Electronic equipment product safety introduction

AN OVERVIEW *BASED ON IEC 62368-1 PRINCIPLES*

Presentation Outline

1. About the author & disclaimer
- What are standards documents?
2. Safety risks and terms
- 3. When is it a risk?
- 4. Safeguards overview
- 5. Specific hazards & safeguards
- 6. Going to market
- 7. Conclusions
- 8. Thank you

Image source: ISO, the International Organization for Standardization

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About the author

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What are standards documents?

- **National/International standards documents are:**
  - Prepared collaboratively by organizations to share knowledge by engineers, users, & communities,
  - Contain uniform agreed product or system objectives,
  - Presented in concisely worded technical documents.

Impact and importance of standards

- **Standards facilitate & determine how things work:**
  - Repeatably, reliably, economically, sustainably, trustfully
  - Interconnection & information exchange between products,
  - Safety: prevent harm to persons, domestic animals, property.
  - Include metrics and tests to prove compliance by test labs
  - Help to meet customer needs and legal regulatory compliance
  - Facilitate trade with other States, Geographies, & Economies

Safety risks from electrical articles

Hazards that can cause pain or harm*:

1. Electric shock
2. Fire
3. Materials & chemicals
4. Mechanical
5. Thermal burns
6. Radiation

** Based on IEC 62368-1 safety principles*

Definitions from ISO/IEC GUIDE 51:2014

Hazard: potential source of harm

Harm: injury or damage to the health of people, or damage to property or the environment

Risk: combination of the probability of occurrence of harm and the severity of that harm

Residual risk: risk remaining after protective measures have been taken

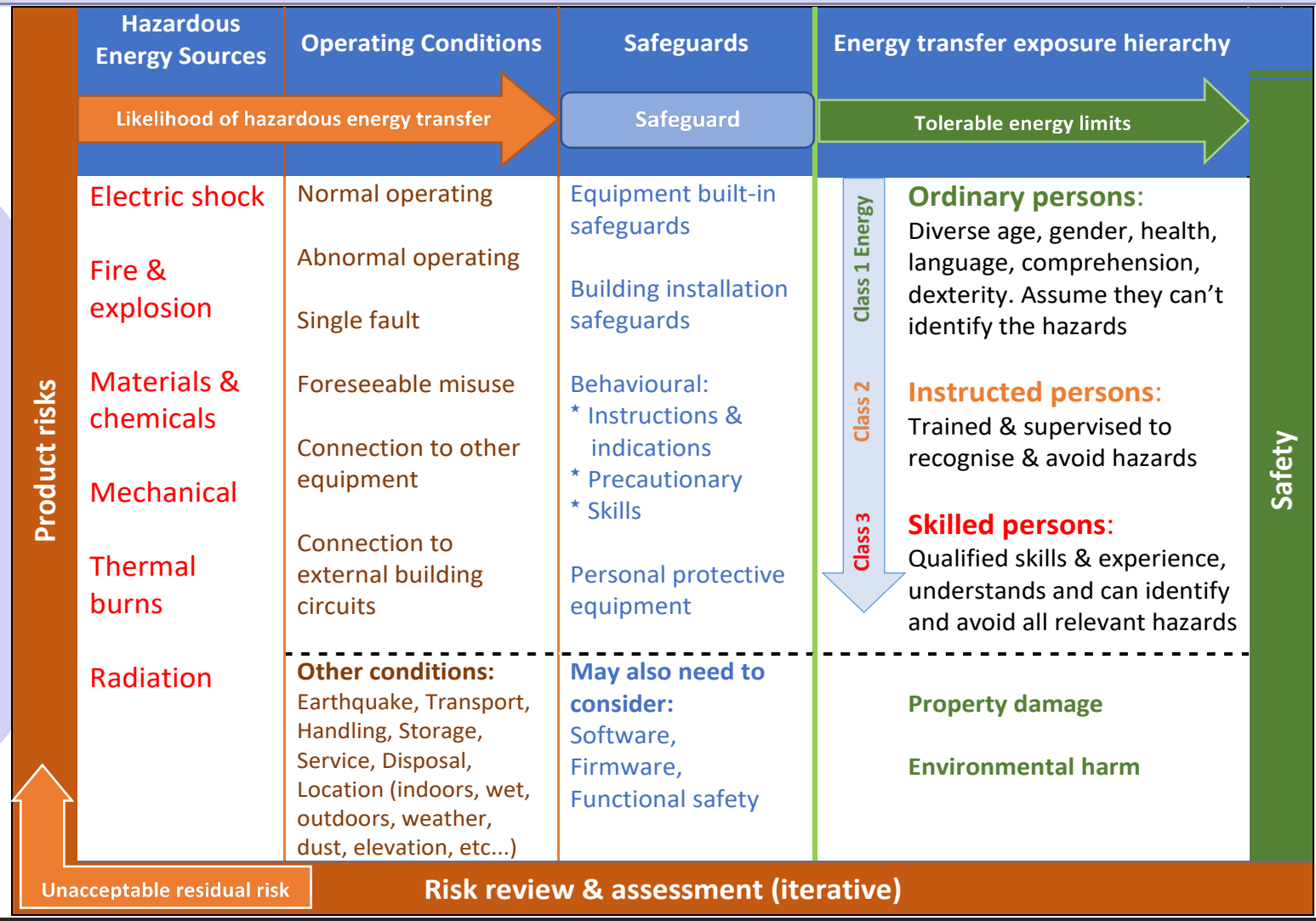
Tolerable risk: level of risk that is accepted in a given context based on the current values of society

Safety: freedom from risk which is not tolerable

When is it a safety risk?

When energy that can cause pain or injury can transfer from an energy source to a body part or can cause fire

- Consider energy transfer & duration against body part or fire susceptibility
- Safeguards must reduce transfer to tolerable levels
- Harm might not be obvious for a very long time after energy transfer
- Equipment standards are minimum requirements
- Limits are based on years of research & experience



Energy source classes - general

Energy source classes are defined based on relationships between:

- Magnitude and duration of energy source parameters, and
- Body responses to those potential energy transfers, and
- Responses of combustible materials to energy transfer

Parameters for responses to different energy sources and classes are based on experience & basic safety standards

Response to energy class*		
Energy source	**Effect on the body**	**Effect on combustible materials**
Class 1	Not painful, but may be detectable	Ignition not likely
Class 2	Likely to be painful, but not an injury	Ignition possible, but limited growth and spread of fire
Class 3	Injury is likely	Ignition likely, rapid growth and spread of fire

** Based on IEC 62368-1 Table 1 (modified)*

Safeguards - general

***Safeguard**: physical part or system or instruction specifically provided to reduce the likelihood of pain or injury, or for fire, to reduce the likelihood of ignition or spread of fire*

- Equipment safeguards
- Installation safeguards
- Behavioural safeguards
- Personal safeguards

Functional safety is not included in IEC 62368-1 at this time

Equipment safeguards

- ***These don't rely on user knowledge or action***
- **Basic** safeguard – the first line of defence against harm
- **Supplementary** safeguard – required in case basic safeguard fails
- **Double** safeguard – basic + supplementary together
- **Reinforced** safeguard – single safeguard equivalent to double

Installation safeguards

- ***Characteristics of the installation*** where the equipment is used:
- Protective earthing (supplementary safeguard)
- Installation fuses, breakers, residual current devices (RCDs)
- Restricted access areas

Behavioural safeguards

- ***Used to further lower residual risk** after other safeguards applied*
- **Instructional safeguard** – symbols, words, indicators, audibles etc, to identify the hazard & change user behaviour to avoid harm
- **Precautionary safeguard** – used by an instructed person
- **Skill safeguard** – used by a skilled person

Personal safeguards

- **PPE** - personal protective equipment

Electric shock risks

Touch <u>current</u> causes electric shock

- Touch voltage limits are derived from touch current limits

Body response is affected by:

- Current path in the body
- Contact area, moisture, skin damage, age (affecting body impedance)
- Frequency, waveshape, pulse cycles

IEC 60479 series is the basic safety publication describing electric shock effects on the human body

AC time/current curves (LF RMS sinusoidal)

Thresholds of:

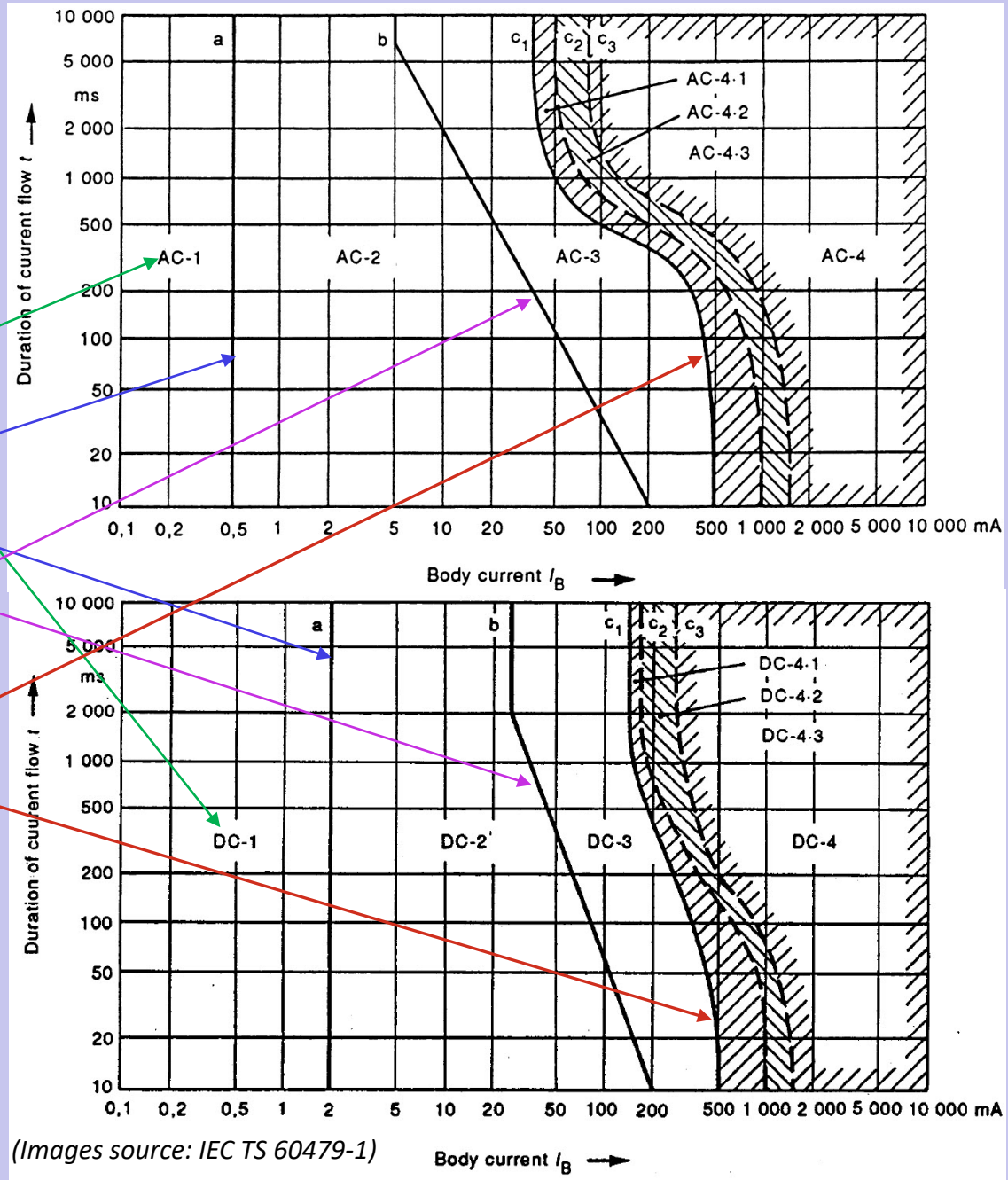
Perception

Reaction

Immobilisation (let-go)

Ventricular fibrillation

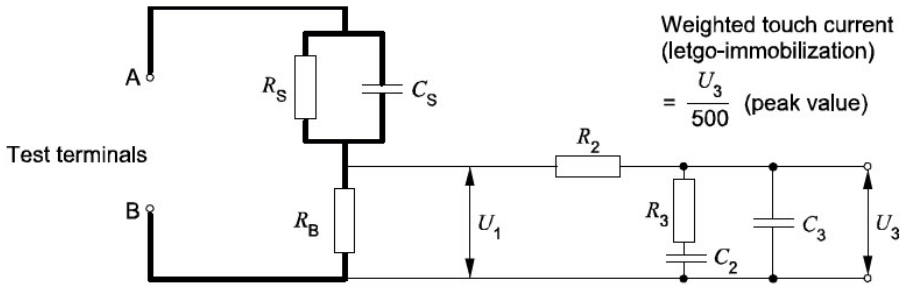
Other possible zone 4 effects: burns, breathing arrest, cell damage



DC time/current curves *(Images source: IEC TS 60479-1)*

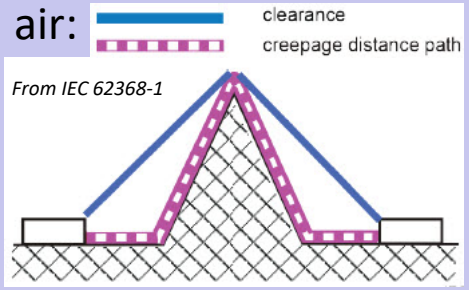
Equipment electric shock safeguards

- Identify & classify energy sources
- Accessibility – can it be touched? What parts? By who?
- Impedance & insulation limits the touch current
- Protective earthing diverts current
- Touch current limits are measured by IEC 60990 networks, e.g.:



Electrical energy source classifications	
ES1	Limits are touchable/accessible by all persons in normal and abnormal conditions. Must not exceed ES2 limits under single fault conditions
ES2	Requires basic safeguard between ES2 & ES1
ES3	Exceeds ES2 limits. Requires double or reinforced safeguards from ES1

- **Insulation safeguard** (not functional insulation)
  - Solid insulation, thin film, compounds, coatings, liquid, air
  - Withstand voltage (operating voltage + transient overvoltage)
  - Minimum thickness, voids & partial discharge
  - Creepage distances and clearances through air:
  - Temperature rating, ageing
  - Pollution degree, tracking
  - Securement & robustness
- **Protective earthing** (not functional earthing)
- **Electrical enclosures** (supplementary)
  - Prevent ingress of body parts, objects, dust, water (e.g. IP rating)
- **Components as safeguards**
  - Resistors, capacitors, transformers, relays, optocouplers, SPCs, RCDs, interlocks – meeting specific safety standards/tests
- **Backfeed safeguard in battery backed up supplies**



Electrical fire risks

Fire may be caused at potential ignition sources (**PIS**) by:

- **Resistive PIS** - resistive heating of components and connections dissipating more than 15 W after 30 s
- **Arcing PIS** - arcing at broken connections or opening contacts (switches, plugs, relays etc): <50 V or <15 W

PS Energy Classes		Effect on combustible materials
PS1	< 15 W after 3 s	Ignition not likely
PS2	> PS1 ≤ 100 W after 5 s	Ignition possible, but limited growth and spread of fire
PS3	> PS2 or unclassified	Ignition likely, rapid growth and spread of fire

Venting and burning electrolyte capacitor caused by mains overvoltage, resulted in a burned hole in the enclosure*

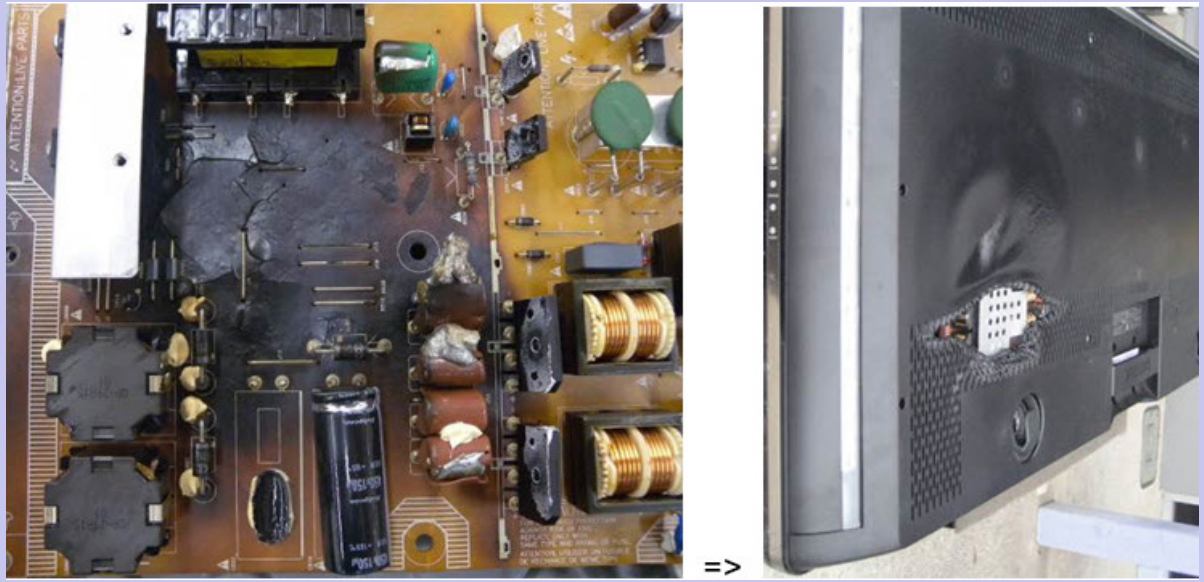


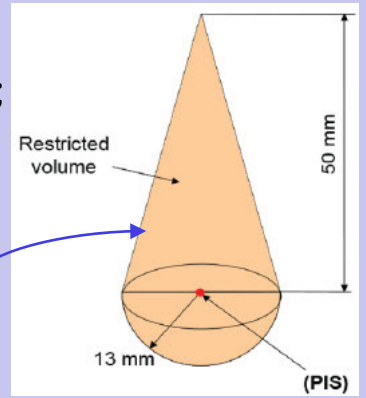
Image source: IEC 108/644/INF TC108 Standards Advisory Panel Question

Equipment fire safeguards

- Control the amount of available energy
- Limit temperature below auto ignition
- Control liquids flashpoint limits
- Use non-combustible materials
- Limit amount of combustible materials
- Test normal & abnormal conditions
- No fire propagation outside of product
- Limit power to external circuits or connected equipment
- Minimum wire sizes to mains power outlets to other equipment

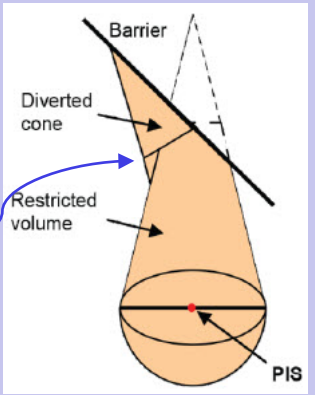
Supplementary safeguards for PS2:

- Use a limited power source
- No ignition under single fault conditions
- Mount PIS on VT-1 or better flame-rated printed boards;
  - wire insulation & tubing to pass flammability tests
- Transformer and motor overload and locked rotor tests
- Apply flammability ratings of component standards
- Separate PIS and combustible material
- Control the size or mass of combustible material
- Mount PIS in non-combustible sealed enclosure



Supplementary safeguards for PS3:

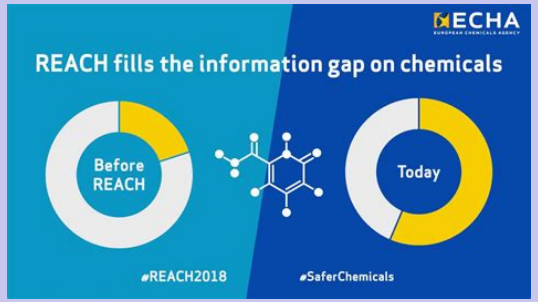
- Conductors & devices to meet PS2 requirements, **and**
- Arcing devices flammability-rated or mounted on V-1 or VTM-1 material, or have volume or mass controlled, **and**
- Use non-combustible or V-1 or VTM-1 material fire enclosure, or enclosure tested for heat and fire resistance
- Fire barrier between combustible material and PIS



Materials & Chemicals risks

- Injury is due to a chemical reaction with a body part:
  - Chemical burns to eyes & skin
  - Organ damage hazard
  - Poisoning hazard
  - Aspiration hazard
- Other chemicals risks generally managed by regulations:
  - Carcinogen hazard
  - Narcosis (if it could lead to safety incidents)
  - Environment hazards

- The extent of injury depends on:
  - magnitude and duration of exposure and
  - body part susceptibility to that substance
- Hazardous substances are classified and risk-managed by regulations in many regions. For example:
  - Restriction of Hazardous Substances Directive (RoHS) - Europe
  - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) - Europe
  - Globally Harmonized System of Classification and Labelling of Chemicals (GHS), by the European Chemicals Agency (ECHA)
  - Australian Industrial Chemicals Introduction Scheme (AICIS), and the Hazardous Chemical Information System (HCIS)
- These regulations classify risks differently to IEC 62368-1



Materials & Chemicals safeguards

- Limit quantities & reduce exposure
- Container & storage safeguards
- Control emissions
- Personal protective equipment (PPE)
- Instructional safeguards

IEC 60095-1 Six Colored Symbols for safety labeling

IEC 60095-2 Marking of plastic for recycling are :
Recycling of Lead
Recycling of plastic material (material code 7 and other to cover additive to the polypropylene

- Hazardous chemical containment in non-reactive vessels
- Store bulk or replenishment chemicals in a safe, secure place, and be properly labelled, with safety data sheets (SDS) available
- Control leakage/spillage due to container cracking, rupturing, bursting, or pressure relief that could damage or bypass a safeguard
- Control airborne emission concentrations below explosion limits and exposure standards limits:
  - 8-hour time-weighted average (TWA)
  - Short term exposure limit (STEL)
  - Peak limitation
- Provide handling and use instructional safeguards on the equipment and in the manuals as required by regulations and standards
- Use PPE in case of exposure risk during handling and use
- Follow washing, first aid, and clean-up instructions in case of accidental exposure or release.

Mechanically-caused risks

- Due to kinetic energy transfer from equipment parts to a body part
- Relative motion contact between accessible equipment & body parts
- Parts ejected from equipment colliding with body
- Also: choking hazards

Hazard: If a projector falls from its ceiling or wall mounting, it may cause an injury to a user or a bystander.

** Ref: IEC 62368-1:2018 clause 0.9*
Images sources: Product Safety Australia and USA CPSC

Examples of kinetic energy source hazards include:

- Person's body motion relative to sharp edges and corners
- Equipment motion due to:
  - instability
  - failure of mounting: floor, wall, ceiling, or rack rails
  - lifting handle failure
  - cart or stand instability or failure
- Parts motion due to:
  - loosening, exploding, or imploding parts
  - rotating or moving parts
  - exploding battery, high pressure lamps
- Pinch points, entanglement

Hazard:
The weld between the "VESA" style mounting plate and the mounting ring can fail, allowing the monitor or TV to fall. This poses a risk of injury to bystanders.

Mechanically-caused deaths…

Australia toppling television & furniture fatalities*

- 27 deaths since year 2000
- Head & crush injuries & asphyxiation
- Children under 5y: 67% of deaths
- Adults above 60y: > 22% of deaths

Products involved in fatalities (Australia since 2000)	Number
Storage furniture (e.g. chests of drawers and cupboards)	15
Television only	4
Television and associated furniture	7
Other furniture (table)	1
Total	**27**

Comparison of USA and Australia deaths by age group			
	0-17	**18-59**	**60+**
Australia	74%	4%	22%
USA	85%	3%	12%

- *Source: ACCC Toppling Furniture and Televisions Issues Paper August 2021*

Mechanical safeguards…

- **Classify the energy level**
- Smooth accessible edges & corners
- Secure & control mass & kinetic energy of moving parts
- Enclosures or interlocks to control access to moving parts
- Stop or limit motion of part before access
- Contain expelled parts
- Instructions & indications where necessary

- **Risk level classifications:**
  - **MS1:** Not cause pain or injury
  - **MS2:** Painful but no injury
  - **MS3:** Injury requiring medical treatment

- Spinning parts: control mass, speed, diameter, elasticity, shape
- Use interlocks to reduce energy to MS1 before the part is accessible
- Use equipment safeguards to prevent contact with MS2 or MS3 by body parts or entanglement of hair/jewellery/clothing etc
- If MS2 moving or sharp part needs to be accessible for function:
  - guard it as much as practicable and
  - use instructional safeguards
- If MS3 moving or sharp part must be accessible for function it must;
  - be obvious and not be life-threatening,
  - guarded as much as practicable,
  - use instructional safeguards (warnings), and
  - have an emergency stop control close by

…Mechanical safeguards

- Stabilize against tipping or falling
- Robustness of handles for lifting or carrying
- Robustness of mountings
- Carts & stands
- Wheels or castors attachment
- Telescopic rod antennas
- High pressure lamps
- Work cells

- **Equipment stability:**
  - Equipment type: floor-standing, non-floor standing, controls or display, fixed mounted equipment
  - Tests: tilt, downwards force, relocation, glass slide, horizontal force, mounting means to a structure
  - Consider child-access risk, earthquake risk
- **Carts & stands stability**, loadings, impact, instructions
- **Mounting means for slide rail** mounted equipment
  - Downwards and lateral forces, end stops
- **Telescoping antennas** – button or ball on end to protect eyes
- **High pressure lamp** – simulate explosion & test containment
- **Work cell enclosure safeguards:**
  - Access via safety interlock or key or tool
  - Lockout/tagout procedures
  - Visual indicators prior to restoring movement
  - Emergency stop system

Thermal skin burn injury risks

Thermal energy transfers when a body part contacts hot equipment parts

- Injury depends on the:
  - temperature difference
  - thermal mass of the object
  - rate of thermal energy transfer to the skin
  - duration of contact

Note: thermal energy transfer can also occur by convection or radiation, but this is not generally covered by IEC 62368-1

Image source: IEC 62368-1

Material	Body worn skin > 8h		Normal use touch > 1 min		Touch > 10 s & < 1 min		Short touch >1 s < 10 s		Need not touch (< 1 s)	
(Max °C)	TS1	TS2	TS1	TS2	TS1	TS2	TS1	TS2	TS1	TS2
Metal	43-48		48	58	51	61	60	70	70	80
Glass, porcelain	43-48		48	58	56	66	71	81	85	95
Plastic, rubber	43-48		48	58	60	70	77	87	94	104
Wood	43-48		48	58	60	70	107	117	140	150
All	TS3 is anything higher than the TS2 limits									

This table is adapted and simplified from IEC 62368-1 Table 38

Thermal skin burn safeguards

For a thermal energy source that can cause:

- **Pain** - use a basic safeguard between the energy source and body part
- **Injury** - Use a basic and supplementary safeguard between the energy source and body part

Classify the energy sources :

- TS1, TS2, TS3

Basic safeguards

- Control the electrical energy source of thermal energy
- Select materials with high thermal resistance
- Apply heat sinks to components to dissipate excess heat
- Implement forced air or liquid cooling systems
- Restrict body-part access to hot equipment parts
- In some cases, instructional safeguards may be adequate

Supplementary safeguards

- Use equipment safeguards to control thermal energy transfer under abnormal operating conditions or single fault conditions
- Apply instructional safeguards/warnings

TS2 or TS3 accessible parts that require heat for the intended function:

- Must be unlikely to be touched during operation or maintenance
- Requires an instructional safeguard/warning
- Must be unlikely to be touched by children

Wireless power transmitters

- Must avoid burns due to high temperatures of foreign metallic objects

Radiation injury risks

- Non-ionising electromagnetic radiation sources:
  - LF (1 Hz-1 kHz)
  - RF (100 kHz-300 GHz)
  - Infrared (780 nm-1 mm)
  - Visible light (380-780 nm)
  - Ultraviolet (100-400 nm)
  - Lasers (IR-UV)
- Ionising radiation (X-Ray)
- Acoustic sound radiation

*Non-ionizing radiation (NIR) is a generic term used to describe electromagnetic radiation that does not carry enough photon energy to ionize atoms or molecules and includes mechanical waves in the low and high frequency range (infra- and ultrasound)**

- Exposure to NIR can injure by heating a body part
  - Lasers (optical fibre & free air communications, other)
  - Lamps, LEDs, & image projectors with lamps or LEDs
- X-Ray (e.g., CRTs) - classify energy source:
  - **RS1 limit: 36 pA/kg @ 50 mm** (= 5 µSv/h or 0,5 mR/h)
  - **RS2 limit: 185 pA/kg @ 100 mm**
  - **RS3 (exceeds RS2)**
- Personal music players: can cause hearing loss via excessive listening dose and time
- Other sources (RF EME/radioactivity/ambient acoustic/ultrasound etc.) are managed in regulations so also need to be considered in risk controls

** Source: ICNIRP – International Commission on Non-Ionizing Radiation Protection*

Radiation safeguards…

- Laser & Lamps safety standards
- Contain energy within opaque enclosure
- Control duty cycle to limit dose
- Interrupt energy source if enclosure or communication channel interrupted
- Provide warnings and instructions

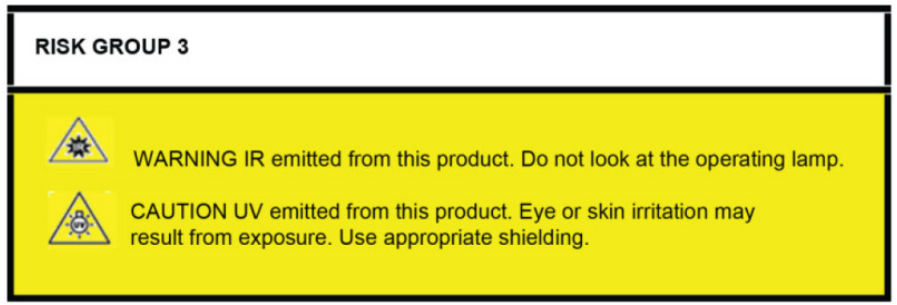


Image source: IEC 62368-1

Apply laser & lamps standards IEC 60825 & IEC 62471 series

- Lamp radiation limits IEC 62471 Exempt Group (maybe Risk Group 1):
  - Where not needed to be accessible for the function
  - An enclosure to achieve this is a reinforced safeguard
  - Enclosure to be resistant to UV degradation from lamps
- Instructional safeguard where accessible functional limits exceeded
- Where used by ordinary or instructed persons:
  - Lamps and lamp systems not to be IEC 62471 Risk Group 3
  - Laser equipment not to be IEC 60825 Class 3B or Class 4
- Laws for safety in the workplace and for the general public may contain additional or different requirements
- Under development: IEC 60825-20 risk-based safety for lasers intentionally directed to eyes or face, including collateral radiation
  - e.g. facial recognition, VR headsets, gesture tracking, etc.
  - uses Failure Modes and Effects Analysis (FMEA)

Classify X-Ray energy sources: RS1, RS2, RS3

- Equipment safeguard required above RS1
- Instructional safeguard placed on removable doors & covers used as safeguards that could expose a skilled person to RS2 or RS3

...Radiation Safeguards - acoustic

- Personal music player (PMP): classify energy source by exposure or dose:
  - **RS1: 85 dB(A) / 27 mV / -25 dBFS**
    or
    100 % CSD is 80 dB(A) for 40 h
  - **RS2: 100 dB(A) / 150 mV / -10 dBFS**
  - **RS3: exceeds RS2**

Requirements do not include hearing aids, analogue PMPs, professional equipment

PMP: portable audio or audiovisual equipment intended for use by the ordinary person, using a listening device in or on or around the ears, that can be body worn while walking around in continuous use

- Warnings at 100% of the Calculated Sound Dose (CSD) - RS1 limit
  - Do not exceed without user acknowledgement
  - Listening above 100 % CSD is risk to hearing damage
- Warnings if momentary exposure level (MEL) ≥100 dB(A)
- Provide instructions for dose management system and optional controls (e.g. parental controls)
- Optional controls must not defeat safeguards

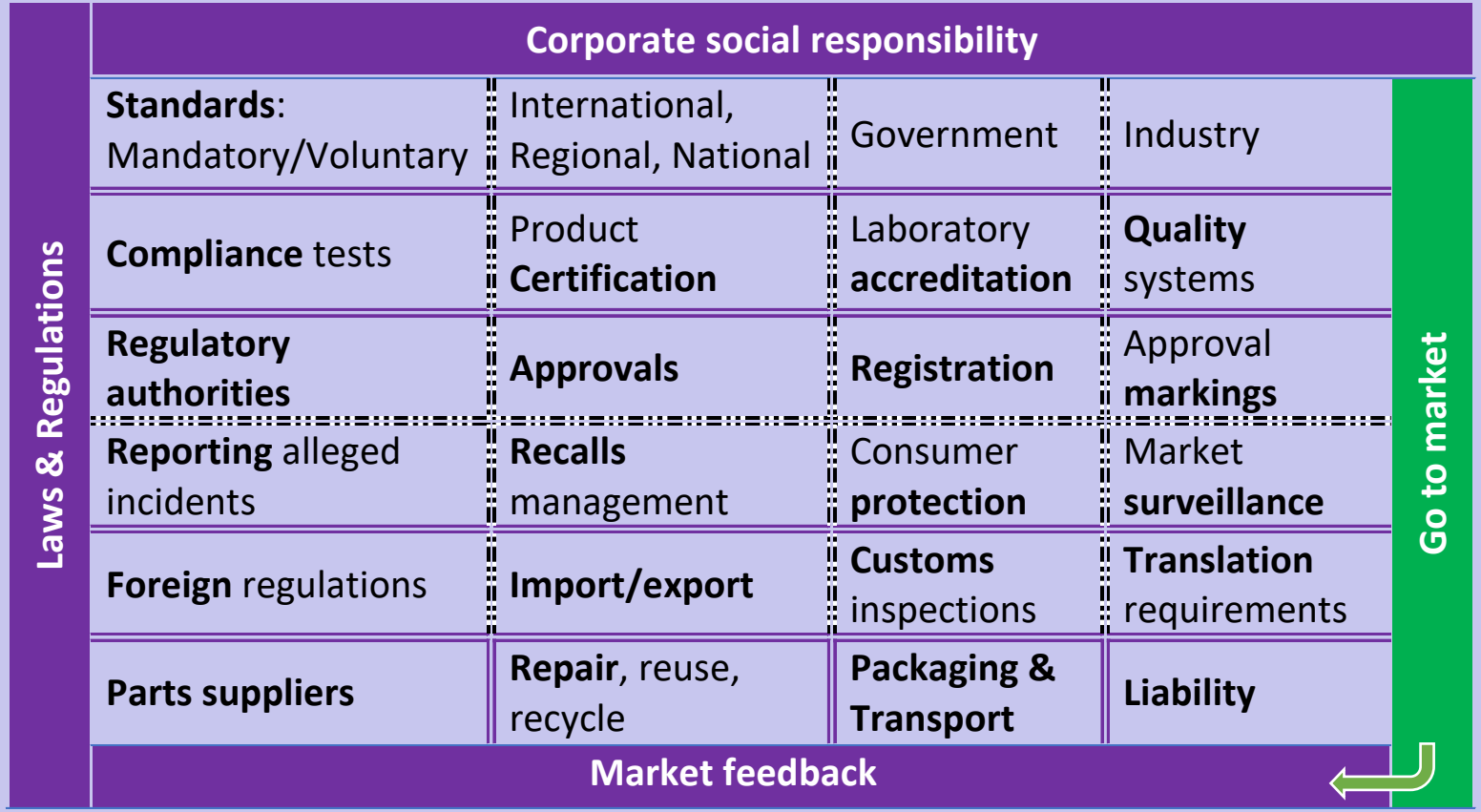
For listening devices supplied separately (headsets, ear buds, etc):

- Analogue input: ≥ 75 mV at 94 dB(A) LAeq acoustic pressure output
- Digital or cordless input of –10 dBFS, Output level ≤ 100 dB(A)

- External sound may significantly add to total daily sound dose
  - work, transport, concerts, clubs, cinema, car races, etc.
- Use primarily by children may also have toy standards requirements

Going to market

- Safety standards only specify minimum requirements
- Before going to market ensure the equipment:
  - Complies with mandatory standards and regulations AND
  - Is at least as safe as regulators and the community expects
- After going to market monitor for unforeseen failures, standards developments, regulatory changes
- Liability is ongoing… it doesn't stop when you ship the box



Conclusions

- Users have the right to expect their products remain safe during normal use, abnormal use, reasonably foreseeable misuse, and fault conditions
- Laws impose obligations on suppliers to meet minimum standards & regulations
- Corporate social responsibility fills in residual exposures not explicitly covered
- Thorough understanding of energy hazards that can cause pain and injury, as well as safeguards against hazardous energy transfer, is vital to ensure the safeness of products placed on the market

Thank you for your attention!

Your questions on information in this presentation are welcome.

(Image sources this & front page, & page 3 from PowerPoint's "Corporate classic corporate teach a course slide" template)