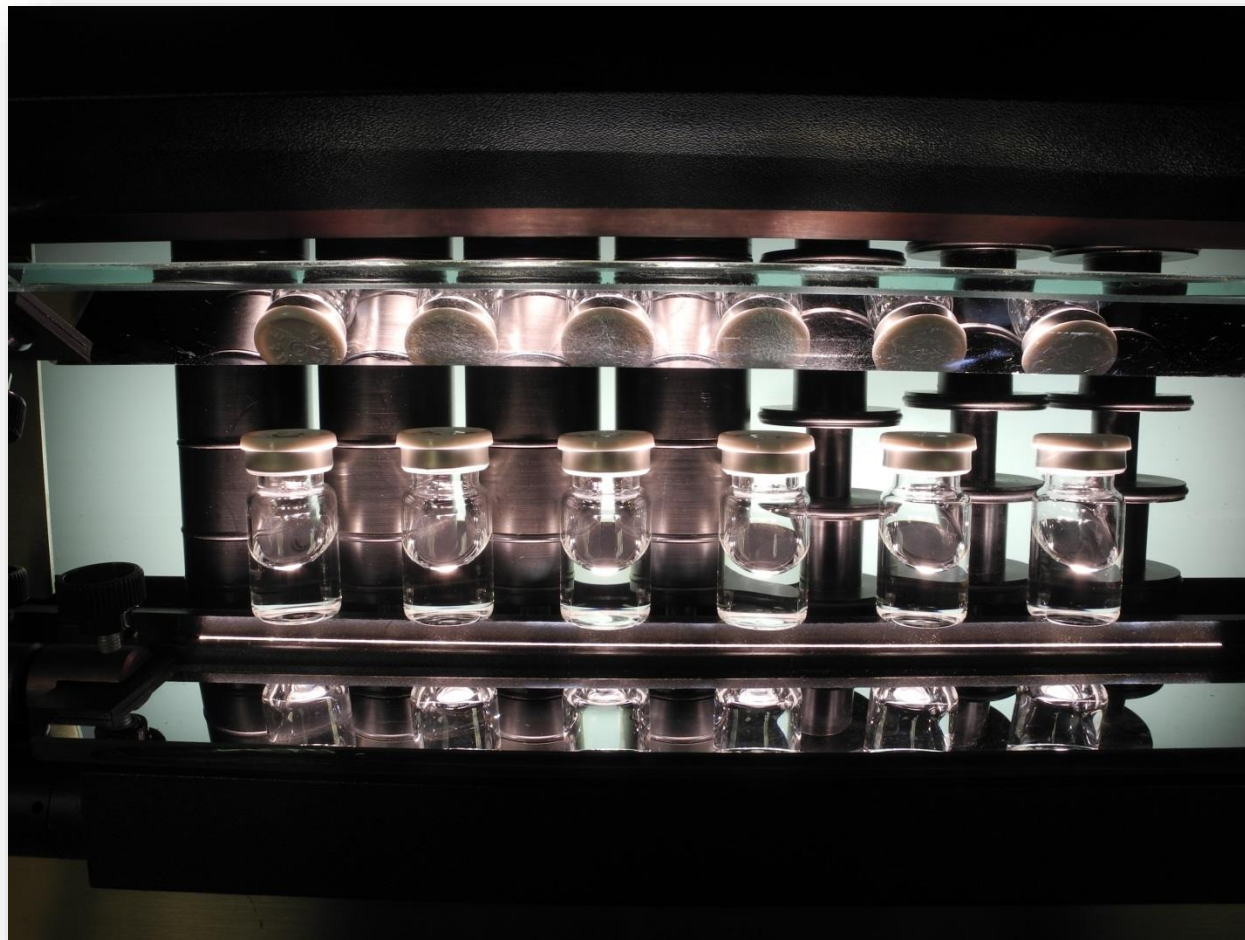
Semi-Automated Inspection



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

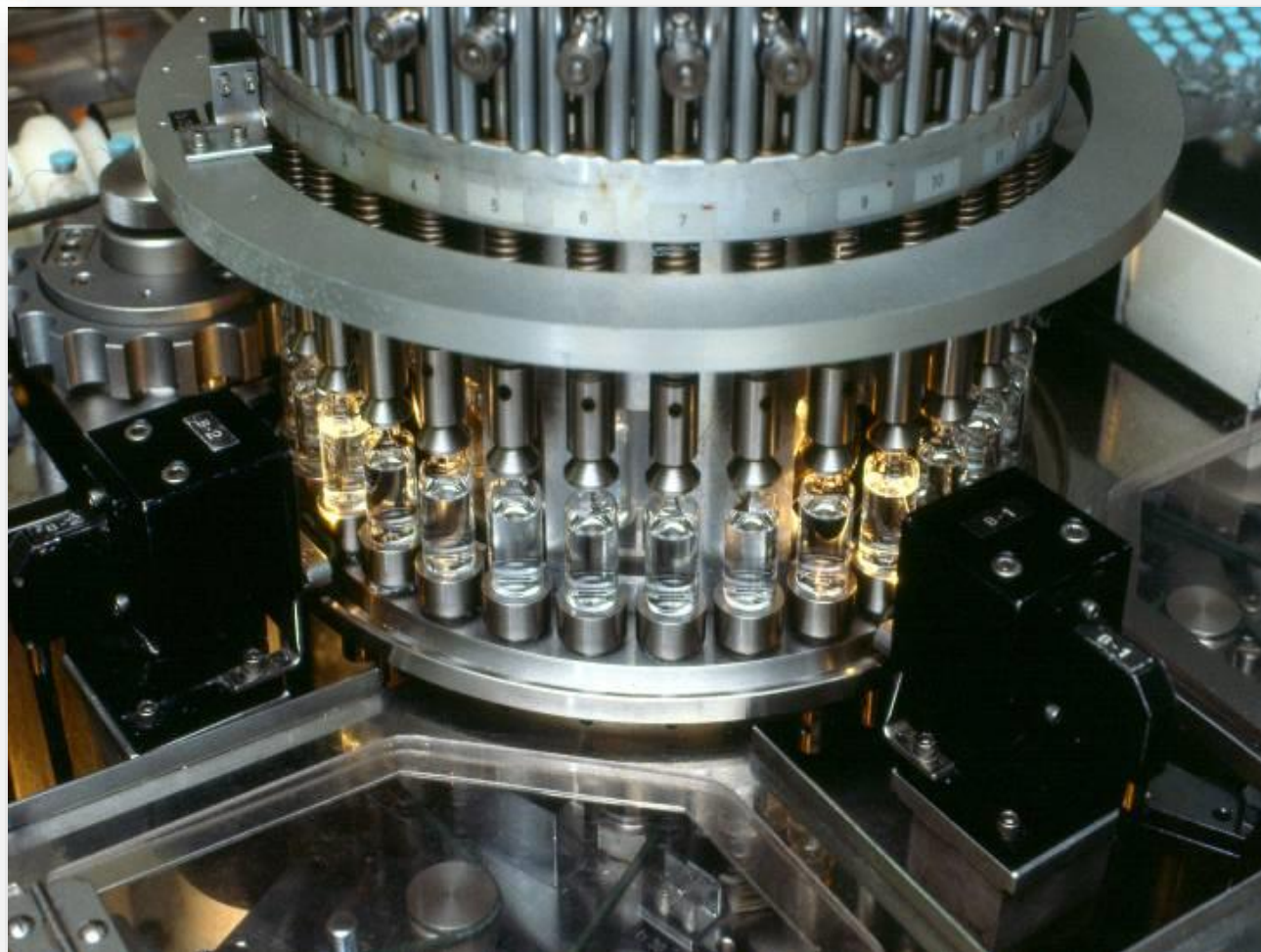
Linear Detector



Bosch Static Detection (SD)



Automated Particle Inspection



Eisai AIM-288

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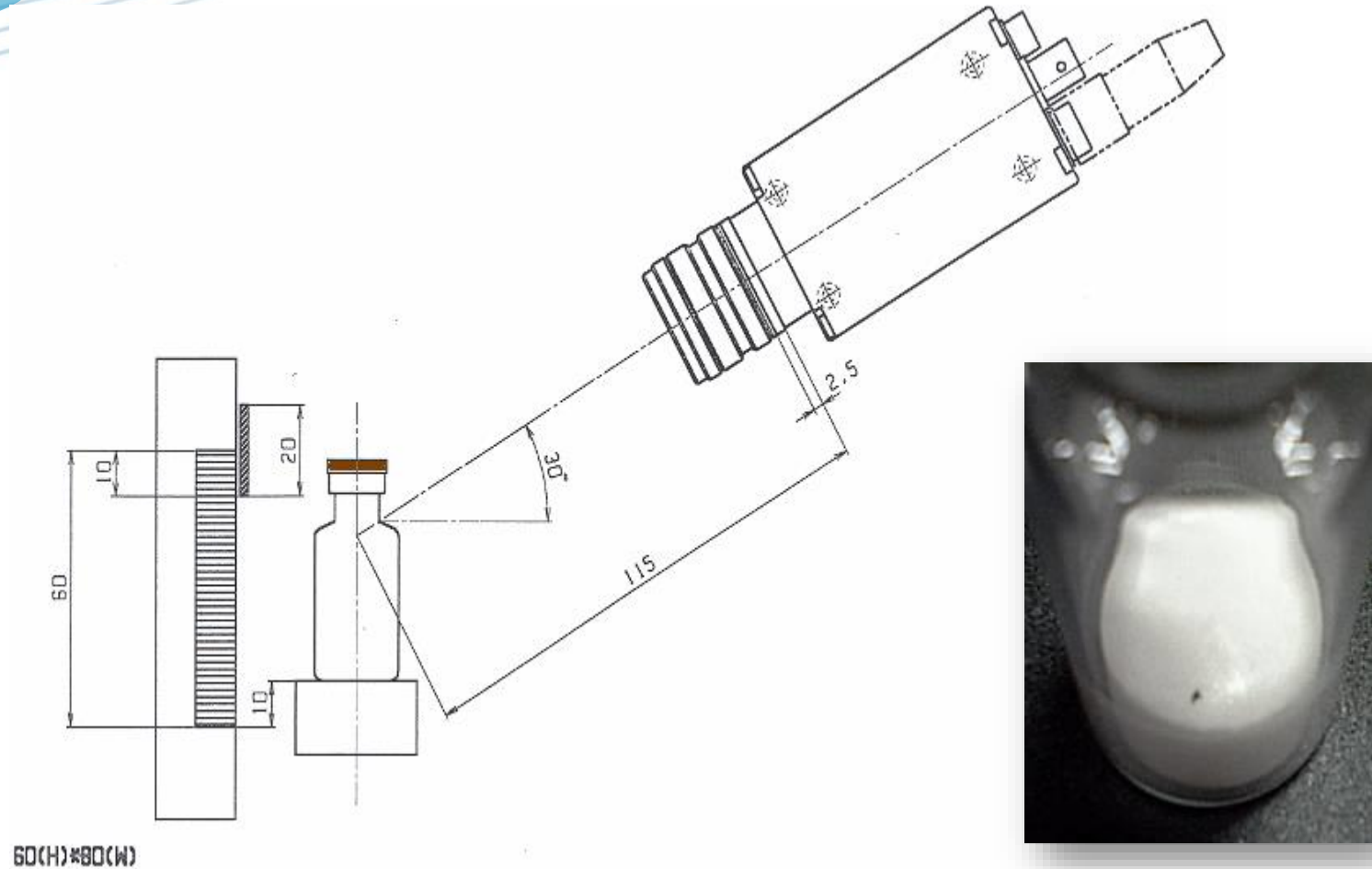
Automated Inspection



Eisai EIS-596



Automated Inspection





Inspection Performance

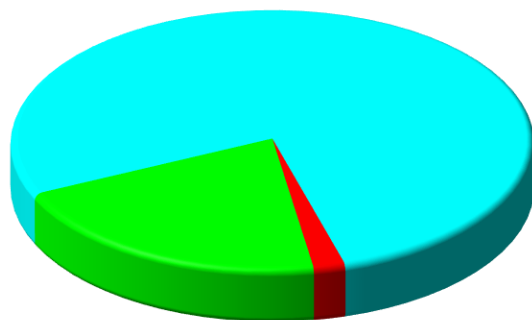
- Machine Inspection
 - Adjustable Sensitivity
 - Increased sensitivity must be balanced with increased false rejection rates.
 - Often product dependent
 - viscosity, surface tension, container design and variability
- Improved Reproducibility
- Improved Throughput
- High Initial Investment



Machine Inspection Performance

Human

Inconclusive

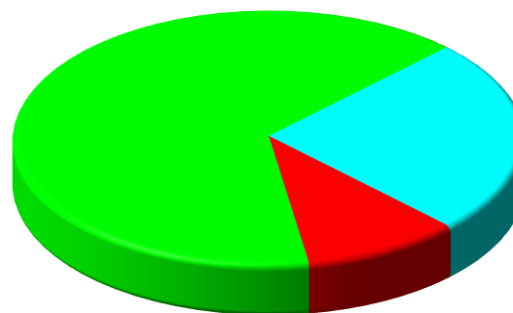


Good

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 ...

	2023	2014	2008	2003	1996
Particles:					
Manual	50%	49%	33%	46%	33%
Semi-Automated	21%	17%	24%	19%	20%
Automated	30%	33%	43%	35%	42%
Container/Closure:					
Manual	48%	54%	36%	63%	48%
Semi-Automated	20%	18%	26%	15%	42%
Automated	29%	28%	39%	20%	5%



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

	2023	2014	2008	2003	1996
Shift to Automated Inspection	57%	50%	67%	50%	68%
Justification:					
Quality	66%	85%	75%	92%	92%
Productivity	ND	87%	92%	92%	100%
Increased Capacity	69%	ND	ND	ND	ND
Cost Savings	54%	ND	ND	ND	ND
Ergonomics	2%	ND	ND	ND	ND

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

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How frequently do you challenge or retest automated inspection equipment?

	2023	2014	2008	2003	1996
Never	4%	1%	0%	0%	15%
Each Shift	7%	1%	8%	13%	8%
Start of Lot	50%	46%	42%	75%	38%
End of Lot	3%	ND	ND	ND	ND
Start and End of Lot	1%	8%	ND	ND	ND
Daily	15%	15%	25%	19%	23%
Weekly	2%	2%	0%	0%	8%
Monthly	0%	2%	ND	ND	ND
Quarterly	4%	1%	ND	ND	ND
Annually	25%	19%	ND	ND	ND
Other	3%	ND	ND	ND	ND

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

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Questions?

**BEAUTIFUL,
BUT OBSOLETE.**

