

The Brunswick logo features a stylized 'B' icon followed by the word 'BRUNSWICK' in a bold, white, sans-serif font. The background is a solid blue color with decorative white line art in the top-left and bottom-right corners.

BRUNSWICK™

NEXT NEVER RESTS™

IBWSS CONFERENCE – ALBUQUERQUE, NM

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Designing and Manufacturing Compliant, Safe Product



Product Integrity & Compliance

Manufacturer's Obligations

Consumers choose marine products for their quality and reliability. It is critical that those products live up to their high reputation.

Obligations

- As a US MIC holder, it is imperative that all products meet Title 33, Boats and Associated Equipment and EPA evaporative emission requirements
- As an NMMA member, you can comply to a subset of ABYC standards and receive industry association certification
- American Boat and Yacht Council standards are voluntary. Manufacturers are held to those standards when tested in the courts
- Expectations are that products are manufactured and sold as safe, reliable and compliant

MANUFACTURER'S OBLIGATIONS – WHAT REGULATIONS AND STANDARDS DO WE BUILD TO?



Primary Regulations/Regulators:

- USCG (generally aimed at boats under 20')
- Recreational Craft Directive (vessels up to 20m)
- AU/NZ (recreational marine craft)
- CARB (evaporative emission requirements ie carbon canisters, etc)
- EPA (fuel systems and component evaporative emissions, clear water & air)

Voluntary Standards

- ABYC/ANSI
- SAE, NFPA, ASTM
- ISO standards
- Internal standards and policy statements (ie HIN)

Third Party Certifiers

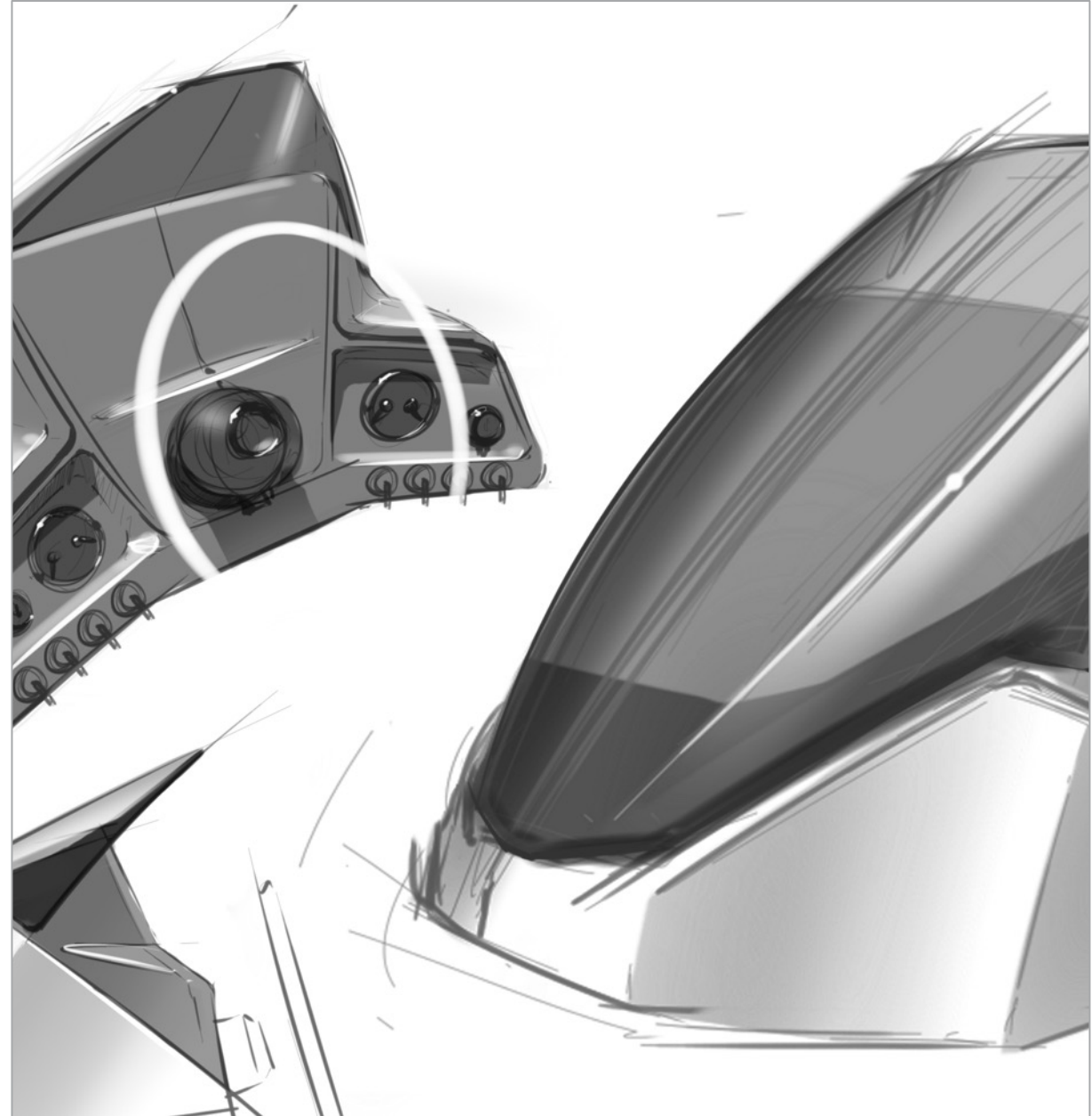
- NMMA (US and Canada)
- IMCI (EU)

Design and Engineering

Start with compliance in mind

Standards are the floor not the ceiling so make sure all required testing and compliance is done according to followed guidelines (i.e., USCG, ABYC, SAE, ISO, AU/NZ)

- Start with the end game in mind - understand what standards will affect your project before you start the design and engineering process
- Create a compliance or engineering book
- Document all testing
- Create detailed work instructions / PRINTS and keep them updated
- Call out safety critical operations and provide guidance to manufacturing
- Design and build systems that fail safe



Design and Engineering

Using Standards to Make Compliant Product

- Requirements:

- Domestic regulations (USCG, FMVSS) generally cover basic safety requirements
- Domestic voluntary standards (ABYC, UL, SAE) give guidance in the absence of federal law and hopefully provide some parity to the ever-growing regulatory agenda overseas
- Internal standards (Best Practices) help fill in the void where regulations and voluntary standards are not

- International standards can require more:

- Requires us to be vigilant of changes to rules abroad
- Generally, requires certification by manufacturer or notified body
- Most countries have their own requirements (i.e., Australia, EU)



Production

Producing Compliant Product

- Build the product as designed
- Have a way to document the construction and inspection process (Construction Record and Quality Inspections)
- Use controlled work instructions and sign off all paperwork. You may get asked to provide this later it has to be legible and make sense
- Keep all documentation in a central location that is easily accessible (electronic or hardcopy)
- Vendors – Do installation validation and occasional vendor audits with documentation.
- Conduct production compliance audits on the line



Production

Product Audits

- Conduct periodic audits to validate that compliance requirements have been appropriately applied and are in the manufactured product as designed
- Feed findings from internal product audits and supplier audits back into the design process. Identify findings that result from non-conforming work, improper or ineffective print documentation, training deficiencies or where there is no criteria for acceptance



Production

Manage Change Accordingly

- When modifications need to be made, ensure you conduct an engineering analysis that documents when, where, what and why the change happened for:
 - Vendor or part change
 - Safety Critical components
 - Deviation from past practices
- Unvalidated changes can be a risk for your business
- Make sure you document when an engineering change occurs on a model or series
- FMEA or similar may be required to substantiate changes to fit, form or function and for safety critical processes or components



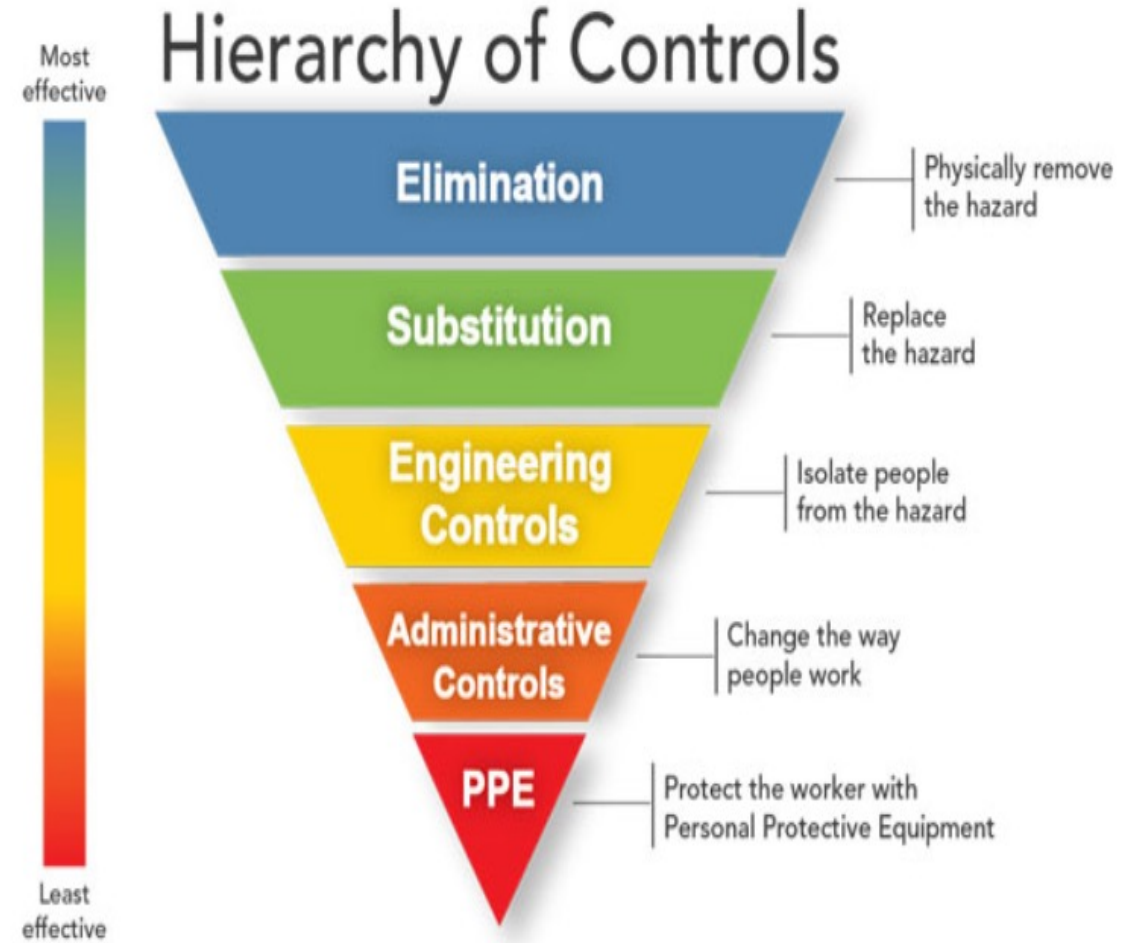
Corrective Actions

Seek to eliminate hazards in the products you design and manufacture to as low as reasonably practicable (ALARP)

Establish a process for achieving feasible product risk reduction based upon the Hierarchy of Controls

The Hierarchy of Controls shall be used in the corrective action process from findings that stem from manufacturer's product compliance audits and manufacturing quality functions

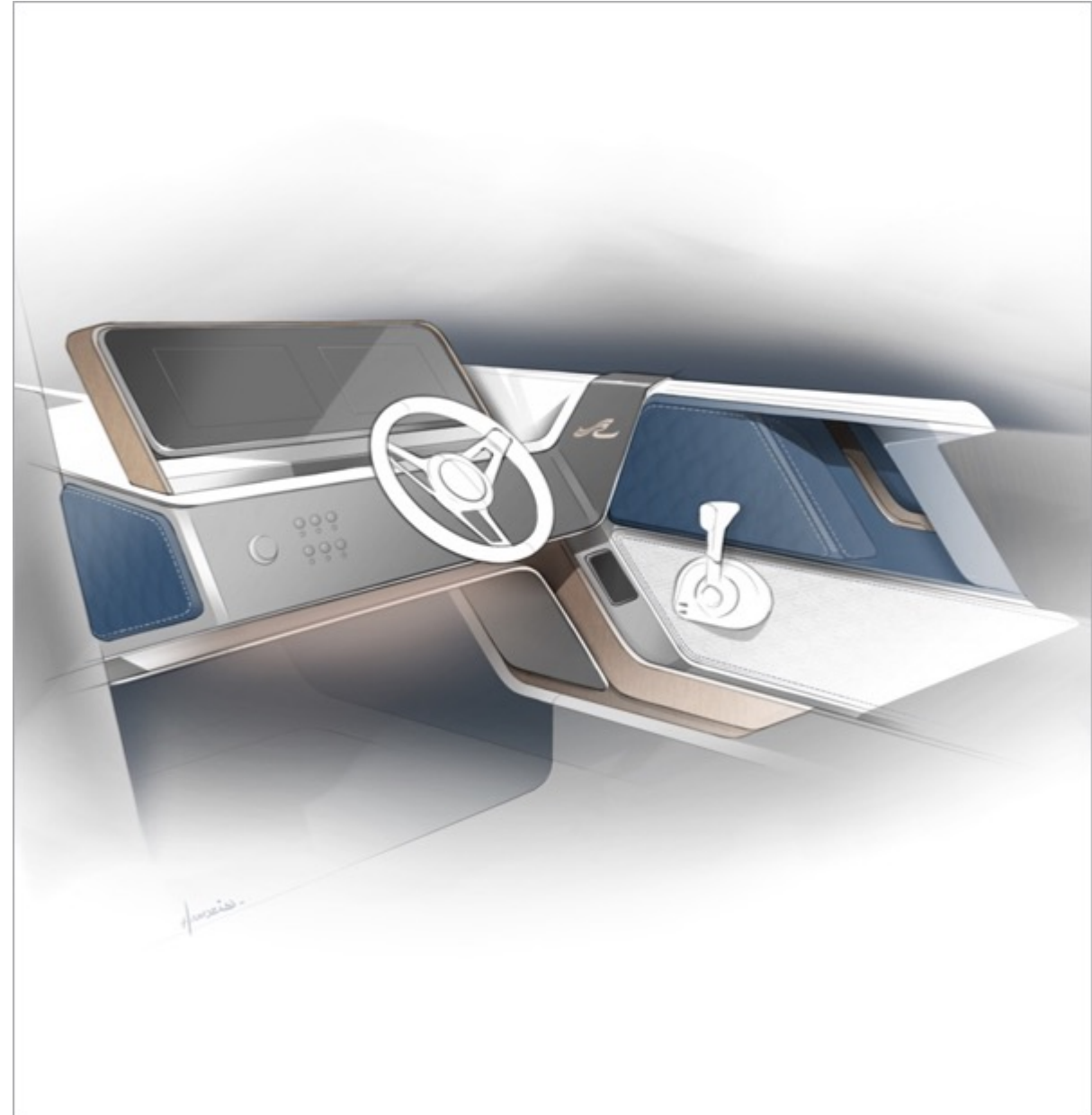
Regulatory and standards non-conformities shall require the use of higher order controls



Post-Production

Warranty Documentation

- Document all warranty history of product. Remember, USCG requires first purchaser information for 10 years.
- Warranty documentation needs to be accessible and reviewed with manufacturing and engineering regularly
- Pay particular attention to safety critical reports or issues that involve consumer safety
- Key word searches can assist in the data review and reporting functions
- Remember all this information can be asked for in litigation
- Have a retention policy for documents and follow it



Service Bulletins and Recalls

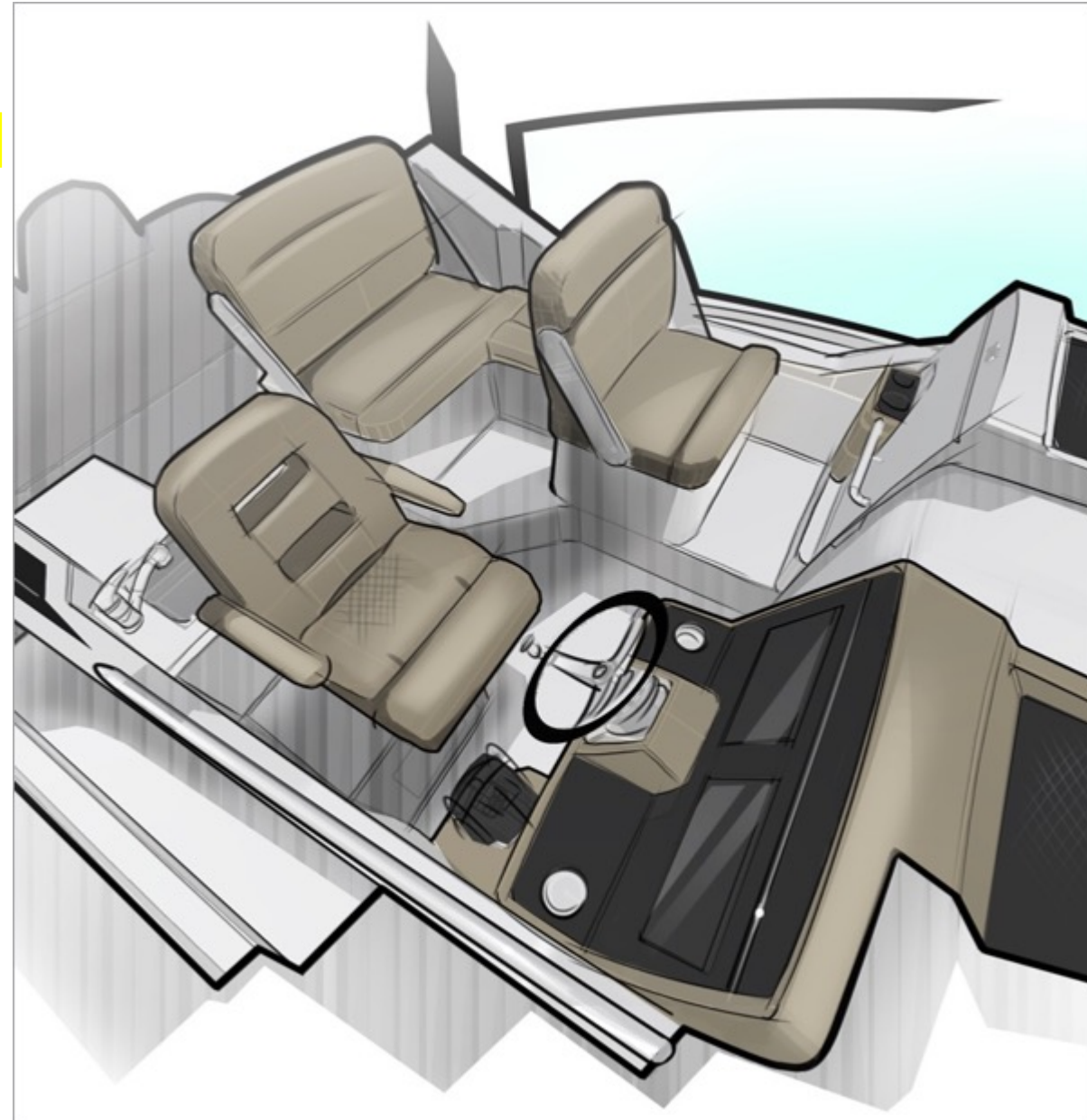
- Know who is responsible in the organization for assisting in the creation of outreach to the consumer and dealers
- It is important that our instructions are correct and easily understood
- Document all affected product, the issue, the resolution and what product has been fixed
- Track progress and resolution of open service bulletins and recall campaigns
- Recalls require notification to the USCG, CPSC or even NHTSA
- If recalled products were distributed into the EU, a RAPEX may also need to be filed



Service Bulletins and Recalls

USCG Sec. 4307. Prohibited acts(a) A person may not - (1) manufacture, construct, assemble, sell or offer for sale, introduce or deliver for introduction into interstate commerce, or import into the United States, a recreational vessel, associated equipment, or component of the vessel or equipment unless - (A)(i) it conforms with this chapter or a regulation prescribed under this chapter; and (ii) it does not contain a defect which has been identified, in any communication to or by the manufacturer of that vessel, equipment or component, as creating a substantial risk of personal injury to the public

RAPEX - If a manufacturer or distributor finds out that one of their products on sale is dangerous, they have to inform the competent national authority.



Minimizing Risk and Promoting Product Safety

How Do We Minimize Product Risk?

- Follow industry regulations and recommended practices (USCG/ABYC/ISO)
- Design and Manufacture products that are reasonably safe for their intended uses and foreseeable misuses
- Focus on compliance & safety critical standards in design, development and manufacturing
- Require vendors to supply compliant product/parts
- Train employees – conduct training on changes to industry standards and regulations
- Regularly inspect our products to ensure compliance (product audits)
- Create a closed loop system for findings & corrective actions
- Pay attention to reports of product failures and warranty claims
- Report safety issues to our divisional product performance committee
- Follow litigation trends within the company and the industry
- Watch industry product trends

Minimizing risk requires us to be vigilant and to follow our protocols

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Thank You.