



# Visual Inspection of Injectable Products:

## Inspection Technologies

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January 2025

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“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

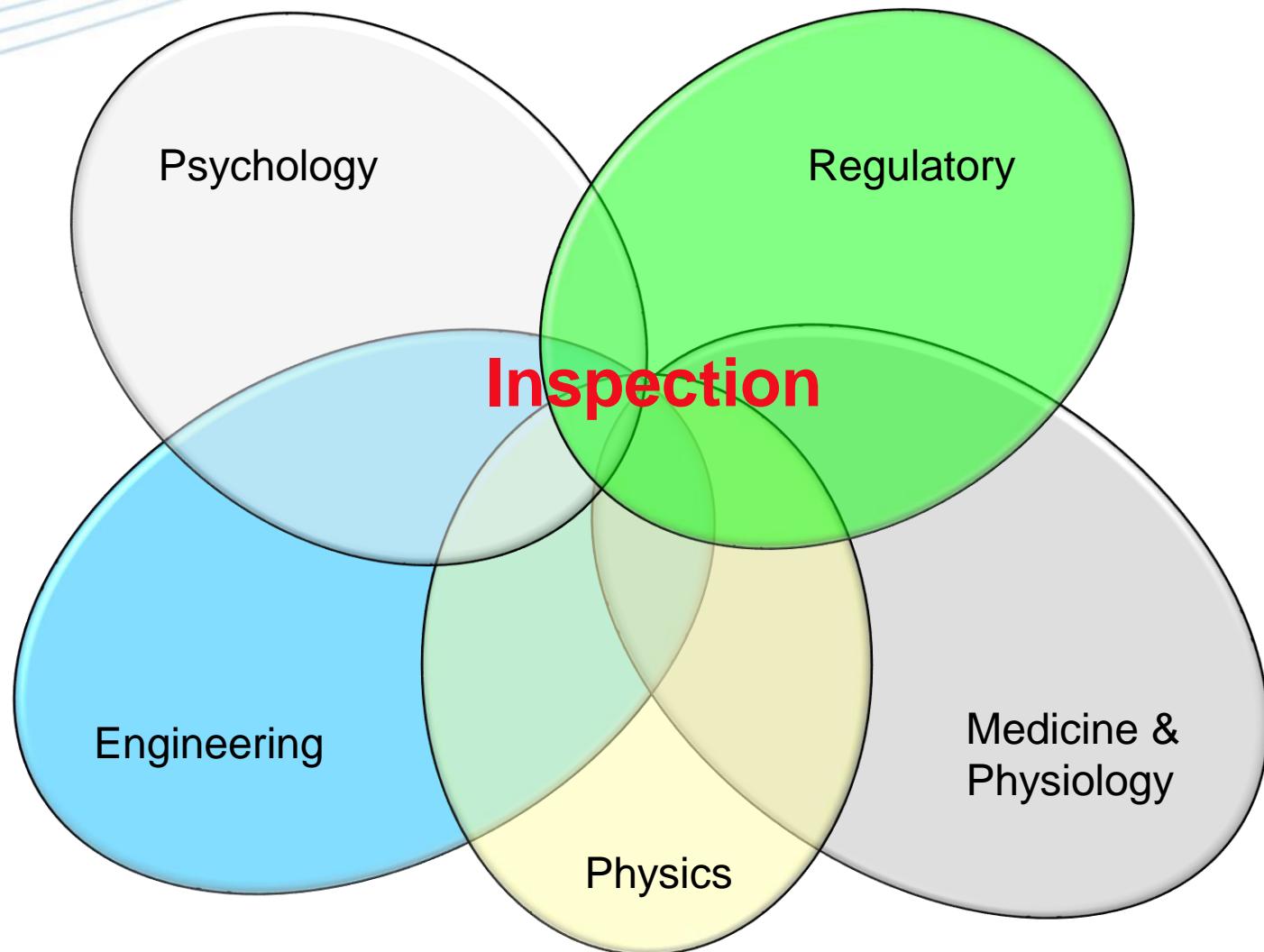


# Manual Inspection

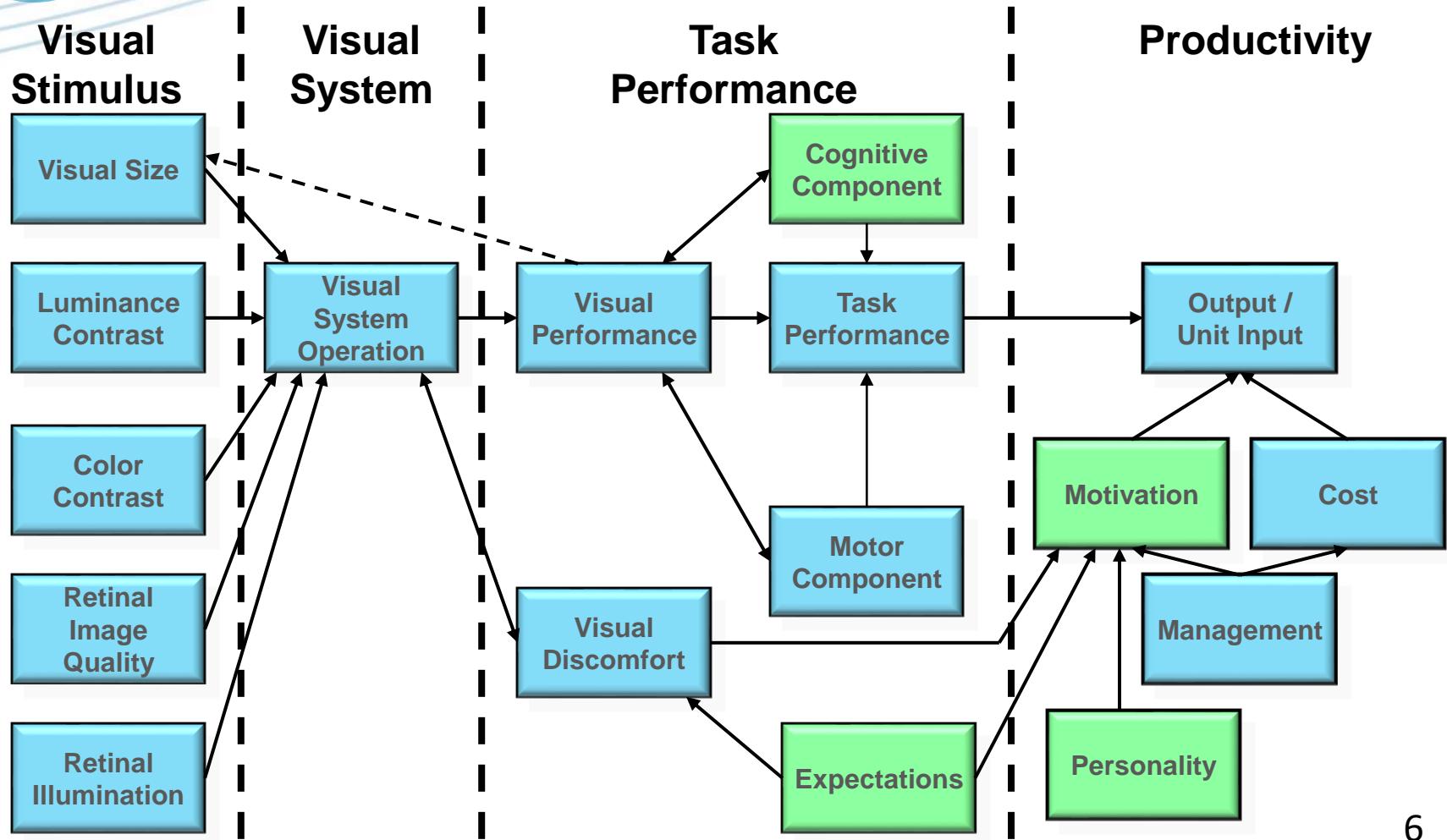
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# Inspection Influences



# Inspection



From G. Salvendy, Handbook of Human Factors and Ergonomics, 2<sup>nd</sup> Edition



# Manual Inspection



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# Manual Inspection



Phoenix Imaging MIB-100

# Manual Inspection



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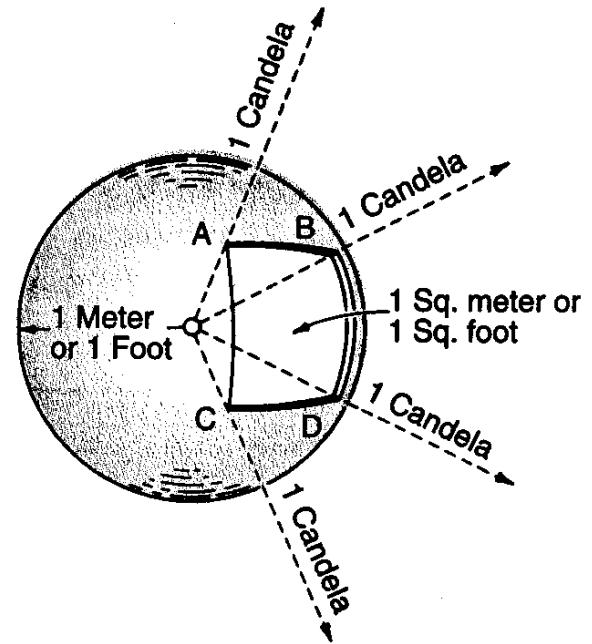


# Critical Inspection Parameters

- Lighting
  - Illumination Intensity (2,000-3,750 lux)
  - Uniform, Flicker-free
    - LED, Fluorescent, Incandescent
    - 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 =  $1/638 \text{ W/sr}$ 
    - 1 lumen = 1 candela in all directions
    - 1 candela formerly 1 candlepower
- Illuminance
  - 1 lux = 1 lumen/ $\text{m}^2$
  - 1 foot-candle = 1 lumen/ $\text{ft}^2$
  - 1 fc = 10.75 lux
- Inverse Square Law
  - illumination = luminous intensity/ $d^2$





# 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

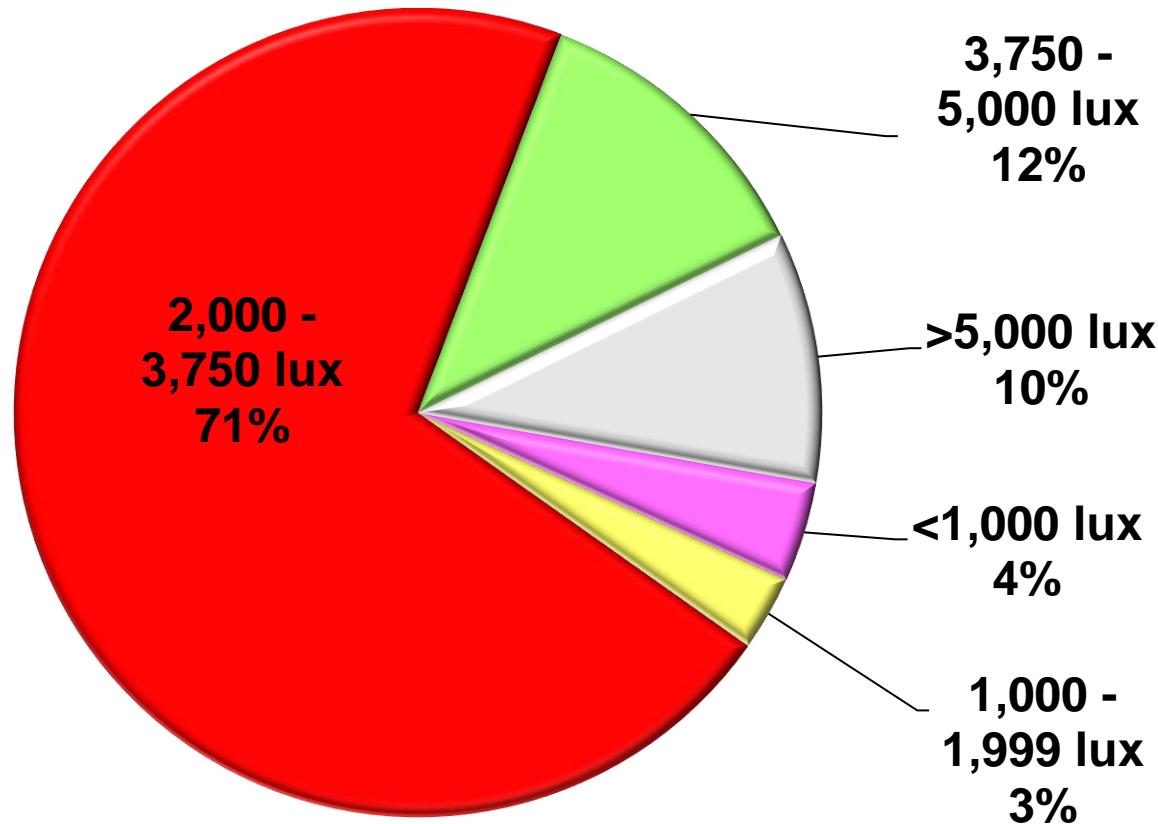


# Illumination Intensity

- 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



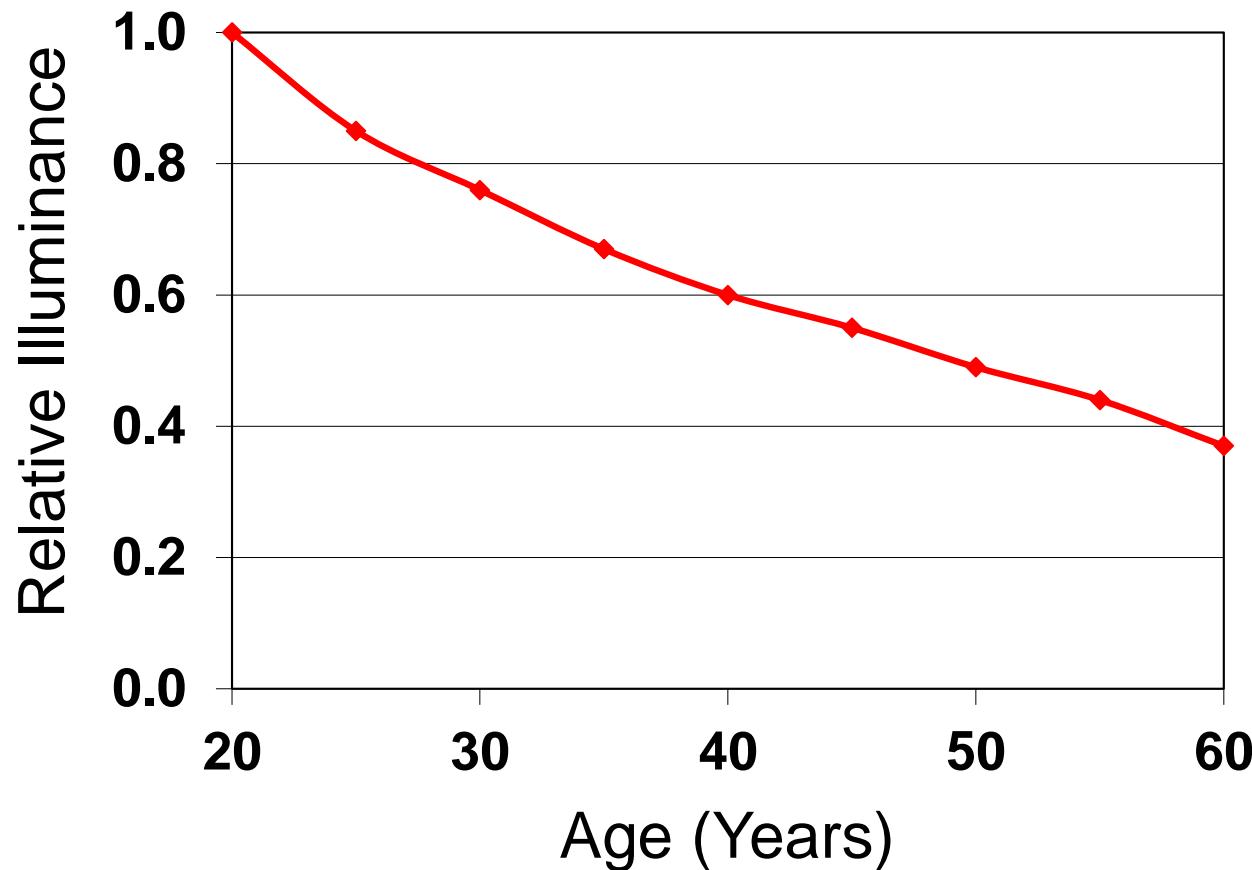
# What is the average illumination intensity at the container during manual inspection?



From 2023 PDA Visual Inspection Survey



# Aging and Relative Illuminance



From IESNA Lighting Handbook, 9<sup>th</sup> Edition



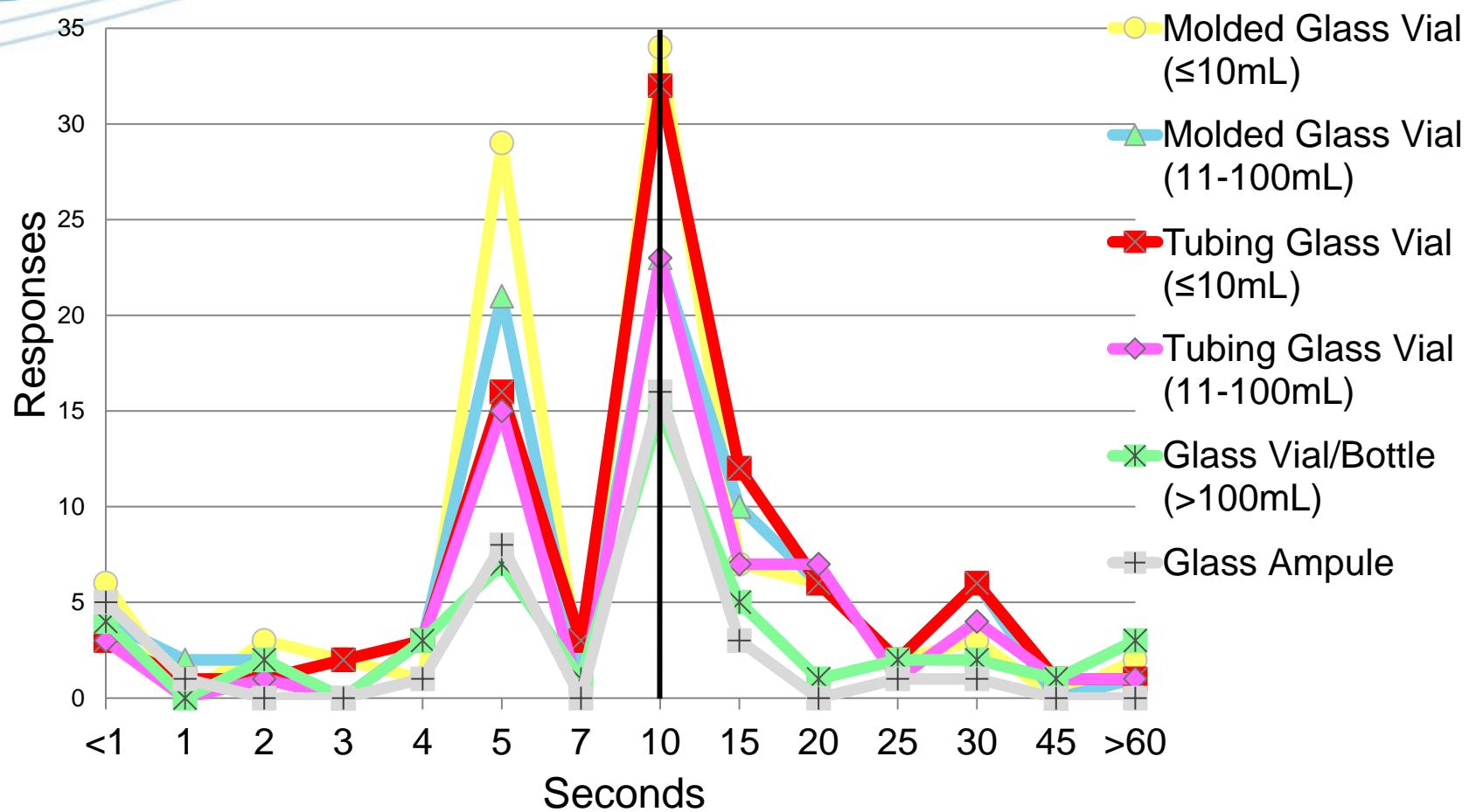
# Manual Inspection Conditions

- 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



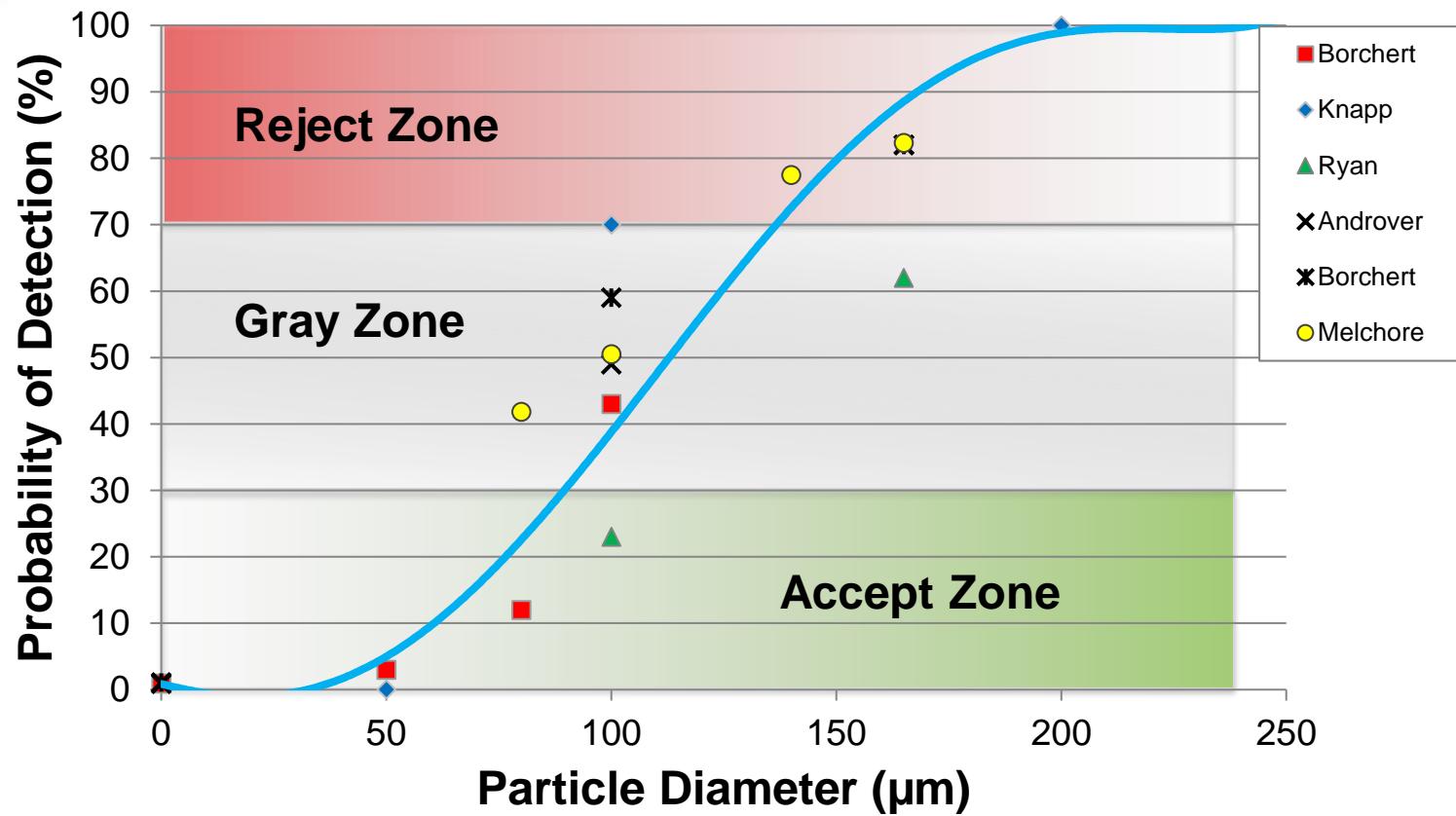
# What is the average inspection time for this container type?



From 2023 PDA Visual Inspection Survey



# Human Inspection Performance



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



# 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

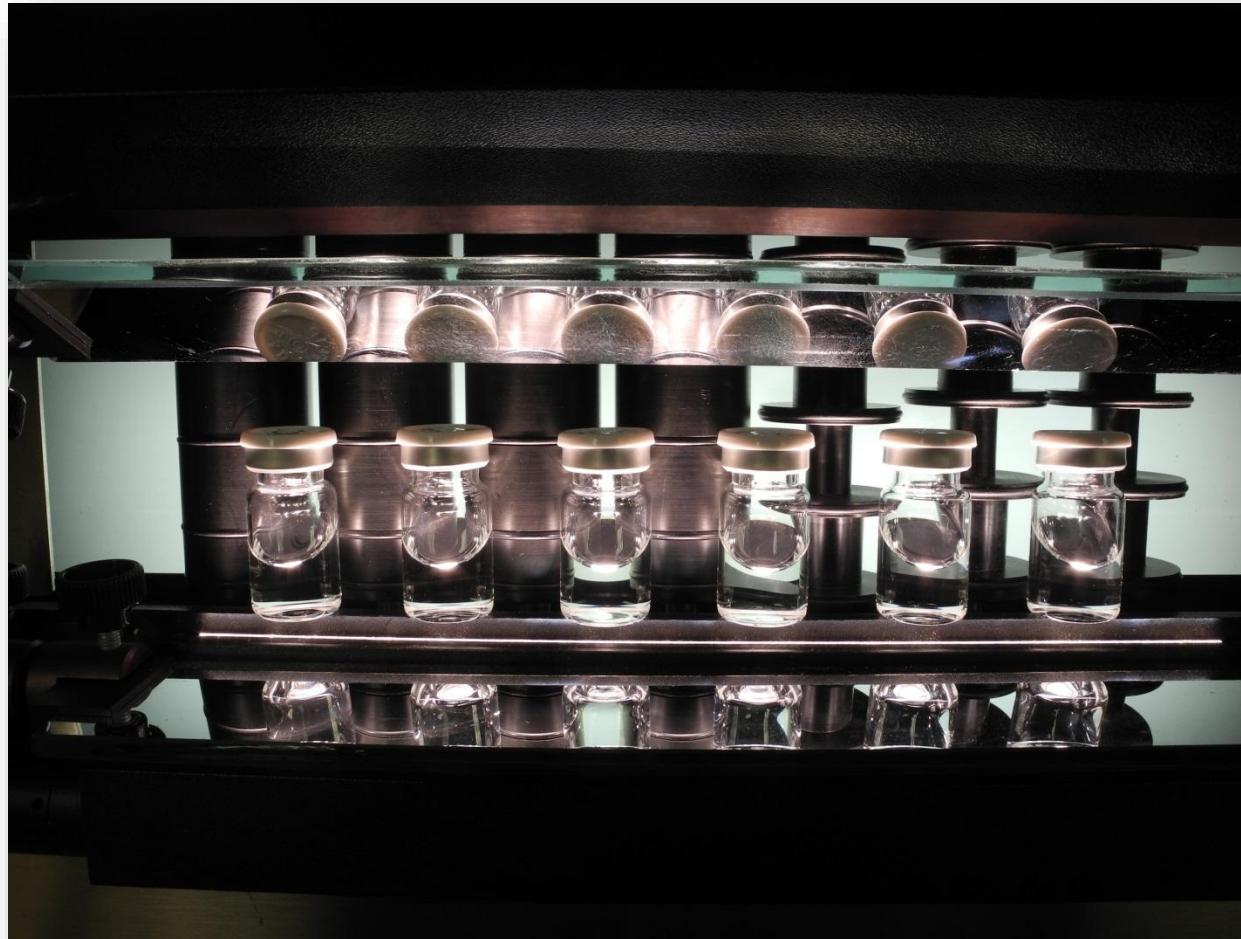
- Machine Material Handling
  - Transport, Spin/Rotation, Traying
    - Consistent lighting and presentation
  - Manual or Machine Rejection
- Human Inspection
  - Quality Decision

# Semi-Automated Inspection



Seidenader

# Semi-Automated Inspection



Seidenader

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# Inspection Performance

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

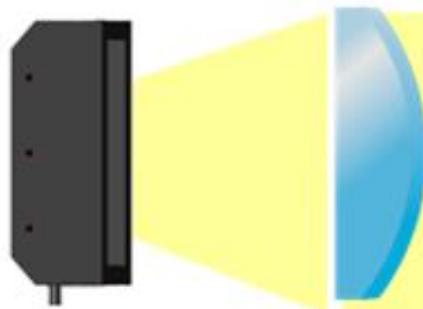


# Automated Inspection



# Automated Particle Inspection

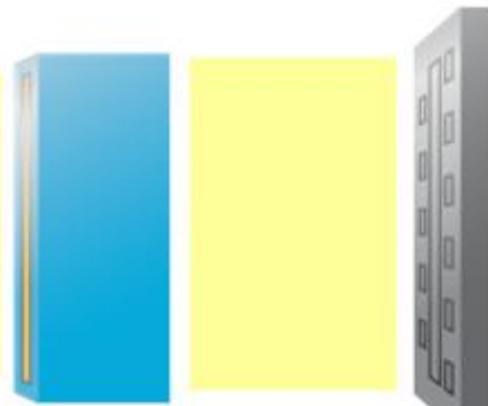
Light Source



Product



Linear Detector

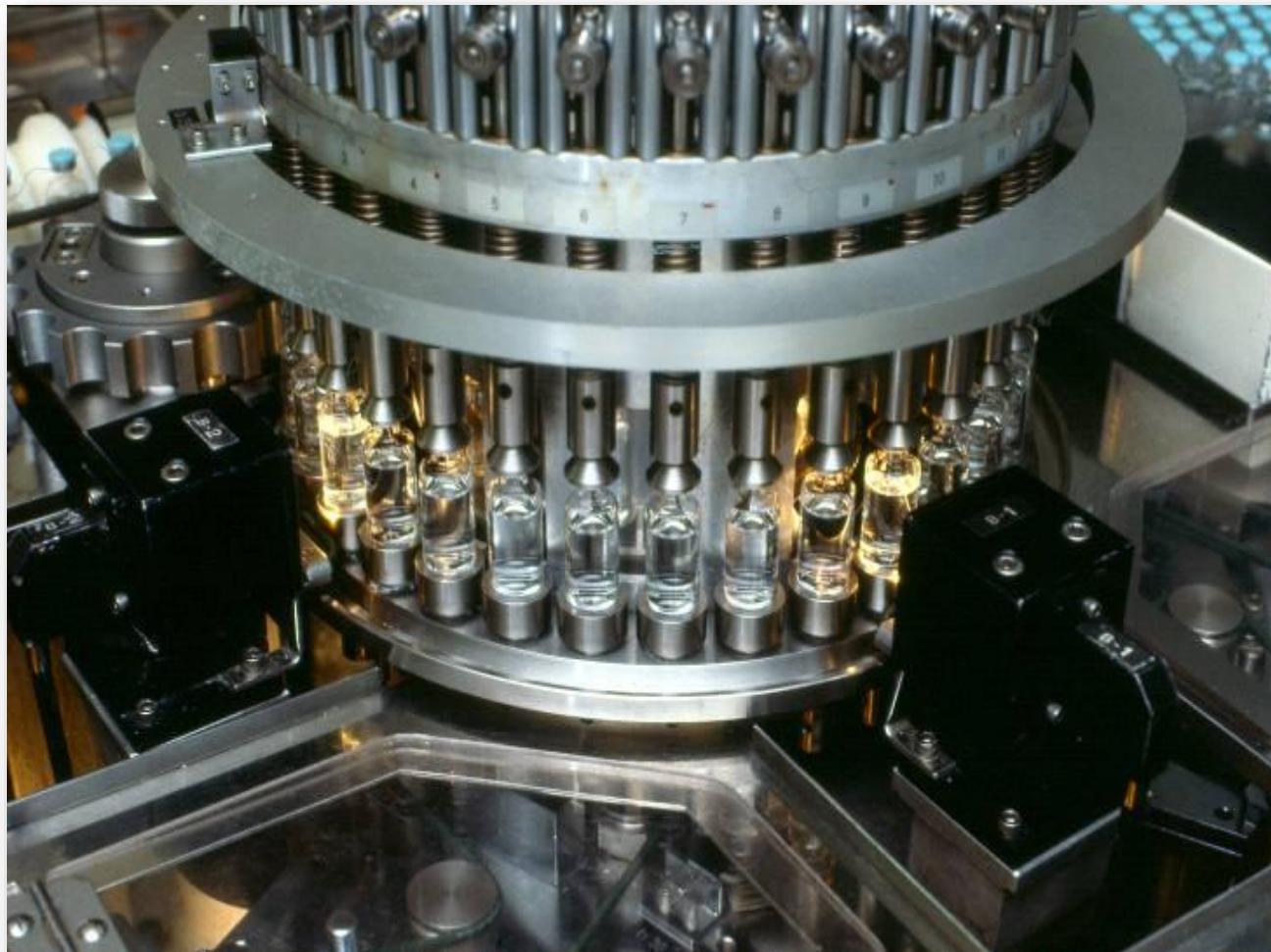


Lens

Lens

Bosch Static Detection (SD)

# Automated Particle Inspection



Eisai AIM-288

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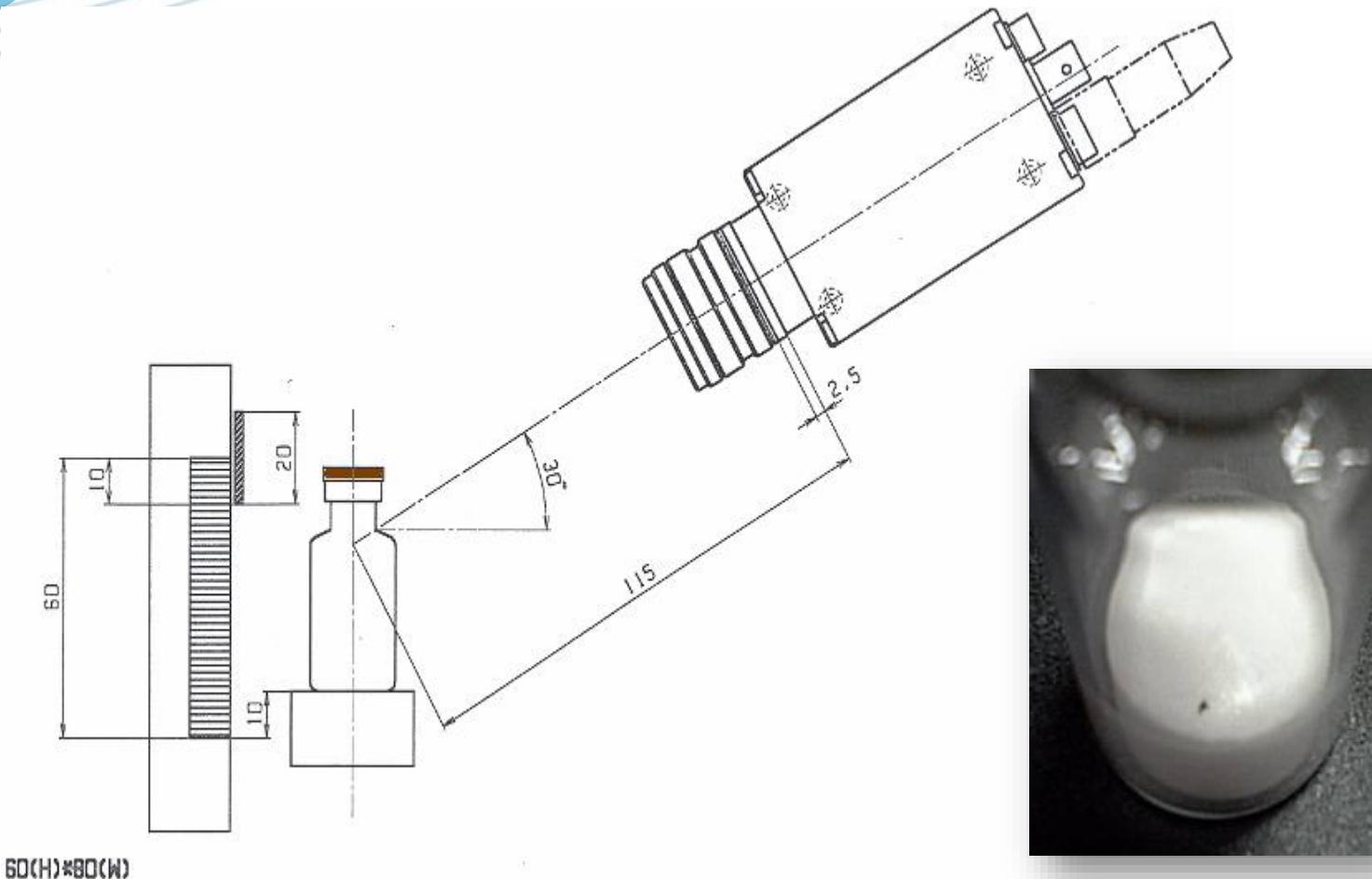
# Automated Inspection



Eisai EIS-596

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# 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



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

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



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

	2023	2014	2008	2003	1996
<b>Shift to Automated Inspection</b>	57%	50%	67%	50%	68%
	<b>Justification:</b>				
<b>Quality</b>	66%	85%	75%	92%	92%
<b>Productivity</b>	ND	87%	92%	92%	100%
<b>Increased Capacity</b>	69%	ND	ND	ND	ND
<b>Cost Savings</b>	54%	ND	ND	ND	ND
<b>Ergonomics</b>	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
<b>Never</b>	<b>4%</b>	1%	0%	0%	15%
<b>Each Shift</b>	<b>7%</b>	1%	8%	13%	8%
<b>Start of Lot</b>	<b>50%</b>	46%	42%	75%	38%
<b>End of Lot</b>	<b>3%</b>	ND	ND	ND	ND
<b>Start and End of Lot</b>	<b>1%</b>	8%	ND	ND	ND
<b>Daily</b>	<b>15%</b>	15%	25%	19%	23%
<b>Weekly</b>	<b>2%</b>	2%	0%	0%	8%
<b>Monthly</b>	<b>0%</b>	2%	ND	ND	ND
<b>Quarterly</b>	<b>4%</b>	1%	ND	ND	ND
<b>Annually</b>	<b>25%</b>	19%	ND	ND	ND
<b>Other</b>	<b>3%</b>	ND	ND	ND	ND

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

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# Questions?

**BEAUTIFUL,  
BUT OBSOLETE.**

