

Product Safety & Compliance



Discussion Topics

- Product Liability in the Americas
 - Examples of National Court Verdicts
 - Recent liability cases in the news
- Product Safety Program
 - Overview of an example Zodiac Pool Systems, Inc.
 - Why Focus on Safety & Compliance?
 - Product Documentation and WARNINGs
 - General Compliance Facts



US Court Verdicts

(some data provided by NJL)

<u>Year</u>	<u>State</u>	<u>Manufacturer</u>	<u>Injury</u>	<u>Verdict</u>
1993	Florida	Withheld	1 death	\$900,000.00
1993	Wisconsin	Withheld	4 deaths;	\$1,007,400.00
			1 vocal cord damage;	
			Short-term memory loss	
1991	Michigan	Withheld	1 death (child)	\$1,250,000.00
2004	Texas	Withheld	1 death, 1 injury	\$2,000,000.00
1999	Illinois	Withheld	1 brain injury	\$3,515,000.00
2003	Michigan	Withheld	2 deaths, 2 injuries	\$25,691,000.00
2007	Alabama	Withheld	1 death	\$50,000,000.00
2003	Wisconsin	Withheld	Permanent brain damage	\$104,000,000.00



More Recent and Current Product defect/liability cases in the media

- Ford/Firestone (2000)
 - Issues:
 - Tread Separation problem on Firestone tires; primarily on tires mfd. at Decatur, IL factory.
 - Failure in manufacturing process control at factory.
 - Rollover incidents in Ford Explorer models (and brand twins) from 1991-2000
 - Failure to test product properly during product development

- Ramifications:

- 103 deaths "linked" to Ford/Firestone combination.
- 2200 injuries connected to the Ford/Firestone combination
- Estimated \$1B legal costs.
- Significant loss in market share for Firestone in 2000 from 21% down to 4%.
- Loss of customer confidence in both firms.
- Accusations of hiding the truth after knowing a problem existed in various parts of the world.







More Recent and Current Product defect/liability cases in the media

- Toyota Motor Corporation
 - Sudden Unintended Acceleration (SUA)
 - Faulty mats?
 - Faulty electronics?
 - Sticking accelerator linkage
 - Failure of proper DFMEA?
 - Failure to properly qualify products?



- Ramifications:
 - Now linked (by firms like "Safety Research and Strategies, Inc") to the following allegations:

Toyota Unintended Acceleration Incidents, Reported from 1999 to the Present

Incidents	3306
Crashes	1159
Injuries	469
Deaths	39



More Recent and Current Product defect/liability cases in the media



- 8M+ cars recalled worldwide
- \$5.5B loss estimated in current financial year BEFORE calculating costs of recall in 2010.
- Recall alone could cost up to \$2B
- Lost market share in an already troubled economy
- Significant "hit" in customer confidence
- Factory shutdowns
- Layoffs





ZODIAC POOL SYSTEMS, INC.





As a Leading Manufacturer:

 How Does one address the everincreasing risk of suffering productliability issues?



Be a Responsible Manufacturer

- Establish and implement -:
 - an effective strategy/program to ensure Product Safety and minimize litigation.



Example: Zodiac Pool Systems, Inc. Product Safety Program

- Based on a <u>Product Safety Policy</u>
- Led by the <u>Product Safety Council</u>



Product Safety Council

The Product Safety Council's primary responsibilities are to:

- Establish all Company policies and procedures related to product safety.
- Drive risk assessment and hazard analysis for new and existing products and practices.
- Regularly review product allegations and claims to identify and implement the appropriate corrective action.
- Minimize Company's exposure to product liability issues.



ZODIAC POOL SYSTEMS, INC.



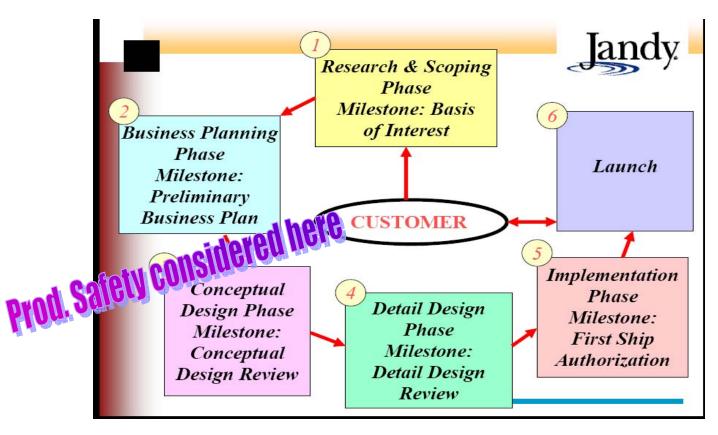


Safety & Compliance – Integral part of NPD process

- Product Safety and regulatory compliance should NOT be an "afterthought"
- Product Safety and Compliance is focused upon early in the NPD process
 - During "Conceptual Design Phase/Review (CDR) and Detailed Design Phase/Review (DDR)



Safety & Compliance – Integral part of NPD Process





Product Safety Council

- Involved in all stages of a product's life
 - > product concept
 - > product development
 - product sales
 - product service and support at customer site



Product Safety Program – Fundamentals

PSC also involved in development of product manuals and Service Bulletins:

- Technical Writing of manuals, product literature, bulletins, etc is reviewed/overseen by Product Safety & Compliance team.
 - Instructions and Warnings All labels meet or exceed applicable regulatory standards (e.g. ANSI Z535 series) and they warn of misuse.
 - Manuals, before being finalized & released, are subjected to a detailed review by a Document Review Board (DRB) consisting of members from engineering, marketing, production/operations, and the PSC. Among others, the following items are considered during the manuals development process:
 - Compliance of the manual with applicable product safety codes e.g.: ANSI Z21.56; UL 1563; UL 1995; UL 676; NSF-50; UL 1081;
 - Proper CAUTION/WARNING statements to instruct installer and consumer on hazards that can arise due to improper installation and usage of the product;
 - Ease and accuracy of assembly and/or installation instructions;
 - Inclusion of all necessary conditions such as gas supply, water flow, ventilation, environmental conditions, electrical connections, etc... for proper and safe operation of the product.

Field & Service Bulletins

- Are issued in the event that any safety or serious quality issues are identified as existing on any product.
- Are logged and controlled by bulletin number



Product Safety Program - Fundamentals

Policies and Procedures have been established for:

- Incident Reporting Procedures and systems exist to address
 - consumer feedback.
 - product abuse/misuse,
 - product liability claims.
 - These matters are reviewed periodically:
 - Service Managers' meetings,
 - Quality review meetings,
 - Warranty reviews.
 - Trends and potential problems are identified and acted upon.
 - All serious incidents are immediately investigated on site by a multi-disciplinary team, typically including an outside expert witness, an outside products liability attorney, a senior Company design engineer and a Company field service representative.
- Product Recall A formal products recall procedure is in place. This procedure allows traceability of date and place of manufacture of a product. Critical components used in products are also coded and traceable.



Product Safety Program – Claims Handling

Claims Handling

- A structured procedure to address claims involving personal injury or property damage has been implemented;
- The procedure dictates the formation of three types of claims handling response teams "A", "B", or "C". The type of team and its members are driven by the following factors:
 - Level of personal injury involved in claim none, minor, or serious;
 - Level of property damage involved in claim minor, substantial, or very substantial.

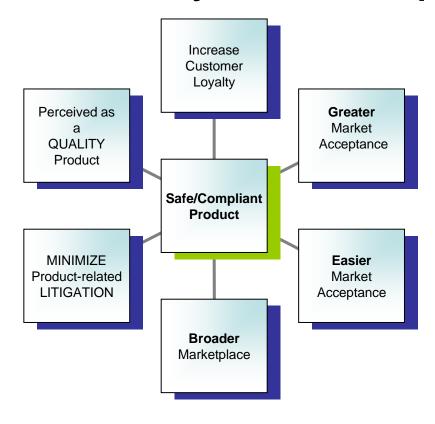


Why Focus on "Product Safetv" & "Compliance"?





Why Focus on "Product Safety" & "Compliance"?

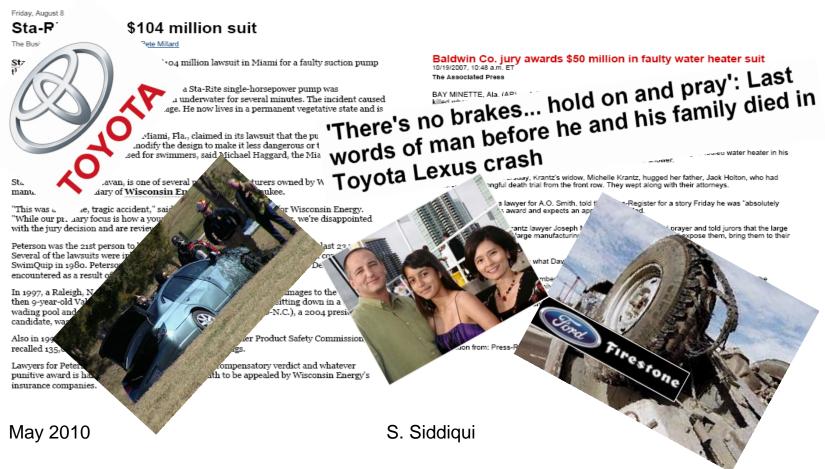




Why Focus on "Product Safety" & "Compliance"?

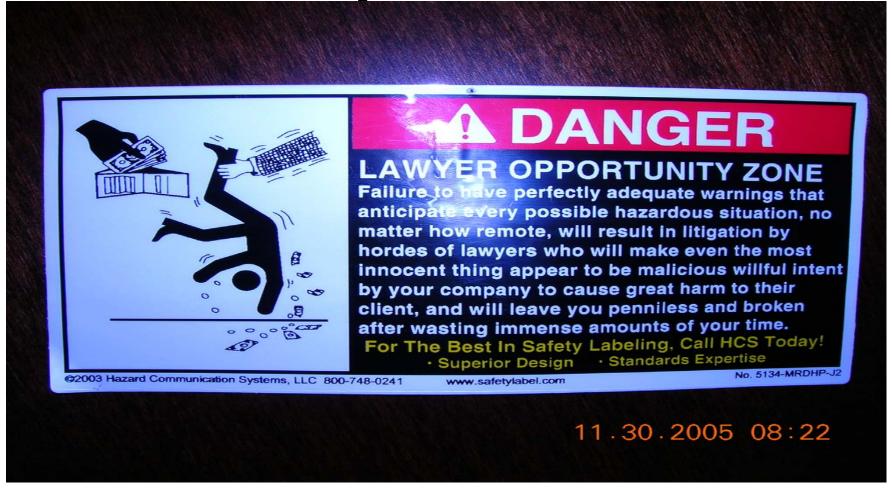
- While the benefits of a Safe/Compliant product include:
 - Increased sales and profits
- Minimizing Product-Related Litigation can mean the difference between keeping a business or losing it.
 - Juries in North America award very large \$\$\$ amounts to plaintiffs

Why Focus on "Product Safety" & "Compliance"?





Why Focus on





Safety & Compliance – Many Standards apply

- CODES, STANDARDS, DIRECTIVES -
 - Identify, acquire, and review applicable Safety and regulatory standards, codes, and directives
 - Ensure standards are accessible to team –
 - Be familiar with critical requirements of the standards

- UL
- CSA
- EN
- SCAQMD
- ASHRAE
- ASTM
- ANSI
- AS
- NZ
- NOM
- LVD
- GAD
- EMC Directive
- MEA
- Mass Plumbing Board
- Etc.....



Safety & Compliance – Pre-Certification Testing

- Pre-Certification Qualification & Testing
 - Incorporate "pre-certification" testing as part of the Qualification Test Plan (QTP).
 - Components and materials should be chosen in accordance with regulatory standards guidelines. A Materials Info. Form (MIF) may be used to detail/list all critical components and their/critical relevant details.
 - Helps ensure compliance when submitted to the regulatory testing agency.



Safety & Compliance – Pre-Production Safety Review

- Preliminary Safety Review
 - Identifies key elements needing completion before First Ship Authorization (FSA)
 - Assigns actions to appropriate personnel from Engr., Ops., Quality., Marketing., etc...
- Final Safety Review
 - Ensures all actions Id'd during preliminary review are indeed completed with documented completion

Pre-Production Product Safety Review

Project: LX-I Heater

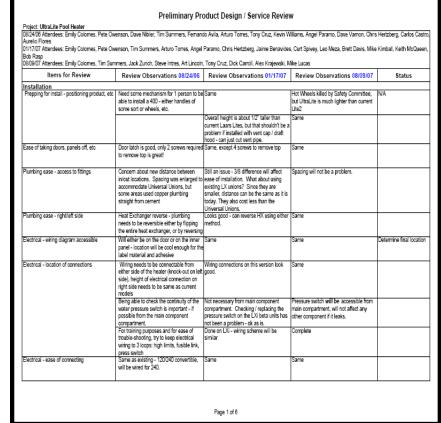
Items for Review	Review Observations	Status
		Otatas
Agency Certification:	Eval. & Testing complete - No safety issues found.	Complete
Labels are visible and understandable	All labels and scheme identified - Will use scheme and labels very similar to existing LX- series heaters	Complete
Label locations defined and available for manufacturing	Label sheets and scheme completed. Very similar to existing LX-series heaters	Complete
Serial Number Scheme defined and Implemented	Scheme has been defined Will continue to use current Moorpark format	Complete
Final Test Procedure approved by Engineering	FIT complete. Method sheet format complete	Complete
IOM Manual released	Complete	Complete
User's Manual released	Part of IOM	N/A
Training Planned and implemented according to schedule	Pete Owensen has developed plan and schedule	Complete
Mechanical Hazards: Contact with sharp edges or burrs	Hex head screws can cause very MINOR abrasion potential - Not deemed hazardous	Complete
Electrical Hazards: Contact with live parts	Electrical enciosurus is quite close to front edge of healer. Investigate further proceeding live parts from water intrusion and from instrument contact 4644 extend familit violtage florier forunts part of mall to patitis influent universal contact with any ill-violtage an- important parts. Mild and adults gaugist molecular to grown water interprise.	Complete
Qualification Test Plan Results	All results are acceptable final report being compiled and pending - Engring okay to move forward based on results	Complete
Beta test results documented. Major failures identified and addressed	BETA Testing is On-going - All issues to date have been considered and addressed. Engr. okay to move forward. Report from Engr is being compiled	Complete
Forseeable Use or Misuse	Unit is fixed and of substantial size. Any potential for misuse was addressed in DFMEA	Complete
Potential Failure Modes, hazards, causes and actions required to prevent them (Run away condition, power failure, valve failure)	DFMEA conducted to address potential Issues	Complete

Shajee Siddiqui Digitally signed by Shajee Siddiqui DN: cm-Shajee Siddiqui, cmUS, cmJandy Pool Products, inc., our-Product Safety an Compliance, email-residdiquiglandy.com Resison: I am approving this document Debt. 2007, 07 25 54 54 54



Safety & Compliance – Serviceability Review

- Preliminary Service Review
 - Identifies any serviceabilityrelated issues needing attention.
 - Involves engr., ops., safety, and service staff.
 - Assigns action items to appropriate team members to complete before final Service Review
- Final Service Review
 - Ensures that all open items from preliminary review are completed.





Safety & Compliance – Product Certification

- Initiate, Manage, and DRIVE regulatory compliance projects –
 - targeted towards achieving market driven and jurisdictionally required product certifications
- Interface with regulatory bodies
 - to properly understand, interpret and meet applicable requirements
- Engage in healthy discussions, and debates if necessary, with agencies
 - to ensure that your products are not "excluded" from scopes of regulatory requirements
 - i.e., ACTIVE participation to ensure a "Level playing field"

- ETL SEMKO, UL for global electrical product safety certifications;
- CSA, BSi, AGA for global gasproducts certifications
- FCC certification for RF emissions
- SCAQMD for combustion emissions regulations
- Various state, county, city regulatory bodies regulating health, emissions, energy efficiency, product installation, etc.
- EPA
- Many Others...



Document Generation – Review/Approval

- Document Review Board (DRB)
 - Integral part of the Documentation process
 - All product-related manuals, literature, labels, and boxes/cartons are reviewed by the DRB
 - DRB consists of key members from
 - Engineering
 - Operations
 - Service
 - Manufacturing
 - Quality
 - Safety/Compliance
 - Legal
 - Marketing



Proper review of docs. & labels





Users of our products vary widely, therefore docs should be CLEAR







Zodiac Pool Systems, Inc





Selecting proper Product Safety









Inadequate Warnings –

Found to be one of the leading causes of product liability lawsuits for at least one major insurance company



Just as the design of products with the latest safeguards is critical –

So too are the WARNINGS and instructions associated with the products.



Plaintiffs look for opportunities to challenge:

- ➤ the adequacy of WARNINGS
- the conspicuousness and placement of the WARNINGS

EXAMPLE -- Lakey vs. Mfg. of pool drain cover:

- 5-yr old Valerie Lakey dis-emboweled due to missing/broken drain cover in pool
- Lakeys sued the Club (pool), County, pump mfg., and drain cover mfg.
- Club, pump mfg. and County settled with Lakeys for total of \$5.9M
- Settlement against cover mfg. for "FAILURE to WARN" -- \$25M



EXAMPLE -- Marcon vs. K-Mart:

- > 12-yr old boy thrown from a snow-sled while riding it on his knees
- Becomes quadriplegic
- Sled manufacturer out of business
- Jury finds K-Mart Corporation (seller) liable for "FAILURE to WARN"
- > \$8 Million



EXAMPLE – Zodiac Case:

- Pool heater
- alleged high levels of Carbon Monoxide (CO) led to fatality
- Product clearly installed and vented incorrectly
- Plaintiff pursued "FAILURE to WARN"
- Zodiac/Jandy staff deposed
- Potential \$10 Million case settled favorably since Zodiac was PROACTIVE and WELL-PREPARED





It is a <u>Legal Duty</u> To Warn (Third Restatement of Torts)

A Product can be considered "DEFECTIVE" if WARNINGS and INSTRUCTIONS accompanying the product do not apprise consumer of foreseeable risks involved with the use of the product.



 Product Safety and PROPER hazard WARNINGS should NOT be an "afterthought"

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Adequate instructions & WARNINGS/CAUTIONS must be:

- Included on the product
- In manuals and all relevant product documentation
- Technical/Service bulletins
- R-kit instructions
- > Etc...



Proper CAUTIONS and WARNINGS

How to develop them?

- May be specified by applicable regulatory product safety codes & Standards
- Based on Industry accepted standards e.g., ANSI Z535 – series
- Go directly to ANSI Z535.4 when regulatory product standard does not have any specific requirements.



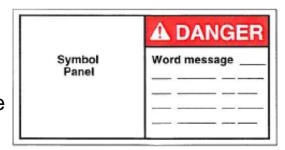


Key parts of an effective Safety Sign or label:



➤ <u>Signal Word</u> – "NOTICE", "CAUTION", "WARNING", "DANGER"

- Signal word may or may not need to be accompanied by the "safety alert symbol"
- > Word Message Communicates info. to the observer:
 - > Type of hazard
 - Consequences of not avoiding the hazard
 - How to avoid the hazard
 - Must be as CONCISE and CLEAR as possible



➤ May or may not have a "symbol panel"



Signal Words – ANSI Z535.4 definitions



DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.



WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.



NOTICE is used to address practices not related to personal injury.



CAUTION, used without the safety alert symbol, is used to address practices not related to personal injury.



Proper CAUTIONS and WARNINGS

Which Signal Word to use?

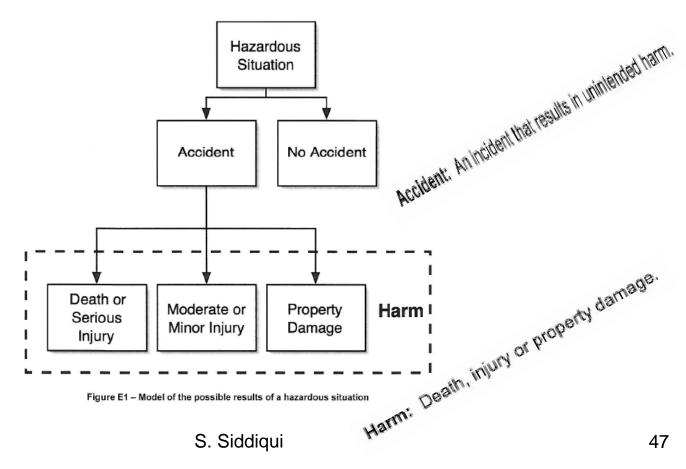
- Conduct a Risk Estimation
 - ➤ Annex E of ANSI Z535.4 gives guidance on "RISK ESTIMATION" to help determine which signal word to use

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Risk Estimation Model ANSI Z535.4





Signal Word Selection - ANSI Z535.4

E4.2 Signal Word Selection Process

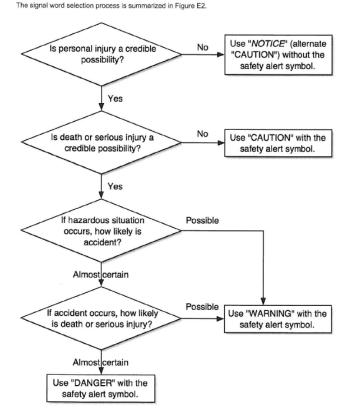


Figure E2 - Signal word selection process

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Signal Word Selection - ANSI Z535.4

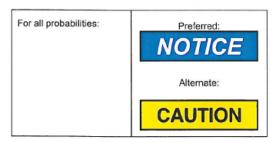
If Worst Credible Severity of Harm is Death or Serious Injury



If Worst Credible Severity of Harm is Moderate or Minor Injury



If Worst Credible Severity of Harm is Property Damage











Effective Product Hazard Warnings:

- DO NOT mean that a product is "inferior" in any way
- Are LEGALLY REQUIRED
- Indicate that the manufacturer is a RESPONSIBLE one and is concerned about the CONSUMER'S SAFETY and well-being

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Effective Product Hazard Warnings:

- Should be based on accepted standards, such as: <u>ANSI Z535.4</u>
- Require a <u>Hazard Risk Estimation</u>
- Have the proper <u>Signal Word included</u>
- Include the <u>Safety Alert Symbol</u>, when needed.
- Are Clear & Concise



GENERAL COMPLIANCE FACTS



- There are many compliance requirements dependant upon, and often different for:
 - Type of product
 - Heater
 - Control
 - Light
 - Filter
 - Pump
 - Pool Cleaner
 - Water Treatment (Chlorine Generators, Nature2, etc...)
 - its intended market
 - Country
 - State
 - Province
 - its function.



- Once again, "Why Comply?"
 - Be a responsible manufacturer
 - Make "safe" products
 - Req'd by Authorities Having Jurisdiction (AHJ's)
 - City, County Inspectors
 - Minimize Risk & Liability

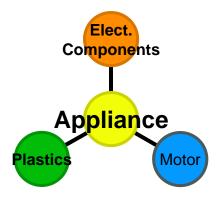


- There are regulatory standards for "end-products" and for "components"
- Generally, our products are considered "end products" because they are "complete" or can "stand alone".
- "Components" are parts used to make the "end product". Examples of components:
 - Switches/relays,
 - Transformers,
 - Motors,
 - Plastics, and
 - Gaskets/sealing materials

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- Use of listed/certified components ensures easier path towards compliance and certification of endproducts
- Helps minimize end product manufacturer's responsibility/liability for the component.



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- Electrical Product Standards applicable to pool products include, but not limited to:
 - UL 1563 US "Standard for Safety for Electric Spas, Equipment Assemblies, and Associated Equipment"
 - UL 1081 US "Standard for Safety for Electric Swimming Pool Pumps, Filters, and Chlorinators"
 - UL 676 US "Standard for Safety for Electric Underwater Luminaires and Submersible Junction Boxes
 - CSA C22.2 No. 218.1 Canadian Electrical Safety Standard for "Spas, Hot Tubs, and Associated Equipment
 - EN60335-1 & EN60335-2-41 European National standards for Pumps
 - EN60598-1 & EN60598-2-18 (AS/NZ 60598-2-18) European National Standards for Underwater Luminaires (Australian/New Zealand version)
 - Many others...



- Gas Product Standards applicable to pool products include, but not limited to:
 - ANSI Z21.56 Safety of "Gas-Fired Pool Heaters"
- Sanitation standards applicable to pool products include:
 - NSF-50 "Circulation system components and related materials for swimming pools, spas/hot tubs"
- Environmental Protection Agency (EPA) rules
 - For Chemical products



COMPONENT COMPLIANCE



Remember –

- Use of listed/certified components ensures easier path towards compliance and certification of end-products
- Helps minimize our responsibility/liability for the component.

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Critical Electrical Components –

- Transformers;
- Motors
- Switches/Relays/Contactors
- Wiring
- Fuses/Circuit Breakers
- Generally anything operating at over 24Volts
- Gaskets/Seals/Plastics used to protect electrical components from the environment.



Critical Gas Components –

- Transformers;
- Ignition controllers
- Gas Valves
- Regulators
- Temp. limit controls/switches
- Heat Exchanger materials



- Critical components should be listed/certified by an ACCEPTABLE TESTING AGENCY (Certification Body/ NRTL) as being compliant with applicable component standards.
- Components can also be "Recognized". This means that they
 have been evaluated, tested and found to comply with the
 essential requirements of the applicable standard but may have
 certain "conditions of acceptability".
- Beware of Components sold/marketed as
 - "tested to UL Standards" -- By Who?
 - or "meets UL standard..." -- Says Who?
 - "UL approved" -- By Who?



Standards applicable to critical components used in Pool Products:

- Transformers
 - UL 506 & CSA C22.2 No. 66 "Specialty Transformers" generally applies to "small 'power' transformers"
 - UL 1585 "Class 2 & Class 3 Transformers" generally applies to "current-limited" or "low-voltage" transformers such as control transformers.
 - NEW UL standard for x-frmrs UL 5085-1 and associated sub-parts. Replace the above older standards
 - IEC 61558-2-6 European standard for Safety Isolating Transformers; Usually needed for transformers used in products destined for European Union (EU) for CE compliance.

Check with Compliance staff to confirm which standards need to be met for a particular application.



Critical components used in Pool Products:

- Gaskets/Seals, when used to protect electrical components from the environment:
 - UL 157 Standard for Safety for Gaskets and Seals
- Always make sure you get proof from vendor to demonstrate that the material is "Listed", "Certified", or "Recognized" by a NRTL.
- Example of "proof" is the "UL Yellow Card" listing as it appears in the UL Directory;
- You can also get the UL File No. which we can use to verify listing.
- If product is "Recognized", we should also get the "Conditions of Acceptability" from the Vendor.

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- <u>Plastics</u> used to "enclose" or "protect" critical electrical components:
 - UL 94 for flammability ratings
 - Usually target a UL 94 V-0 rating
 - (Lowest) UL 94 HB → UL94 V-1, V-2, V-0 → UL 94-5V (Highest)
 - UL 746C for suitability for use as an enclosure material
 - Addresses additional considerations such as strength and resistance to environmental factors; e.g., UV resistance.



- For products which are to be NSF-certified (for Sanitation), Non stainless-steel materials used in components which come in contact with pool or potable water AND which have contact area of 100 sq. inches or more:
 - Component material must be NSF-listed as compliant with at least one of the following:
 - NSF 14
 - NSF 50
 - NSF 51
 - NSF 61





- For Electrical/Electronic Products destined for EU, all materials must be RoHS compliant:
 - Get "Declarations of Conformity" (DOC's) from vendors documenting compliance with the RoHS Directive (2002/95/EC)
- We are still required to further prove that our products, which utilize all purchased components comply with the applicable requirements of the RoHS Directive.
- We could be required to have our BOM analyzed and/or have our product physically tested for compliance.
- This could be expensive, and time-consuming

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Once Again, Remember –

- Use of listed/certified components ensures easier path towards compliance and certification of endproducts
- Helps minimize responsibility/liability for the component...
- PUT THE ONUS OF COMPONENT
 COMPLIANCE AND CERTIFICATION ON THE COMPONENT VENDOR.

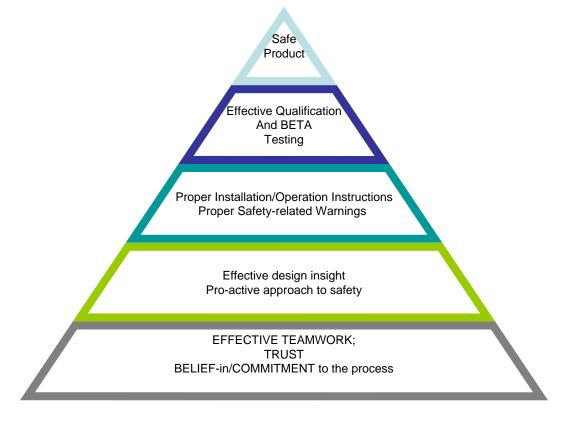


Important Points to Remember

- Involve Compliance/Safety Staff EARLY in any project regardless of whether it is a NEW product or modification of an existing product;
- Changes to manuals, labels, box art, etc... do affect compliance, legal, safety issues;
- Following established company processes related to product safety and document review is critical to ensuring:
 - Continued regulatory/agency compliance status of product
 - Mitigation of any possible legal issues that can arise from incidents involving products in the field



Product Safety & Compliance





END.