



# **Institute of Medicine Workshop on PPE for Healthcare Workers**

**Designing & Engineering PPE: Next Steps  
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# Key Technical Challenges

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- From Gown Manufacturing Standpoint:  
Building a gown that works for all end users
- From Material Manufacturing Standpoint:  
Develop a material that is comfortable and protective
- Overall Challenge  
What gown provides protection and comfort at a competitive price point?



# Call for “Prescription” of Isolation Gowns

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- Does not exist for isolation gowns
- Some choose a gown for its comfort
- Some choose a price point gown
- Too many choices – room for error
- National Patient Safety Initiatives are suggesting standardization
  - Hard to do the wrong thing
  - Includes procedures and products



# Standardization of Isolation Gowns

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## Existing PPE “Prescriptions”

### Face Masks

“... The transmission of SARS appears to occur predominately by direct contact with infectious material, including dispersal of large respiratory droplets. However, it is also possible that SARS can be spread through the airborne route. ... **CDC has recommended the use of N95 respirators**, consistent with respiratory protection for airborne diseases, such as tuberculosis.”

Source: CDC Website - Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS - May 3, 2005

### Gloves

Classified as a device under 21 CFR 880.6250, as recently as December 19<sup>th</sup> Federal Register **updated acceptance criteria to 2.5 AQL** on water leak test for pinholes

### Isolation Gowns – AAMI PB70

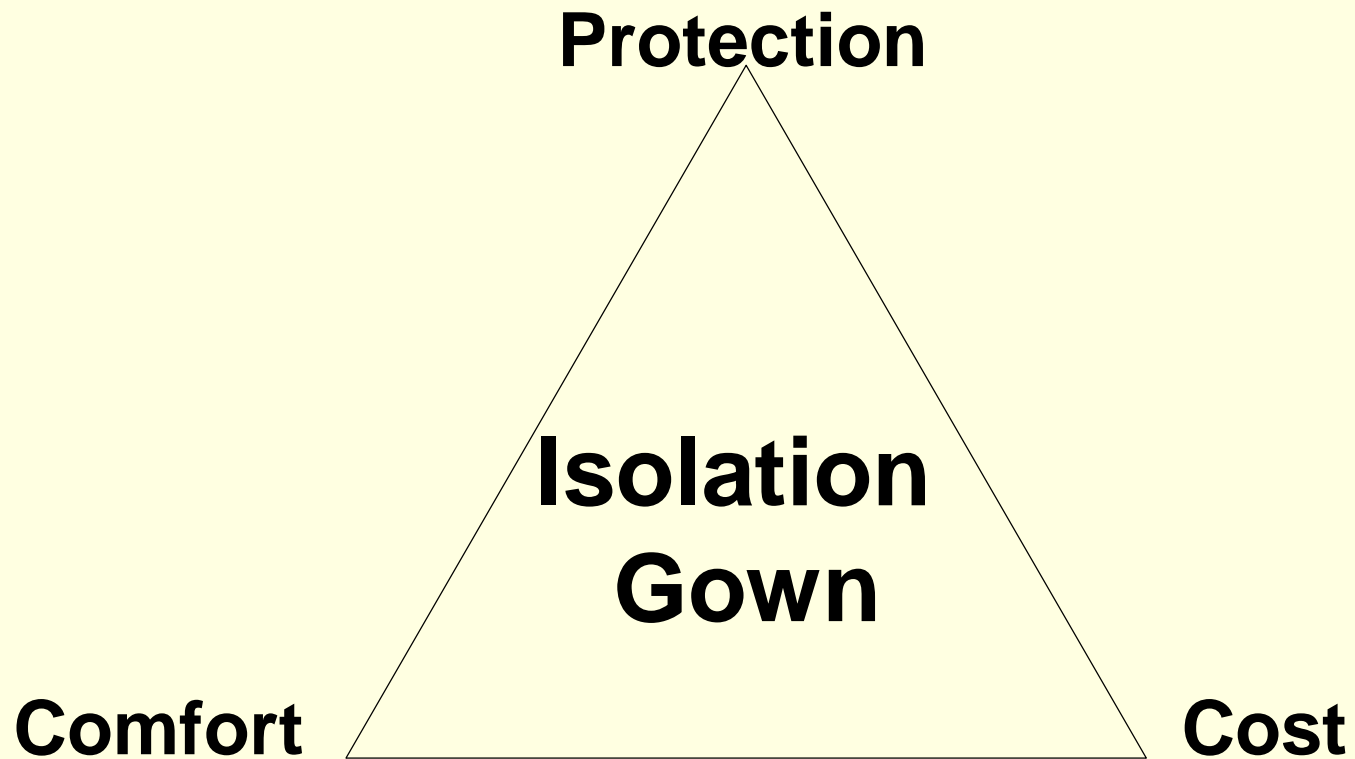
Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities

**System for grading of isolation gowns** – levels of choice – no prescription



# Standardization Challenges

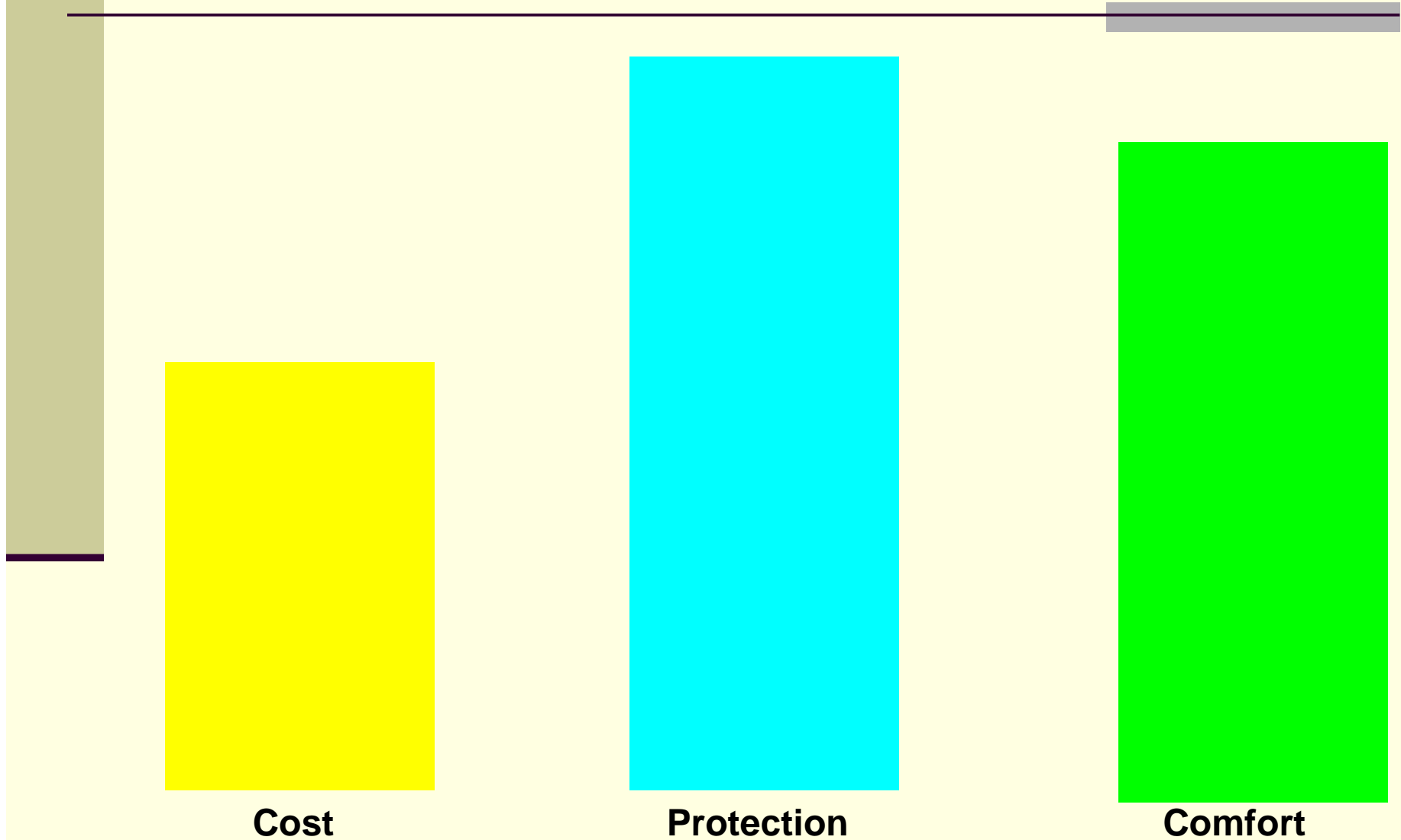
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**Can only get 2 of 3**



# Ideal Isolation Gown



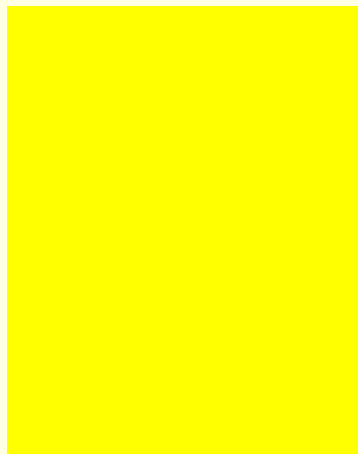


# Sample A – Lightweight Spunbond

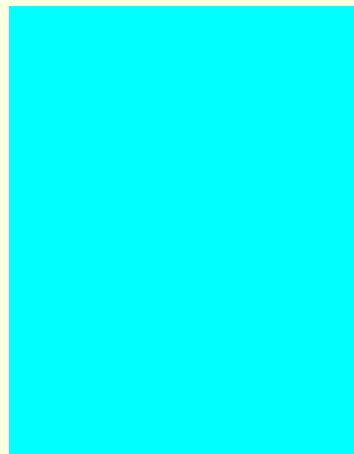




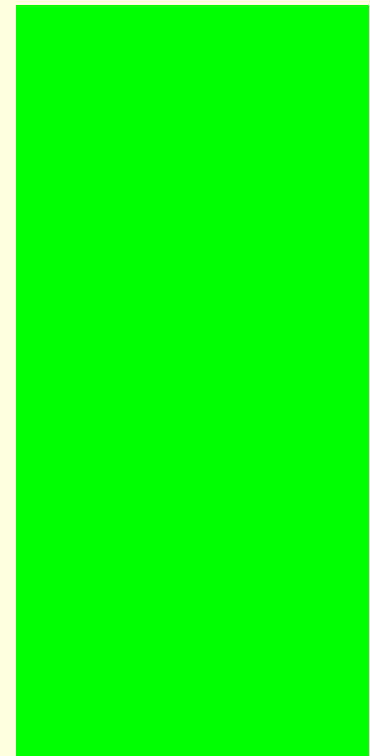
# Sample B – SMMS



**Cost**



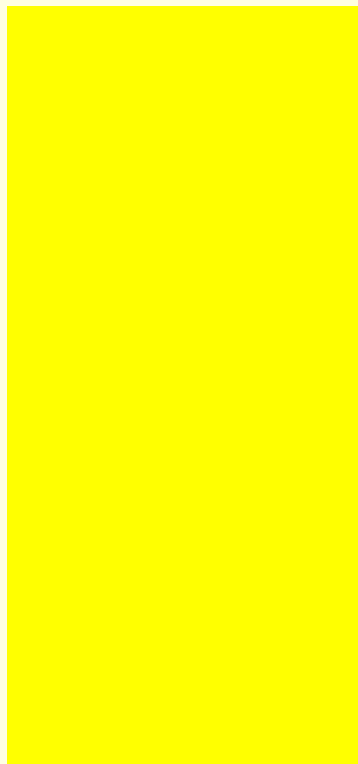
**Protection**



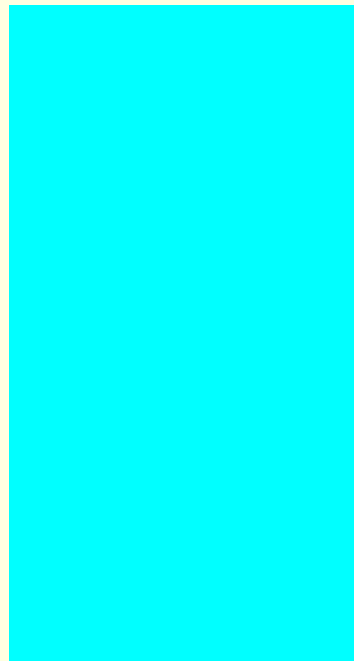
**Comfort**



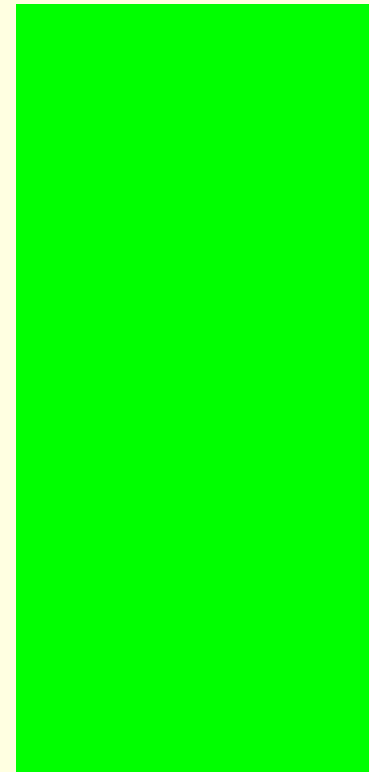
# Sample C – Bi-Component



**Cost**



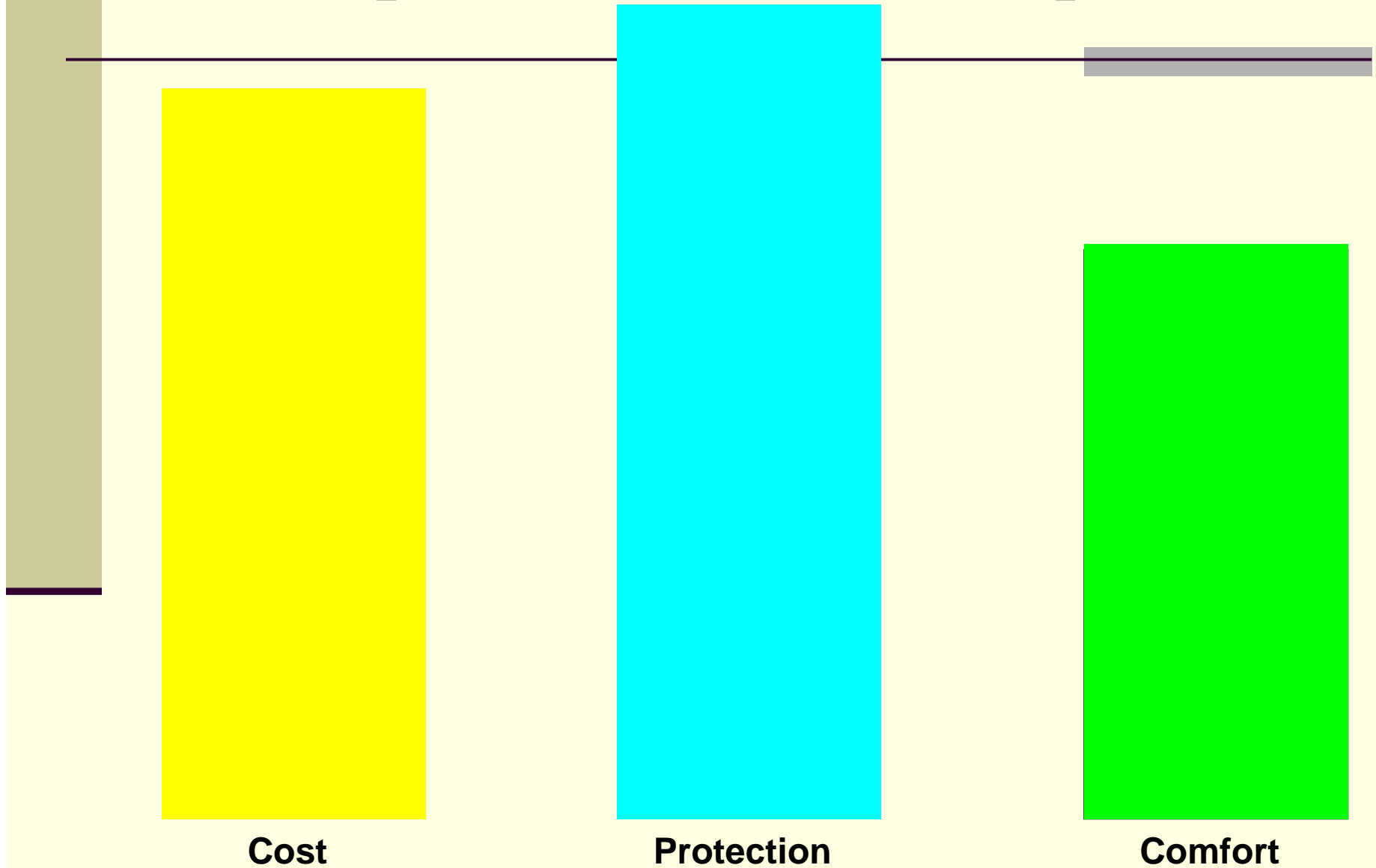
**Protection**



**Comfort**

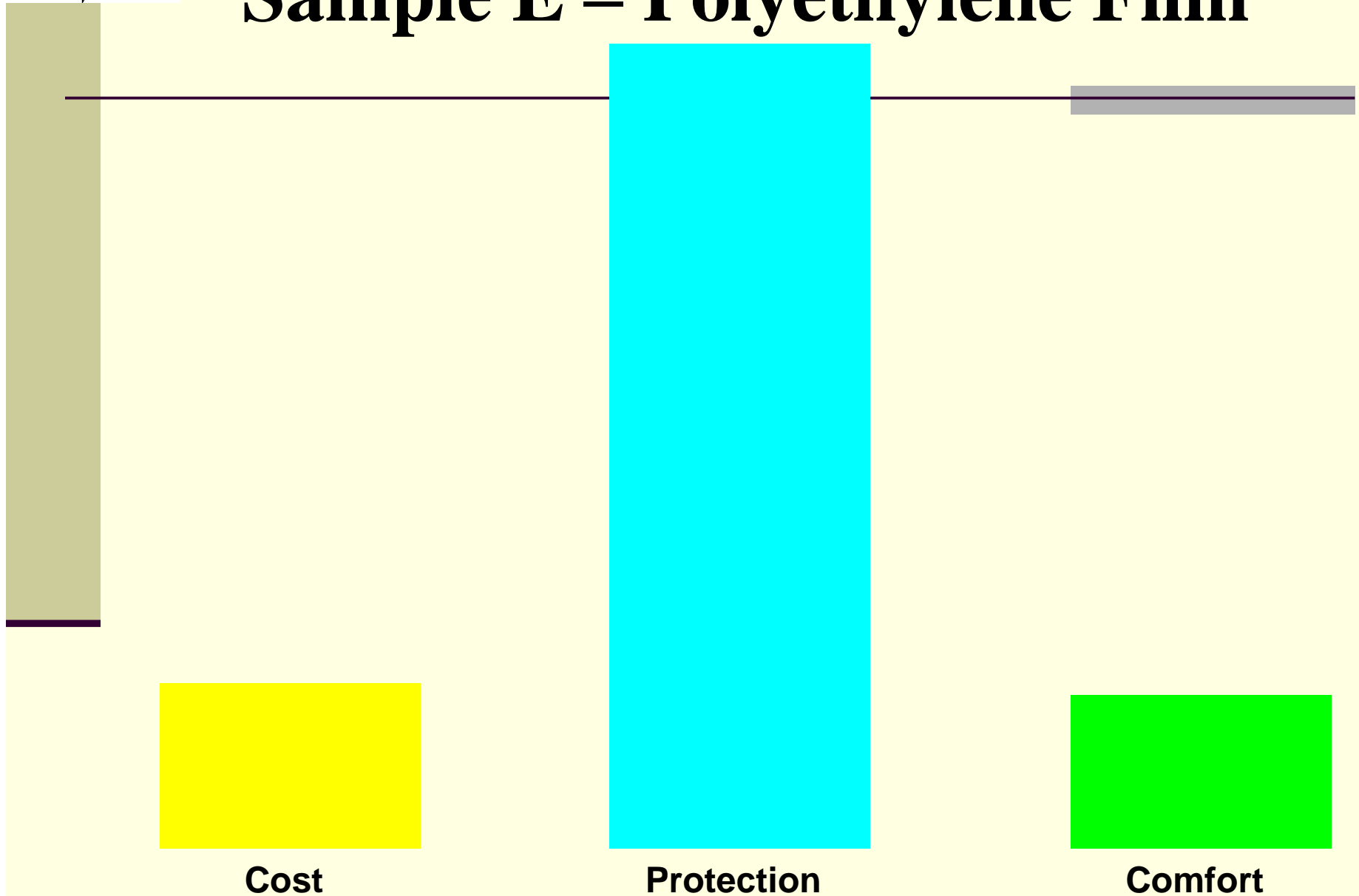


# Sample D – Breathable Impervious





# Sample E – Polyethylene Film





# Survey Results

## 1. Please rank your top compliance issues.

|                   |     |
|-------------------|-----|
| Comfort (too hot) | 27% |
|-------------------|-----|

|                   |     |
|-------------------|-----|
| Cost (high price) | 23% |
|-------------------|-----|

|                                   |     |
|-----------------------------------|-----|
| Protection (gowns not protective) | 21% |
|-----------------------------------|-----|

|   |     |
|---|-----|
| Education (don't know which gown to choose) | 16% |
|---|-----|

|                                     |     |
|-------------------------------------|-----|
| Product Availability @ Point of Use | 13% |
|-------------------------------------|-----|



# Survey Results

## 2. Who is the most non-compliant offender of proper Personal Protection Equipment (PPE) use?

|                     |     |  |  |
|---------------------|-----|--|--|
| Doctors/Physicians  | 60% |  |  |
| Family/Visitors     | 21% |  |  |
| Nurses/Staff        | 15% |  |  |
| Patients            | 2%  |  |  |
| Technical Personnel | 2%  |  |  |



# More Survey Results

## 3. What are your recommendations for compliance improvement?

Overall responses included:

- Education – need more – posters, signs, communication
- Enforce – administration – mandate – a big stick
- Comfort – make gowns that provide more & not as hot

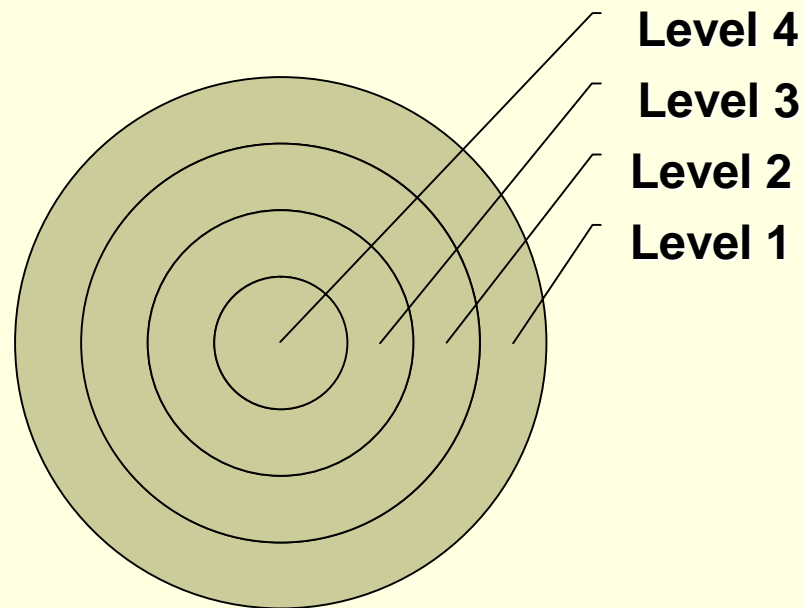


# Summary

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- “the” gown that provides great level of protection, adequate comfort, competitive price
- Can build any gown, have technologies
- Standardization is needed
  - Will eliminate # of choices manufacturers offer
  - Eliminate choices reduces costs
- “Prescription” makes it hard to choose the wrong gown
- Development for standardization criteria that is evidence based would result in manufacturers providing materials/gowns that offer protection, comfort and cost

# Conclusion



- System of grading exists – no prescription
- Which target do you want us to hit?
- We need you to prescribe the level of protection