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Eurofins MET Labs

PRODUCT SAFETY PRINCIPLES

Your industry, our focus

AMANDA NEBEL
PRODUCT SAFETY ENGINEER

Disclaimer

This presentation addresses many of the more common pitfalls. The standard is always the primary and final resource.

Product Safety Principles

- **Importance of the Standard**
- **Common Hazards**
- **Specific Hazards for Medical and 62368-1**
- **Risk Assessment**
- **Designing for Safety**
- **Product Submission**
- **Summary**

Emphasis on the Standard

We have many documents for guidance during the evaluation and testing process, but ultimately the standard has the final say.

Manufacturers should obtain the applicable standards for each desired region (US, Canada, Europe, International) and be aware of updates and revisions.

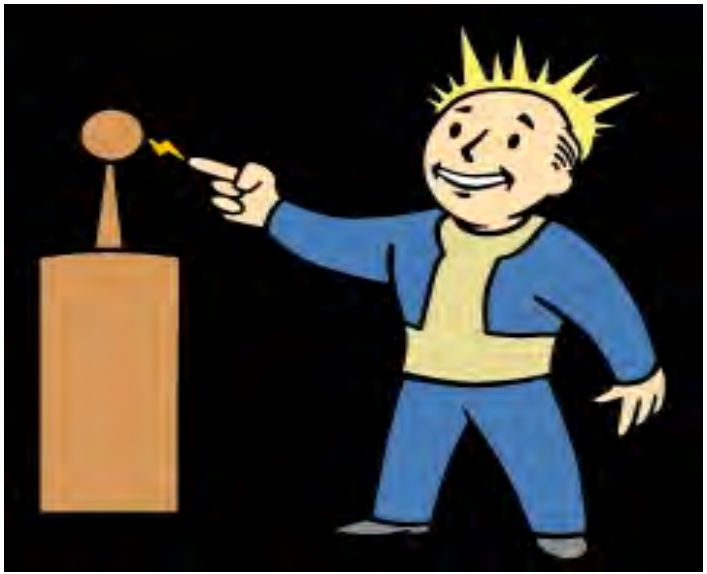
CEN/CENELEC

Hazards Related to Safety

- Electric Shock
- Fire
- Heat
- Mechanical
- Radiation
- Chemical

Hazards – Electric Shock

- **Electric shock is the physiological reaction or injury caused by electric current passing through the (human) body.**
- **Generalized**
  - **Voltage paired with current – too little voltage or too little current reduces electric shock even if the other parameter is high.**
- **Common Sources**
  - **Energized bare conductive parts**
  - **Breakdown of insulation**
  - **Inappropriate spacings between parts**



Hazards – Electric Shock

Reducing risk in your product

- **Preventing user access**
  - Provide an enclosure (Non-metallic or grounded metal)
  - Minimize openings
- **Protecting accessible surfaces and ports from conducting hazardous voltage or current**
  - Earth/Ground
  - Double insulation

Electric Shock – 62368-1 and Medical

62368-1 has three categories of electric shock hazards:

- **ES1: Below 60VDC, 30Vrms, or 2mA (in most cases)**
- **ES2: Between ES1 and 120VDC, 50Vrms, or 25mA**
- **ES3: Any voltage/current combination that exceeds the voltage and current of ES2**

Each level corresponds to the amount of protection required.

Other considerations for Medical products:

- **More stringent voltage/current requirements for parts that contact the patient.**
- **Extra protection against overvoltages and short-circuits**

Hazards – Fire

Fire can be caused by:

- Excessive temperature
- Component failure
- Insulation breakdown
- Loose connections
- Ignition of atmospheric materials

Hazards – Fire

Ways to prevent a fire hazard

- Design so that no overheating element or electrical fault can cause a fire
- Use construction materials that have appropriate flammability properties
- Limit the quantity of combustible materials used
- Design an enclosure that can contain a fire if it occurs

Hazards – Fire

Design so that no overheating element or electrical fault can cause a fire

- **Use certified overtemperature protection devices**
  - Thermostat – regulating control
  - Thermal cutout – protective control
- **Plan the board layout with adequate spacing to prevent short-circuits**
- **Add fuses to minimize the fault current**
- **Use only certified components, and stay within their ratings**

Hazards – Fire

Use constructional materials that have appropriate flammability properties

- **Printed Circuit Boards V-1 or better**
  - As tested according to UL 94 or IEC 60695
- **Components:**
  - Connectors
  - Conductors
  - Barriers
- **Enclosures:**
  - Metallic, or non-metallic with proper ratings
  - Placement, size, and number of openings

Fire – 62368-1 and Medical

Other considerations for medical products:

- **Use in oxygen-rich environments or with flammable anesthetic mixtures**
- **Compliance with either constructional requirements or fault conditions**

62368-1 has three different categories of fire hazards:

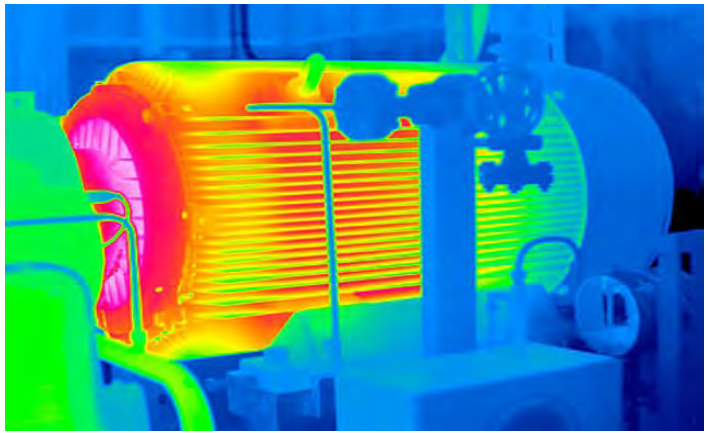
- **PS1: available power does not exceed 15W after 3s**
- **PS2: between 15W and 100W after 5s.**
- **PS3: exceeds PS2, or the power source has not been classified**

62368-1 also has additional testing for batteries, even if they are already certified.

Hazard - Heat

High temperatures in normal operating conditions may cause:

- burns from contact with high temperature accessible parts
- degradation of insulation and of safety-critical components used outside of their temperature ranges



Risks can be reduced by:

- Not allowing accessible parts to reach high temperatures
  - Fans and/or vents
  - Heat sinks or heat pipes
  - Coolant

Hazard - Heat

If heat is produced for functional purposes:

- Mechanical guards to prevent contact
- Proper use of markings/warnings
- Safety interlocks

Heat – 62368-1 and Medical

62368-1 has three different categories for heat/thermal hazards:

- **TS1, TS2, and TS3**
- **Owning the standard will assist you in understanding the limits & requirements of these classifications**
- **Each category has different temperature limits for various materials, and different requirements for protection.**

Medical has very strict requirements regarding touch temperatures.

There is an assumption that the patient may not be able to react or tell the operator that the applied part is “hot” or uncomfortable.

Max temperature of 41°C (105.8°F) on applied parts (parts that are required to touch the patient in operation).

Hazards – Mechanical

Injury may result from:

- Sharp edges and corners
- Moving parts (both striking and pinching)
- Equipment instability
- Falling (if wall- or ceiling-mounted, or handheld)
- Failure of supports

Hazards – Mechanical

Risks can be reduced by

- Rounding of sharp edges and corners
- Providing guards, alarms, or interlocks for moving parts
- Providing sufficient stability for free-standing equipment by ensuring a low aspect ratio or low center of gravity
- Providing markings to warn users where access to mechanical hazards is unavoidable
- Proper mounting and mounting instructions

Mechanical – 62368-1 and Medical

62368-1 has three different categories for mechanical hazards:

- **MS1, MS2, MS3**
- **Examples:**
  - Mass ≥ 25kg is MS3
  - Wall-mounted higher than 2m is MS3 (regardless of mass)
  - Moving parts, edges, or corner that do not cause pain or injury are MS1
  - Fans require calculations based on their blade material and dimensions to determine classification

The mechanical requirements of 60601-1 are largely similar to those of other standards.

Medical includes equipment that supports the patient or operator – entirely or partially.

Medical equipment is more likely to be moved while in service so there are more requirements for mobile equipment.

Hazards - Radiation

Types of radiation hazards

- Sonic (acoustic and ultrasound)
- Infrared
- Ultraviolet and ionizing radiation
- Lasers and LEDs

Risks can be reduced by

- Limiting exposure
  - Full enclosure
  - Radiation blocking material
  - Interlocks
  - Reducing the energy levels

Lasers

- FDA CFR 1040 required for US certifications
- IEC 60825-1 required for CB certifications
- Some standards require component-level and end-product level certifications

Radiation – 62368-1 and Medical

62368-1 has three classifications for radiation hazards:

- **RS1, RS2, RS3**
- **Examples:**
  - Class 1 Lasers are RS1
  - Invisible Class 3R, Class 3B, and Class 4 lasers are RS3
  - Most LEDs are RS1
  - X-rays emitting between 36pA/kg and 185pA/kg are RS2
  - Speakers emitting >100dB(A) are RS3

IEC 62368-1 requires end-product certification to IEC 60825 if the equipment contains lasers.

60601-1 includes additional types of radiation – particle, microwave, and infrared.

Medical considers the possibility of radiation (especially x-radiation) being used for therapeutic or treatment purposes

Radiation is typically where justification occurs for necessary hazardous output – treatment often relies on "higher than safe" amounts of radiation.

Hazards – Chemical

Risks

- Burns
- Inhalation
- Reaction with electronics

Prevention

- Utilize a spill proof enclosure (internally or externally)
- Avoid conditions likely to cause leakage or vaporization
- Warning markings

Chemical – 62368-1 and Medical

62368-1 does *not* classify hazardous substances according to "energy source levels" like other hazards.

Defines hazardous substance as a "substance that has the potential for adversely impacting human health"

Specifically addresses ozone, PPE, and batteries but has general requirements for all "hazardous substances"

Medical has largely the same chemical/hazardous substance requirements as other standards, with emphasis on exposure of the patient.

Biocompatibility of applied parts is an additional consideration.

Risk Assessment

- **The majority of 61010-1 (Laboratory or Measurement) equipment and ALL medical equipment require a Risk Assessment**
- **The risk assessment will capture all aspects of the product which can cause harm, including harm caused by user error or reasonably foreseeable misuse.**
- **Risk Assessment submitted early in the project reduces delays due to developing the assessment or unforeseen additional testing.**
- **62368-1 requires identification and classification of energy sources and hazards. This is not a Risk Assessment but serves a similar purpose.**

Risk Assessment

The core of the risk assessment is the risk analysis. This list contains the following information:

- Each part or mistake that can cause a hazard
- Ranking based on severity and likelihood
- Decision on whether risk mitigation is necessary (via component, warning, etc) and how to mitigate
- Evaluation and ranking of the reduction in risk
- If needed: justification for higher-risk items that are required for proper function

RISK ELEMENTS		
IMPACT	PROBABILITY	RISK RATING
M	L	M
M	H	M
M	H	H
L	L	L
H	L	M
L	L	L
L	H	L
L	L	L
L	L	L
L	M	L
L	L	M

Designing for Safety

- Own and be familiar with applicable standards
- Identify potential hazards and risks
- Choose certified and appropriately rated safety-critical components (known as “safeguards” in 62368-1)
- Obtain certification records and reports for certified components

- Proper spacings and insulation
- Minimize openings in enclosure
- Perform risk assessment and analysis – don’t forget intentional misuse!
- User manual and installation manual

Designing for Safety

Critical components

- **Critical Components are any component that affects safety**
- **Examples:**
  - Components in the mains circuit
  - Bridging insulation (i.e. transformers)
  - Fans and other Motors
  - Batteries/Battery protection circuits
  - Thermal regulators
  - Fuses
  - Safety interlocks
  - Power supplies (internal or external)
  - Lasers
- **Uncertified critical components require additional time and money!**

Whenever possible, use certified components – in particular, components certified for the intended market (North America, Europe, International).

ALWAYS use components which meet or exceed the end product ratings.

Designing for Safety

Markings and Analysis of Certified Components

- For US and Canada - components have been tested by a Nationally Recognized Testing Laboratory (NRTL), and undergo annual surveillance
- For international certification – components have been tested by a CB accredited test lab
- For European evaluations – components need to have a CE mark
- Materials are controlled

Designing for Safety

If Critical Components aren't Certified:

- In *some cases*, MET can investigate the component to the applicable standard → additional cost
- MET may require the component to have special dielectric strength test(s) in addition to the factory test of the end product → longer production time
- MET will require that the component be annually inspected → additional cost

There's no guarantee that the component will pass the investigation

Designing for Safety

Plastics and Printed Wiring Boards

- **Certified to UL 796 for the circuit board**
- **Plastics tested to UL 746 and/or UL 94**
  - Flammability – V-2, V-1, V-0 or 5VA, depending on the standard or the application
  - Temperature rating – to ensure that the properties of the material will hold at the product's internal ambient
  - Special requirements apply to use of conductive coatings
- **MET does not perform this testing or certification, which means extra time and cost for subcontracting**

Designing for Safety

Overcurrent Protection Devices

- **Examples:**
  - Fuses
  - Circuit breakers
  - Positive thermal coefficient devices
- **Purpose:**
  - Prevent situations where too much current flows into the device
  - Excess current can cause fire, high touch temperatures, or electrical hazards

Designing for Safety

The Enclosure

- **What is the purpose of the enclosure?**
  - Mechanical protection
  - Electrical protection
  - Fire hazard protection

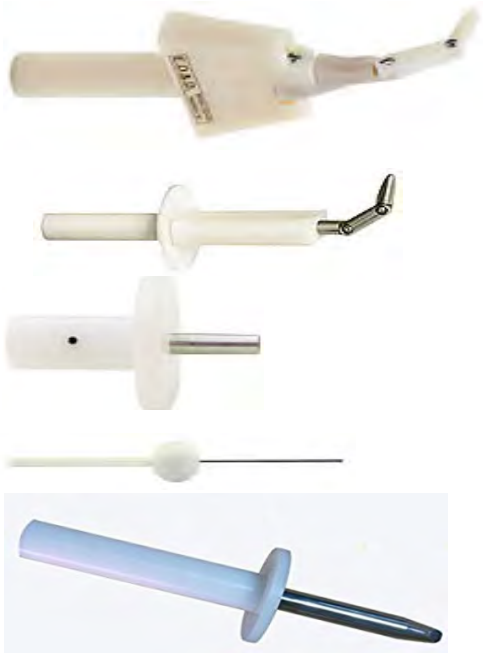
Select materials that satisfy

- **The mechanical tests of the standard**
- **Mechanical strength**
- **Flammability requirements**
- **Exposure to environmental elements if applicable**
- **Safeguard requirements of 62368-1**

Designing for Safety

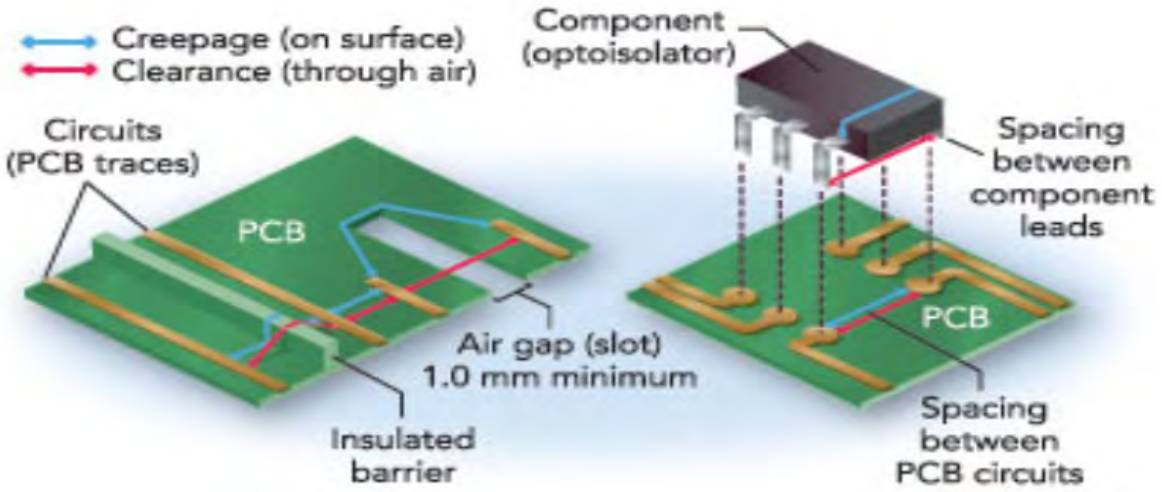
The enclosure openings

- Large enough for cooling
- Small enough to prevent entry
- No openings in the bottom or under fire hazards without mesh
- Far enough from internal conductive objects to prevent electric shock or bridging of components



Designing for Safety

Circuit Separation / Spacings (or, Creepage and Clearance)



Circuit boards and all areas with conductive parts and bare live parts need to meet the standard's spacing requirements

Designing for Safety

Circuit Separation / Spacings

- **Points to consider:**
  - Clearance – measurement of spacings through air
  - Creepage – measurement of spacings along the non-conductive surface
  - What are the circuit types in your product (mains, SELV, TNV, etc.)?
  - What is the maximum altitude the product is designed to operate in? [Typically 2000m or less – extra requirements if higher]
  - Understand the nature of the voltages involved (AC or DC)
  - Special requirements apply where conductive coating has been used

Designing for Safety

Product Markings and Documentation

- Each standard will have its own requirements for markings and documentation

- Common markings:
  - Electrical ratings
  - Model and manufacturer name or logo
  - Safety warnings (text or symbols)
  - Certification mark (MET mark, CE)

- All products need user/operating instructions
- Medical and 61010-1 projects have stringent documentation requirements

Submitting a Product for Investigation

What does MET need?

- **Product sample – multiple samples may be needed**
- **Support equipment for maximum load**
- **All support documents**
  - User manual
  - Service manual (if separate from user manual)
- **Bill of materials (BOM)**
- **List of safety critical components**
- **Datasheets and certifications for critical components**

Submitting a Product for Investigation

What does Eurofins MET do for the evaluation process?

- **Construction review**
  - Does it meet the standard?
- **Component review**
  - Does every component have the proper ratings and certifications?
- **Testing as required for the particular product**
- **Provide findings as necessary**

Submitting a Product for Investigation

Findings Report

- **A list of non-compliant items discovered during the safety investigation**
- **Three examples of non-compliances**
  - Materials and components (e.g., improper ratings or component certifications)
  - Failed tests
  - Documentation, labelling, and missing information

Most non-compliances can be easily solved!

Submitting a Product for Investigation

Expert Services

- **No need to build or submit first and then**
- **We're prepared to provide guidance**
  - Initial technical assessment
  - Review product for any potential non-compli
  - Review of drawings, BOMs, schematics
  - Common pitfalls for your type of product

Submitting a Product for Investigation

For listings or recognitions in the American and Canadian markets, there is more than just the evaluation and testing:

- **Initial factory and quality system inspection**
- **Biannual or quarterly factory/quality system inspections**
- **Annual review of uncertified components**

Summary

- Own a copy of the standard (very highly suggested!)
- Identify the hazards (and the associated safeguards) relating to the product
- Choose certified critical components that are properly rated for the application
- Design enclosure(s) taking the hazards into account
- Design for the appropriate spacing and insulation requirements of the standard
- Develop a user manual and service manual if applicable

Summary

The Ultimate Goal

Certification Record

Listing#: E114706
Report #: 99725
Original Certification: July 27, 2018
Revised Certification: N/A

MET Laboratories, Inc.
First in Certification

This Certification is issued to:
SycoTec GmbH & Co. KG
Wangener Straße 78, 88299 Leutkirch
GERMANY

For the product(s):
Dental Unit, Control Unit and Dental Motor,
Models E-SANAO Prep, E-SANAO Advantage and ETorque

Has been certified to the following standard(s):
ANSI/AAMI ES60601-1: 2005/(R) 2012 - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
CAN/CSA-C22.2 No. 60601-1:14 (R2014). Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010 + AMD1:2013; Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices
CAN/CSA C22.2 No. 60601-1-6:11; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Rick Cooper
Director,
Safety Business Line

All changes proposed in the previously identified product that affects the above information must be submitted to MET for evaluation prior to implementation to assure continued MET Certification status.

The covered product(s) shall be subject to follow-up inspections to ensure that the Certified product(s) are identical to the product sample evaluated by MET Laboratories, Inc. and that all manufacturer's responsibilities are being fulfilled as specified in the Manufacturer's Responsibility section of the Certification report. The applicant named above has been authorized by MET Laboratories, Inc. to represent the product(s) listed in this record as "MET Certified" and to mark this/these product(s) according to the terms and conditions of the MET Applicant Contract, MET Listing Reports, and the applicable marking agreements. Only the product(s) bearing the MET Mark and under a follow-up service are considered to be included in the MET Certification program. This certification has been granted under a System 3 program as defined in ISO/IEC 17067.

MET Laboratories, Inc. is accredited by OSHA and the Standards Council of Canada. The Nation's First Nationally Recognized Testing Laboratory NRTL

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