“Safer by Design”

Presented by-

Abul Kashem **BEng(Hons) MIET**
TÜV Rheinland UK Ltd

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TÜV Rheinland UK Ltd

UK and Ireland

- TÜV Rheinland UK Ltd is a wholly owned subsidiary of TÜV Rheinland group
- Established in Birmingham in 1999
- Opened a safety testing laboratory in June 2015
- Laboratory in process of obtaining UKAS accreditation and becoming a CBTL for CB Scheme and PTL (NRTL regulated testing for US and Canada)

Electrical Products Regulated by Directive 2014/35/EU

Electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current (AC) and between 75 and 1 500 V for direct current (DC)

Household Appliances

- Small Appliances (Warm)
- Small Appliances (Cold)
- Body Care Appliances
- Cooking Appliances
- Sanitary Products
- Pumps

IT, Telecom, Office

- Notebooks
- Printer
- Phones
- Scanner
- Copier
- Charging Station

Audio / Video

- Hifi Systems
- TV Sets

Batteries

- Home Energy Storage Systems

Power Supplies

- Home Automation Systems
- Extension Cords
- AC-Adaptor

Fire & Security

- Access control & safety locks
- Fire and smoke alarms
- Lighting and climate control
- Messaging and location

Luminary/ LED

- Lamps
- LED Driver
- LED bulbs

AC- & Heating

- Air Conditioner
- Heater
- Heat Pump

Lab Equipment

- Multimeter
- Microscope
- DNA analyser
- Blood cell analyser

Procedure 25 of Directive 2014/35/EU

"Member States should take all appropriate measures to ensure that electrical equipment may be placed on the market only if, when properly stored and used for its intended purpose, or ***under conditions of use which can be reasonably foreseen, it does not endanger the health and safety of persons****. Electrical equipment should be considered as non-compliant with the safety objectives laid down in this Directive only under* ***conditions of use which can be reasonably foreseen****, that is when such use could result from lawful and readily predictable human behavior"*

The risk assessment file required to comply with the Annex IIIA of the directive which states:

"*The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the electrical equipment's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).*"

Actions by Test Labs & Economic operators

Suggestive Approaches by Test Laboratories

- Provide training opportunities for economic operators
- Offer review of the Risk Assessment documents

Suggestive Actions by Economic Operators in EU

- Start to implement the risk management process immediately
- Analyse the customer complaints on regular basis and identify any reasonably foreseeable misuse by end user.
- Address the misuse in the Risk Management and inform all the distributors
- Additional safety measures can be taken by the manufacturer where the harmonised standards do not address how a specific risk can be reduced, bearing in mind it should not raise non-conformities mentioned in harmonised standard.

Example of Risk Level Estimation

Example: Charger pin damaged because of using wrong device

Example of a Risk Level Estimation (Continued)

Step 1: Select the severity group

Table Severity Groups

Severity Group	*People*	*Equipment/Facility*
1 – Catastrophic	One or more fatalities.	System or facility loss.
2 – Severe	Disabling injury/illness.	Major subsystem loss or facility damage.
3 – Moderate	Medical treatment or restricted work activity	Minor subsystem loss or facility damage.
4 – Minor	First aid only.	Non-serious equipment or facility damage.

Example of a Risk Level Estimation (Continued)

Step 2: Select the Likelihood of the occurrence

Table Likelihood Groups

Likelihood Group	*Frequency (% of Unit-Years in which there was/is expected to be an occurrence)*[#1]
A – Frequent	More than 1%
B – Likely	More than 0.2% but not more than 1%
C – Possible	More than 0.04%, but not more than 0.2%
D – Rare	More than 0.02%, but not more than 0.04%
E – Unlikely	More than 0.002%, but not more than 0.02%
F – Not reasonable foreseeable	Not more than 0.002%

#1 The frequency (in percent per unit year) is calculated by dividing the number of (observed or expected) occurrences of harm by the number of unit-years that the unit has existed (for observed occurrences of harm) or is anticipated to exist (for expected occurrences of harm), then multiplying the quotient by 100.

Example of a Risk Level Estimation (Continued)

Step 3: Implement step 1 & 2 in Risk Ranking Matrix

RISK RANKING MATRIX		*LIKELIHOOD*					
		FREQUENT A	*LIKELY B*	*POSSIBLE C*	*RARE D*	*UNLIKELY E*	*NOT REASONABLY FORESEEABLE F*
SEVERITY	Catastrophic 1	Very High	Very High	High	Medium	Low	Very Low[#1]
	SEVERE 2	Very High	High	Medium	Low	Low	Very Low[#1]
	MODERATE 3	High	Medium	Low	Low	Very Low	Very Low[#1]
	MINOR 4	Low	Low	Low	Very Low	Very Low	Very Low[#1]

Example of Risk Level Estimation (Continued)

Example: Charger pin damaged because of using wrong device

<u>Example of calculating the risk from the table:</u>

Damage Appearance Probability: **Likely**
Damage Seriousness: **Moderate**
Risk Level Estimation: **Medium**

Some FAQ's

Q: Is this a new requirement?

A: For most of the electrical equipment it is a new requirement. But some of the harmonised standards for electrical products already have Risk Management in place. In another perspective the new directive will harmonise the requirement for all the electrical items manufactured in EU or brought in from outside EU (new and used).

Q: When will the directive be enforced?

A: Any electrical items placed in the EU market place by economic operators from 20th April 2016

Q: How long the economic operators have to retain the technical files required for DoC (Declaration of Conformity)?

A: 10 Years

Q: Will it affect the design of the product in the market?

A: Depending on the design of products, some designs of the electrical products may remain same, because altering the design may void the sole purpose of the application. Nonetheless manufacturer still would require to produce a risk management and reflect the associated risk arising from the reasonably foreseeable misuse by the end user. Where design can be modified it may be ideal to apply the changes.

Any Questions?

Coffee Break

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