

Respirators: Design to Commercialization

3M OH&ESD Presentation

Institute of Medicine

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Agenda

- Review Definitions
- Spectrum of Designs
- Commercialization
- Process Steps
- Use of Biocides



Definitions

- *What is a disposable respirator?*
 - A respirator where the filtering element is integral to the product and can not be replaced or cleaned.
 - It can be used **repeatedly** until it becomes damaged, difficult to breathe through (filter style) or when the sorbent media is exhausted (cartridge style respirators).
 - The useful life is limited by considerations of hygiene, damage, and breathing resistance/sorbent capacity.
 - It has limited cleaning capabilities and cannot be disinfected or repaired
 - This style of respirator is usually for the exclusive use of one person (can not be shared with others once worn).



Definitions

- *What is a reusable respirator?*
 - A respirator designed that can be used **repeatedly** with components (head straps, valves, etc) that can be cleaned, disinfected, replaced, and/or repaired.
 - The filtering element(s) are replaceable. The service life of the filter element is limited by considerations of hygiene, damage, and breathing resistance/sorbent capacity just as with a disposable respirator.
 - This style of respirator can be cleaned and disinfected for use by different wearers.



Definitions

- *What is durability?*
 - It applies to both disposable and reusable devices, and relates to the features that have been added to increase repeated use before disposal, maintenance or repairs.
 - Personal perspective

Spectrum of Half Mask Respirators

Disposable

Reusable



Maintenance



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Steps in Commercialization

Idea

Concept

Feasibility

Development

Scale Up

Launch



Idea

- Identify the market potential for new product or service idea.

Concept

- Gather customer & market needs and translate into ranked product requirements.
 - The type of hazard
 - Exposure level
 - Environmental Conditions during use
 - Level of maintenance
 - Wear Time
 - Expectation of use before disposal
- Develop and evaluate multiple concepts



Feasibility

- ID best concept and identify the technical solution.
- Validate customer requirements.
- Design performance
 - Facial characteristics & Fit
 - Type of Population
 - Anthropometrics
 - Design of sealing surface to conform to population
 - Strap characteristics, from pressure to comfort
 - Demonstrate the product design/prototype can be produced consistently and within preliminary specification limit.
 - Comfort
- Materials science
 - Quality Control of incoming Raw Materials
- Manufacturability



Development

- Develop a robust product that is optimized to customer requirements.
- Verify product capability against the customer & market tolerances
 - Filtration Technology
 - Approval type (performance specifications)
 - Environmental Conditions
 - Facepiece Technology
 - Environmental Conditions
 - Comfort (Material Science)
- Field test the product to validate customer acceptance and develop a marketing plan to maximize the value proposition.
- Validate product efficacy



Development

- Materials science
 - Life Cycle Management
 - Toxic Properties of Materials
 - Environmental
- Manufacturability
 - Quality Control of incoming Raw Materials
 - Refine the manufacturing plan in preparation of scale up.
- Testing all aspects of design from fit, to regulatory requirements, to materials
- Submission and Certification
- Capital equipment



Scale Up

- Optimize the process for robustness while maintaining a robust product and demonstrate long term capability at the targeted manufacturing site.
- Finalize process EHS items.
- Process Engineering
 - Raw Materials
 - Forecast to Volume (Degree of Automation)
- Quality assurance
 - Incoming raw material inspections
 - Product Quality Plans (PQP)
 - Release Specifications



Launch

- Execute the launch plans (e.g. train sales staff, build inventory, prepare marketing collateral, etc.).
- Demonstrate control of the Manufacturing and Sales & Marketing control plans.

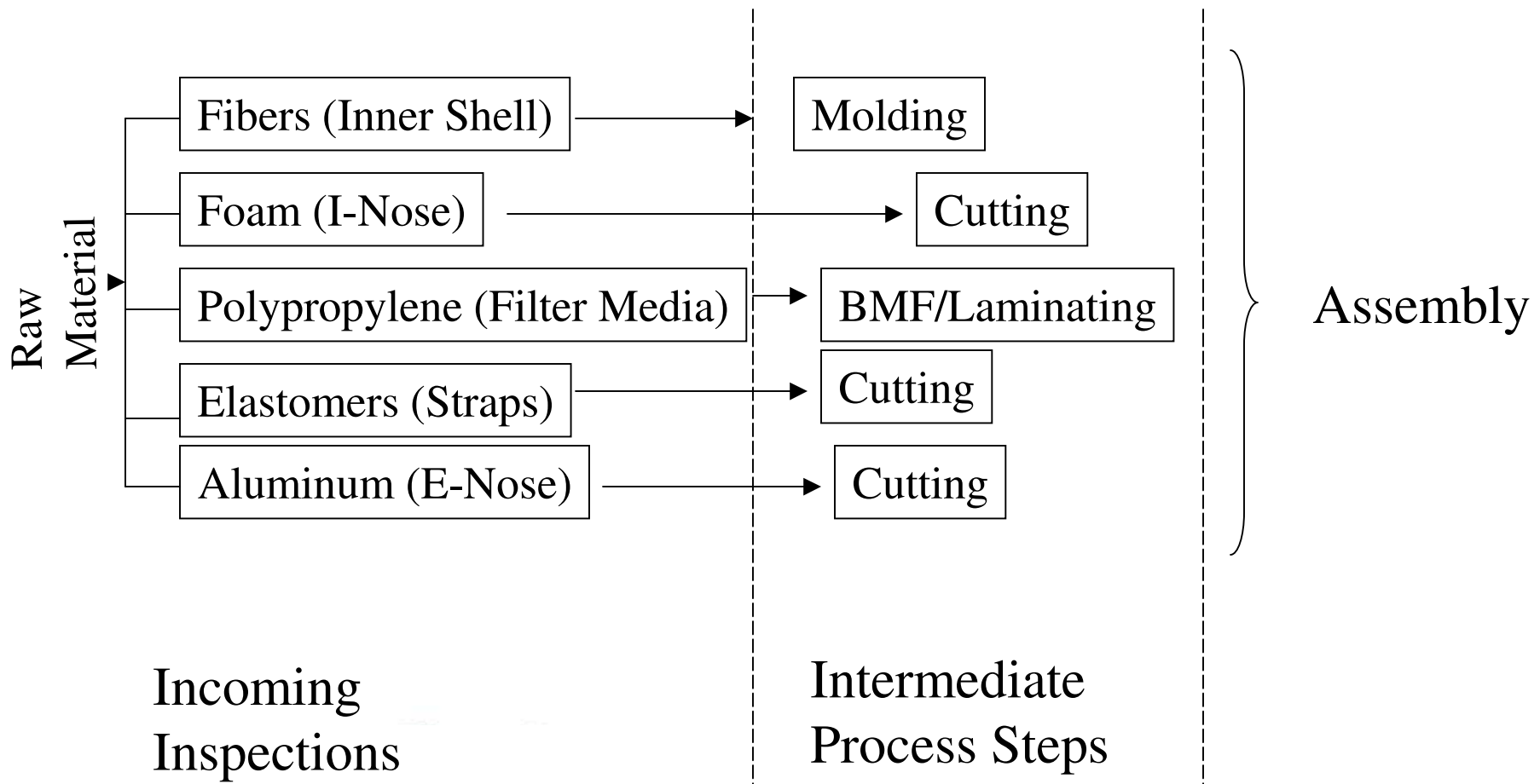


Skills & Competencies

- Polymer Science
- Material Science
- Biological Science
- Chemical Engineering
- Mechanical Engineering
- Environmental Health & Safety



Components & Process of a Typical Disposable Design



Biocides on Respirators

Are they Needed?

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Needed Research Steps on the use of Biocides in RPD

1. Develop bioaerosol test system
 - Generating and detecting airborne particles in approximate ranges of 0.03 microns to over 1 micron.
 - Bioaerosols representative of pathogens encountered in a real world environment.
2. Evaluate and compare the filter efficiency of commercially available respirators and filtration media not containing antimicrobials and those containing antimicrobials against test agents such as viruses and bacteria.
3. If warranted, evaluate approaches to enhance the antimicrobial activity of respirator components, including coverwebs and filter media and develop a prototype new generation respirator that would reduce transmission of infectious agents.
4. Evaluate the health implications for adding a biocide

