

RISK ASSESSMENT CASE PRIORITIZATION METHODOLOGY PRODUCT SAFETY

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Topics Covered

- Electrical Product Safety Regulation Overview
- Guideline Development Process
- Risk Assessment Prioritization Methodology
- Questions

Ontario Regulation 438/07

The *Product Safety* regulation (Regulation 438/07) made under *Part VIII of the Electricity Act, 1998* was proclaimed August 15, 2007. These regulations included requirements for the mandatory reporting of serious electrical incidents or accidents or defects that affect the safety of individuals or cause damage to property or defects.

Ontario Regulation 438/07

An accident or incident must be reported if its actual impact resulted in death, serious injury or substantial property damage or has the potential to cause death, serious injury or potential property damage

ESA interprets '**serious injury**' to mean *permanent impairment of a body function or permanent damage to a body structure, chronic health effects or any injury requiring hospitalization or professional medical treatment.*

ESA interprets '**substantial property damage**' to mean *a loss attributed to flame emitted from a product, or failure to contain an ignition source or hazardous material, or an impact on building and contents ranging from partial to total loss.*



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Guideline Development

Overview of the Process



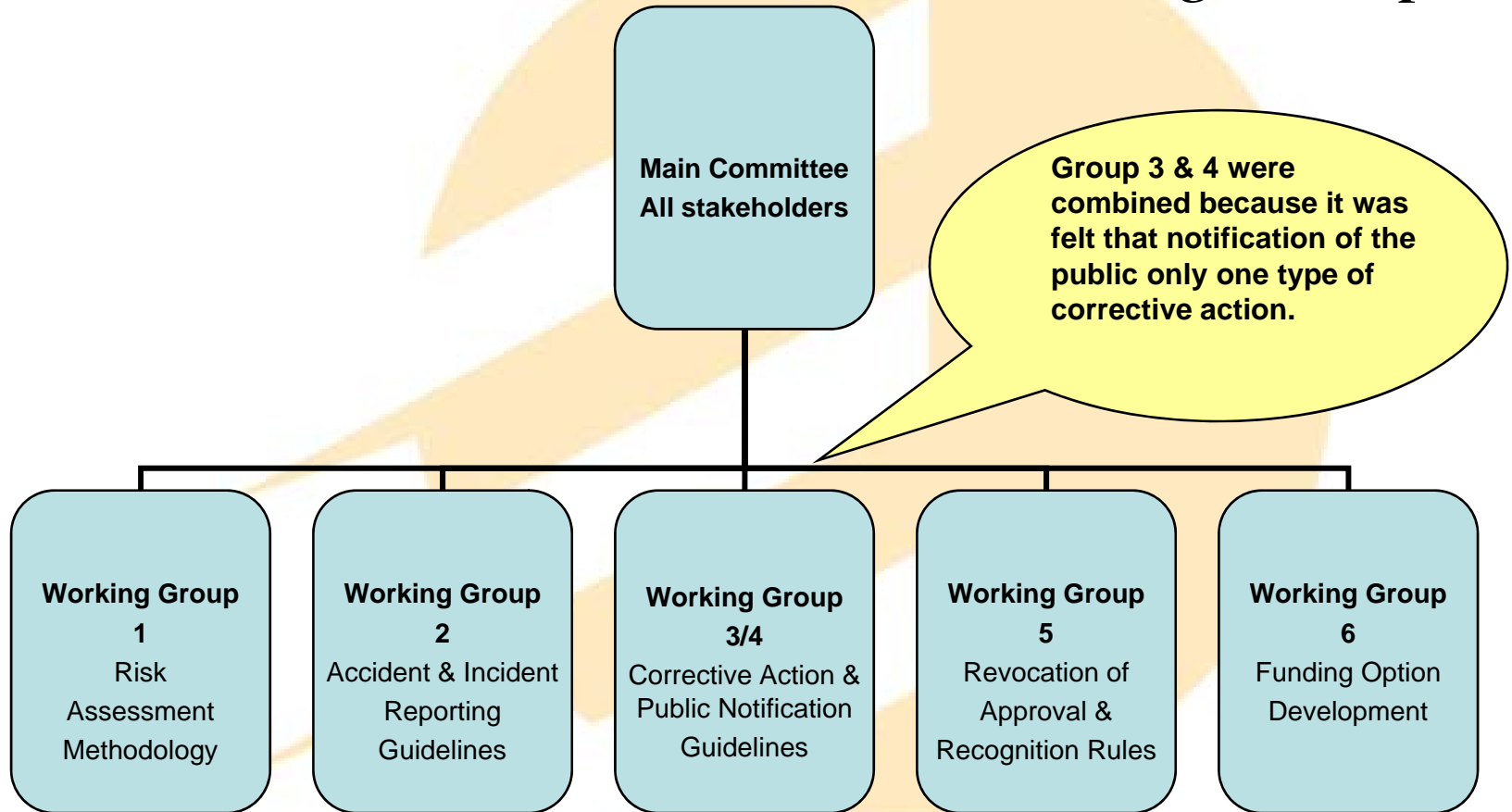
Guideline Development Process

- Stakeholders were invited to take part in the guideline development process.
- The first main stakeholder meeting took place on **October 15, 2007**.
- 5 seed documents (one per working group) were presented and circulated to stakeholders.
- Three external consultants were hired to produce the seed documents based on international best practices.



Guideline Development Process

Revised Working Groups



Risk Assessment Prioritization Methodology

Working Group 1:

Peter Jackson (Chair) *Risk Waves Corp,*

Ed Gulbinas *Office of the Fire Marshal,*

Jeffery Troutt *lawyer*

Mark Chmielewski *Canadian Tire Corp.*

Michael Ng *Office of the Fire Marshal,*

Neeraj Gupta *HBC,*

Paul Schlote *CSA*

Ron Bergeron *Bergeron Electric*

Ted Olechna *Electrical Safety Authority
Canada*

Derwyn Reuber *Intertek Testing Services*

Joseph Neu *Electro Federation Canada*

Maria Iafano *Electrical Safety Authority*

Mel Fruitman *CAC*

Nancy Chambers *Sears Canada Inc.*

Nick Maalouf *QPS Evaluation Services*

Robert J. Pollock *Underwriters Laboratories*

Steve Smith *Electrical Safety Authority*

Whipple Steinkrauss *Consumers Council of*



Guideline Development

Final Industry Guidelines for the Management of Electrical Product Safety were published July 14, 2008.

Section 7 describes in detail ESA's Prioritization methodology based on the estimated risk of future death, injury or property damage.

Risk Assessment Prioritization Methodology

ESA's response strategy varies according to whether the product is:

- uncertified or unapproved;
- counterfeit; or
- certified or approved but unsafe.

ESA classifies cases as Priority 1, Priority 2 or Priority 3, based on the estimated risk of future death, injury or property damage.

Risk Assessment Prioritization Methodology

Prioritization of reported cases may contain elements of subjective judgment. A prioritization methodology provides a consistent framework within which to exercise judgment.

ESA has made available it's risk prioritization methodology to stakeholders to enhance the transparency of the decision-making processes and to better enable the responsible party(s) to assist and cooperate with ESA.

Risk Assessment Prioritization Methodology

ESA uses its case prioritization methodology in the following situations:

- In assessing the potential future harm or damage that may be caused by a known defect;
 - In assessing the potential future harm or damage that may be caused by an unapproved product, where there is no known defect; and
 - In assessing the potential future harm or damage that may be caused by a counterfeit product, where there is no known defect.
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Risk Assessment Prioritization Methodology

ESA's case prioritization methodology has four basic steps:

- Understand the nature of the product defect, if any
- Assess the severity of the potential impact
- Assess the likelihood of the potential impact
- Determine how to act based on the resulting priority rating

The starting point for ESA's case prioritization assessment is a reported incident, accident or defect. The methodology is designed with this in mind. It addresses the most common forms of harm from electrical products, being shock, fire, burns and mechanical as well as other forms of harm.

Assess Severity of the Potential Impact

Loss Severity	Impact on People	Impact on Property
Major	Death, need for permanent life support, permanent impairment of a body function, permanent damage to a body structure, chronic health effect or long term psychological trauma.	Loss attributed to flame emitted from product, or failure to contain an ignition source or hazardous material. Partial or total loss of contents accompanied by structural damage to or total loss of building.
Moderate	Recoverable injury requiring hospitalization or professional medical treatment.	Loss attributed to flame emitted from product, or failure to contain an ignition source or hazardous material. Partial loss to contents without structural damage to building.
Minor	Recoverable injury requiring only first-aid treatment.	Superficial damage to building and contents e.g. smoke ¹ and/or heat emitted from product causing discolouration of adjacent surface or material but without ignition. No evidence that flame, a potential ignition source or hazardous material escapes from product.
Insignificant	Startle reaction or momentary fright without physical injury.	Product fails without external consequence. No evidence that flame, a potential ignition source or hazardous material escapes from product.

Note: 1 Smoke emitted from product in sufficient volume to threaten life is covered by the “impact on People” column.

Assessment of the Likelihood of the Potential Impact

ESA considers the following in its assessment of the likelihood of the potential impact :

- whether an incident or defect meets the threshold for reporting;
- user behaviour and foreseeable product use; and
- what would be considered to be reasonable user behaviour for a given product.

Assess Likelihood of the Potential Impact

The likelihood in most cases is estimated using judgments about qualitative factors that are relevant to the particular hazard or possible hazard.



Risk Assessment

Estimating the likelihood of the product being or becoming defective

FACTOR		RELEVANT?	SUGGESTED WEIGHT	SCORE
Product Certification	Not certified to any Canadian standard.	<input checked="" type="checkbox"/>	30	30
	Not certified to a Canadian standard but certified to another jurisdiction's standard (e.g. certified to U.S. standard but no Canadian identifier is included with certification mark).	<input type="checkbox"/>	10	
Use Environment	Exposed to extremes of weather, humidity, air quality or temperature. Exposed to rough usage or commercial usage.	<input checked="" type="checkbox"/>	10	10
History of Compliance or Previous Product Issues	Manufacturer, distributor or retailer has a history of non-compliance with approval requirements or previous track record with manufacture, distribution or sale of defective products.	<input checked="" type="checkbox"/>	10	10
Ability to detect defect prior to use	Product used or installed by non-skilled persons.	<input checked="" type="checkbox"/>	10	10
Pattern of Incidents	Pattern of individually small incidents that may be warning signs of more serious problems.	<input checked="" type="checkbox"/>	30	30
Total Score				90
Rated Likelihood		HIGH		

Estimating the Likelihood of the Serious Negative Effect Materializing

Risk Assessment				
Estimating the likelihood of the serious negative effect materializing				
FACTOR		RELEVANT?	SUGGESTED WEIGHT	SCORE
Exposure Characteristics (select one from this group)	People who may be at risk are especially vulnerable.	<input checked="" type="checkbox"/>	30	30
	Adults and the hazard is not obvious.	<input type="checkbox"/>	20	
	Qualified persons and the hazard is not obvious.	<input type="checkbox"/>	10	
	Adults and the hazard is obvious.	<input type="checkbox"/>	0	
	Qualified persons and the hazard is obvious (deduct).	<input type="checkbox"/>	(10)	
Impact of Warnings	Evidence or pattern of user behaviour that the normal product usage warnings are not followed or ignored.	<input checked="" type="checkbox"/>	10	10
Human Device Interaction (select one from this group)	Medical Device.	<input type="checkbox"/>	40	
	Human contact when in use (e.g. curling iron, electric blanket, electric drill).	<input type="checkbox"/>	20	
	Usage in a public place by multiple people (e.g. arcade game).	<input checked="" type="checkbox"/>	20	20
	Intermittent contact when used (e.g. operating a switch to turn the device on).	<input type="checkbox"/>	10	
	No contact with human body (e.g. ceiling light fixture).	<input type="checkbox"/>	0	
Undetected Overheating	Heat producing product with possibility of failure while unattended or unobserved (e.g. energized device overheats and causes a fire while occupants are sleeping).	<input checked="" type="checkbox"/>	30	30
Safety Device	Product is used as a protective device of safety.	<input type="checkbox"/>	25	
Total Score				90
Rated Likelihood			HIGH	
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Overall Estimate of Likelihood

The rated likelihood of the product being or becoming defective is based on the total score.

- 50 or higher merits a high rating
- between 25 and 50 merits a medium rating
- less than 25 merits a low rating

The rated likelihood of the serious negative effect materializing is based on the total score.

- 60 or higher merits a high rating
- between 35 and 60 merits a medium rating
- less than 35 merits a low rating

The two ratings of likelihood are combined to provide an overall estimate of the likelihood of injury or damage as shown in the following table. The combined rating is shown *in red*.

Table 3 Likelihood of injury or damage

		Likelihood of product being or becoming defective		
		Low	Medium	High
Likelihood of the serious negative effect materializing	High	<i>medium</i>	<i>High</i>	<i>very high</i>
	Medium	<i>low</i>	<i>Medium</i>	<i>high</i>
	Low	<i>very low</i>	<i>Low</i>	<i>medium</i>

Assignment of Priority

The **final risk assignment** is determined by plotting where the risk falls on the following table. The likelihood of injury or damage is plotted against the vertical axis, and the severity of impact on the horizontal axis.

Assignment of Priority



Risk Assessment

Assignment of priority

Based on a likelihood of injury or damage of: **Very High**
and a severity of impact of: **Major**

According to the following chart:

Likelihood of
Injury or Damage

Very High

High

Medium

Low

Very Low

Severity of Impact Insignificant


Minor


Moderate


Major



Legend

Priority 1 

Priority 2 

Priority 3 

The priority category will automatically identify the follow-up response process

The priority assigned to this file is: **Priority 1**

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Done

Precautionary Principle

ESA has used the precautionary principle in devising this case prioritization approach. ESA will make use of all available information including objective, statistical information where such is available.

Where it proves impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of the scientific study into the risk, but the likelihood of real harm to public safety persists should the risk materialize, ESA will take action under the Product Safety regulation.

Corrective action

The corrective action required by ESA and involved parties is based on the classification of risk and priority level of each reported incident, accident or defect.

The assigned priority level is used to determine the response time for a manufacturer, other parties within the supply chain or a certification body to provide ESA with assistance in determining and implementing the appropriate corrective action

Corrective action

- Priority 1 – 14 days
- Priority 2 - 30 days
- Priority 3 - 60 days

Corrective action

Corrective actions could include one or more of the following:

- Changing the product design, the materials/components or the production process;
- Withdrawing the products from the product supply chain;
- Repairing, modifying, or adjusting the product in the product supply chain, on the customer's premises (e.g. in the case of large domestic appliances) or elsewhere;
- Changing warning labels on the product in the product supply;

Corrective Action

- Recalling the product from consumers, other users or the product supply chain for replacement refund or disposal;
- Asking the consumer to dispose of the product;
- Sending information and warnings about the hazard, additional information about correct use or maintenance of the product to users; Recommending that the product standard be revised or a new standard developed;
- Public notification in order to alert the public or persons to potential risks to their health or safety resulting from defective, counterfeit, or non-approved products in question.



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Questions??

