Electrical Product Safety in Ontario

Consultation on Guidelines for Corrective Action

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Electrical Safety Authority

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This draft guideline has been developed to facilitate consultation and discussion. The ideas and concepts presented do not represent the official or final view of the Electrical Safety Authority.
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Introduction:

The purpose of this document is to provide a starting point for discussion with stakeholders on the development of a guideline that provides practical information to manufacturers, wholesalers, importers, distributors, retailers, certification bodies, and field evaluators of electrical products on how to comply with the new provisions of section 113.13.1 of Part VIII of the Electricity Act 1998, providing the Electrical Safety Authority with the ability to order corrective action.

Part 1 of the document presents background information for this consultation on the case for amending the Act, possible types of corrective action, and the corrective action requirements and guidelines for electrical products in other jurisdictions. It also examines the corrective action responsibilities of certification bodies and discusses the issues related to establishing and implementing strategies and processes for corrective action.

Part 2 of this document presents a draft guideline designed to assist suppliers, certification bodies and field evaluators in complying with the new corrective action provisions. The guideline when finalized and approved by the Electrical Safety Authority (ESA) will be presented for consideration as a Director’s Order to eventually be included in a regulation.

Part 1: The Case for Renewal

The Government of Ontario is committed to modernizing its consumer protection system to meet the needs of Ontarians. As part of that effort, it passed the Ministry of Government Services Consumer Protection and Service Modernization Act, 2006 (Bill 152) which amended Part VIII of the Electricity Act, 1998. The amendments are designed to enhance and strengthen the ability of the Electrical Safety Authority (ESA) to deal with unsafe electrical products. The Ontario Electrical Safety Code (OESC) was previously silent with respect to the responsibility for corrective action on the part of manufacturers or importers of the product into Ontario. In fairness to all, it is suggested that the obligation for corrective action be extended to those in the best position to deal with it. ESA, a private non-profit authority, is mandated by the Ministry of Government Services to administer and enforce Part VIII of the Act.

Before beginning the work of developing guidance documents to implement the amendments, it is important to establish the principles that the guidance documents should embody. The principles to be followed include:

- Ensuring that the guidelines clearly explain the information and steps required so that they are easy to understand;
- Adhering to sound principles of risk management and risk communication for the protection of human life and health;
- Establishing an implementation process that complies with the new Product Safety Regulations under the Electricity Act;
- Ensuring that the corrective action policies and procedures are internationally compatible and are sensitive to the importance of international standardization;
Consultation on Guidelines for Corrective Action

- Respecting the responsibilities of the federal and other provincial and territorial governments and promoting collaboration with them; and
- Ensuring that consensus is reached where possible and that where differences exist they are clearly understood by all parties.

1.1 What is meant by corrective action?

Even the best businesses make occasional mistakes. When a potentially unsafe product is discovered, a range of actions can be used to minimize the effects of potentially faulty products that are in the distribution chain or that have already been purchased. The choice of corrective action to be taken depends on the seriousness of the risk to the public or workers. In determining the seriousness of the risk, reference should be made to the guideline on risk assessment. ESA expects responsible parties to take full responsibility for correcting dangerous or potentially dangerous electrical products in an appropriate and timely manner. 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 distribution chain;
- Repair, modification, adjustment or re-labelling of the product in the distribution chain, at retail, on the customer’s premises (e.g. in the case of large domestic appliances) or elsewhere;
- Recalling the product which means the permanent removal of the product from consumers, other users or supply chain;
- Sending information and warnings about the hazard and/or correct use of the product to users;
- Return of the product by purchasers for replacement or refund;
- Asking the consumer to dispose of the product and claim a refund.

According to Can-P-1527, corrective actions taken by those who certify products could take the form of:

- Notification of parties responsible for initiating a recall when it is deemed necessary to protect the public;
- Removing the mark of conformity from the product;
- Requiring the product to be rebuilt so that it complies with certification requirements, or to be replaced;
- Scrapping or replacing a returned product where it is not practical to remove the mark or rebuild it; or
- Notifying the public of the hazard.¹

1.2 What are the requirements for corrective action?

Amendments were made to section 113 (11) the Electricity Act, 1998 in December of 2006 and were proclaimed August 15, 2007. The amendment states:

“(11) The Authority may issue such orders relating to work to be done, or the removal of things used, in the installation, removal, alteration, repair, protection, connection or disconnection of any of the works, matters and things mentioned in subsection (1) as the Authority considers necessary or advisable for the safety of persons or the protection of property and, in any such order or after having made it, the Authority may order any person to cease and desist from doing anything intended or likely to interfere with the terms of the order.”

This new authority to issue corrective action orders for products was added in order to protect the safety of persons and property by correcting noncompliant or potentially harmful electrical products in a timely manner. The orders will obligate manufacturers, wholesalers, distributors, importers, retailers, certification bodies and field evaluation agencies to establish and implement documented corrective actions in order to address safety problems with a product. All types of electrical products and devices governed by the Ontario Electrical Safety Code are covered by the new provision, including consumer electrical products, electrical medical devices, industrial electrical products, and wiring products. The Electrical Safety Code does not apply to electrical equipment used to generate or transmit electricity or electrical equipment used in transportation vehicles such as aircraft cars and trains; facilities used in the operation of an electric railway or electric street railway; railway vehicles or equipment used to operate a railway; mines; or transportation operations. The regulations under the Electricity Act 1998 also require that all electrical products sold within Ontario be approved or certified to the safety standards under the Ontario Electrical Safety Code.

Canadian Procedural Document, Can-P-1527, published by the Standards Council of Canada identifies, for those who certify products, the conditions under which corrective action can be taken. These conditions include:

- When the mark of conformity is affixed to a product that is hazardous;
- When the product is not authorized to bear the mark;
- When the product bears an unauthorized form of the mark e.g. counterfeit product; or
- When the product is in violation of the certification agreement.

The document also presents the corrective actions that the party responsible for the product can be requested to take when “there is a misuse of its registered mark of authority or a situation in which a certified product is found to be hazardous,” and the procedures to follow in initiating and completing corrective action. No clear definition of what constitutes a hazardous product or the timeframes in which a corrective action must be carried out is presented. The Canadian document follows the responsibilities of certification bodies internationally outlined in ISO Guide 27, “Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.” This document is of critical importance since certification or approval of a product is mandatory in Ontario.

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1.3 Why include the authority to order corrective action?

When Canadians purchase and use products, “they expect that as long as they follow directions, the product will be safe to use.” This, however, is not always the case since there may be defects in components, contamination of materials, problems in the production process or the presence of hazards that are not covered by existing standards. In any system designed to effectively manage the risks associated with electrical products, it is essential that government is able to respond quickly and appropriately to the risks detected or identified in either regulated products or those that are not covered by a regulation. One means of minimizing the risk posed by dangerous or potentially dangerous electrical products is for the supplier or certification body to take appropriate corrective action when a problem is identified. The purpose of such action is to eliminate the risk or to reduce it to an acceptable level.

It is also in the best interest of suppliers, certification bodies and field approval bodies to make sure that unsafe electrical products are effectively corrected or removed from the market. Voluntarily initiating appropriate corrective action reduces the possibility of being held liable if the product causes an injury or damage to property; reduces damage to reputation and brand name if a product causes harm; and reduces the possibility of or prosecution for non-compliance. In the case of certification bodies or field evaluation agencies, it could reduce the risk of revocation of their recognition. Many reputable businesses do take action against unsafe products. However, ESA can be faced with small companies or entrepreneurs who do not have the same motivation and are unwilling to carry out any corrective action if it is not part of the law. Moreover, since the obligations of certification bodies themselves with respect to correcting hazardous products are limited and not clear, it is important that ESA has the authority to order corrective action to protect the public.

It is arguably whether the legislative authorities provided by the former version of Part VIII of the Electricity Act, provided ESA with the authority to require those responsible to initiate corrective action. All that it could do was to request the supplier, certification body or field evaluation agency to voluntarily take action to correct the problem and warn the public of the hazard. The fact that suppliers, certification bodies and field evaluators were not required to take corrective action directly meant that electrical product identified as posing a danger to the public or workers were not always corrected or removed in a timely fashion.

One of the objectives of amending the Act was to improve this situation by providing ESA with the authority to respond quickly and at an early stage to hazardous or potentially hazardous electrical products.

1.4 What Corrective Action Requirements Exist Elsewhere?

1.4.1 Canadian Federal Government

The safety of a wide range of consumer products is the responsibility of Health...
Canada, through the administration and enforcement of the *Hazardous Product Act* (HPA), the *Food and Drugs Act* and the *Radiation Emitting Devices Act*.

The HPA covers "any product designed for household, garden or personal use" including products used "in sports or recreational activities, as lifesaving equipment or as a toy, plaything or equipment used by children." The HPA does not currently include any provisions that require those involved in the sale, importation or advertisement of consumer products to monitor the market and correct any hazardous products. Although no provisions for mandatory corrective action currently exist under the HPA, Health Canada encourages companies to carry out voluntary corrective action. If a supplier refuses to voluntarily recall a hazardous product, Health Canada can publicize the problem and, if the product is regulated and it does not conform to the regulation, it can seize the product or initiate prosecution procedures. To assist suppliers of consumer products, Health Canada has produced a guide on how to carry out an effective voluntary recall of an unsafe consumer product from the marketplace. The guide states that "Health Canada may request that a company initiate a recall when:

- a product does not comply with the applicable legislation; or
- a product poses an unacceptable risk to the health and safety of the consumer or user."

The Minister of Health, Tony Clement, in response to toy recalls, stated that his Department would be “looking at the gaps in the powers that we have and where we need to go further given the current situation.” It is possible that in the future mandatory corrective action requirements will be added to this Act as well.

There are no specific provisions for mandatory corrective action under the *Medical Device Regulations* of the *Food and Drugs Act*. These regulations, however, require manufacturers to report to the Minister when an adverse health incident has occurred inside or outside Canada with a product that is sold in Canada, and to report on any corrective actions being undertaken to deal with the problem including the recall of the product. The corrective actions that can be implemented to deal with an incident are outlined in section 61 of the regulations and include increased post-market surveillance of the device, corrective and preventive action respecting the design and manufacture of the device, and recall of the device. In addition, a manufacturer or importer must inform the Minister when a recall is to be undertaken and provide a strategy for conducting the recall and to prevent a similar problem from occurring again. If the Minister is not satisfied that the product is safe or effective, he can stop the sale of the product and/or suspend the license.

The Health Product and Foods Branch’s (HPFB) Inspectorate has produced a guide on how to carry out a voluntary recall of a hazardous consumer product, including the following recommendations:

- Ensure that a recall has been initiated.
- Notify suppliers and distributors of the recall.
- Provide clear instructions on how to return the product to the manufacturer or importer.
- Communicate with consumers to ensure they are aware of the recall.
- Conduct a post-recall audit to ensure that the problem has been corrected.

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document entitled *Health Products and Food Branch Inspectorate Recall Policy*\(^9\) that states what should be achieved by all parties planning for and carrying out corrective actions, including evaluation of its effectiveness. The guidance document is an excellent example of the type of information that is necessary in order for suppliers and others to comply with corrective actions. It clearly defines what is meant by a serious deterioration in health, one of the triggers for taking action to address a problem, the purpose of the corrective action, the information to be provided, the steps to be followed in reporting an incident, and the corrective action to be followed.

Manufacturers and importers must provide a preliminary report within 10 days on the course of action to be followed to correct a potentially dangerous medical device. Manufacturers, importers and distributors are held responsible for carrying out recalls. Although retailers are not held responsible for a recall, they are obligated to maintain records of reported problems and of actions taken to respond to these problems, and to have written procedures for investigating problem reports and conducting recalls. A final report on the corrective action must also be provided to the Minister.

The *Radiation Emitting Devices Act* which covers products that emit radiation including a number of electrical products (e.g. televisions, microwave ovens, ultrasound, x-ray devices) requires that a supplier report to the Minister any non-compliance with regulations or any product posing a risk. If the Minister determines that the product does not comply with a prescribed standard or creates a risk to any person of genetic or personal injury, impairment of health or death from radiation, he/she can direct the manufacturer or importer to notify such persons that the Minister requires of the defect or non-compliance.\(^10\) The Act is silent on any other mandatory corrective actions.

### 1.4.1 International Jurisdictions

#### 1.4.1.1 United States of America

A number of different government agencies at the federal and state levels are involved with addressing incidents involving electrical products. The corrective action that is undertaken in response to a report of an adverse incident depends on whether the report concerns a consumer electrical product, a medical device or an industrial product. Reporting of injuries or accidents related to consumer electrical products falls under the purview of the *Consumer Product Safety Act* (CPSA)\(^11\) administered by the Consumer Product Safety Commission (CPSC). In the case of medical devices the Food and Drug Administration is responsible while industrial incidents are the responsibility of Occupational Health and Safety authorities.

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\(^9\) Health Products and Food Branch Inspectorate, *Health Products and Food Branch Inspectorate Recall Policy, Policy-0016*, April 2006


\(^11\) Section 15 (b) of the Consumer Product Safety Act
The CPSC requires the manufacturer, distributor or retailer to notify all affected parties about a defect or failure when it determines that there is a substantial risk of injury to the public, either because of a violation of a consumer product safety standard or because of a product “defect.” Moreover, CPSC has the authority to order the supplier to bring the product into conformity, to replace the product or refund the purchase price.\(^\text{12}\)

A company can decide to undertake a ‘fast track’ recall of a hazardous product instead of waiting for an assessment to determine that a product presents a substantial risk and a recall is required. If a company, within 20 days of notifying CPSC of an unsafe product, implements a consumer level voluntary recall, the CPSC will be satisfied and no determination will be made that the product presents a substantial risk. Assistance is provided by CPSC to help companies determine what type of corrective action or recall is required to correct the problem and how to undertake the corrective action. In particular, their recall handbook\(^\text{13}\) provides detailed guidance and information about how to carry out a recall.

In order to identify products where corrective action is required, CPSC suggests that companies involved in the manufacture, importation, distribution, or sale of consumer products develop a system to monitor information about their products. Sources of this type of information include consumer complaints, warranty returns, insurance claims or payments, product liability lawsuits, reports of production problems, product testing or other critical analyses of products\(^\text{14}\).

A number of CPSC’s policies, procedures and documents developed in order to administer the CPSA’s provisions for corrective action (commonly referred to as recalls) are examples of practices that ESA and its stakeholders may wish to consider when developing a system in Ontario. These practices include:

- Clear hazard classification system;
- The publication of detailed information for suppliers on how and when to carry out corrective action;
- The establishment of a fast track recall system; and
- Corrective action for all types of hazards.

One of the weaknesses of the system is the inability of CPSC staff to share information about potential corrective action with other jurisdictions and the public prior to a corrective action strategy being developed.

In the case of medical devices, the Food and Drug Administration (FDA) under the Medical Device Reporting Regulation has established requirements for manufacturers, importers, and user facilities to report serious adverse events and take remedial action to correct them. If remedial action is not undertaken by a company the FDA has the authority to order corrective action.

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1.4.1.2 European Union

The safety of consumer electrical products in Europe falls under two Directives, the “Low Voltage” Directive (LVD)\(^\text{15}\) and the General Product Safety Directive (GPSD)\(^\text{16}\). The GPSD complements the LVD by covering certain provisions that are not contained in the LVD\(^\text{17}\). For example, the LVD like the GPSD “covers all risks arising from the use of electrical equipment, including not just electrical ones but also mechanical, chemical (such as, in particular, emission of aggressive substances) and all other risks.”\(^\text{18}\) As a result, the provisions of the GPSD would not apply. The LVD, however, does not include any requirements for producers or distributors to correct unsafe electrical products. The General Product Safety Directive (GPSD)\(^\text{19}\) introduces this obligation for producers to act to resolve any risks to consumers posed by their products. The producers may take these measures voluntarily and are so encouraged. If they fail to do so, the authorities can order them to inform consumers of the risks posed by the product, to withdraw the product from the market and, as a “last resort”, to recall and destroy it.\(^\text{20}\) In this situation, the obligations of producers and distributors included in the GPSD for monitoring their product on the market and correcting any problems reported apply to suppliers of consumer electrical products that fall under the scope of the LVD. A detailed guide to corrective action has been published in order to assist producers and distributors in meeting their obligations\(^\text{21}\). The guide provides information on how to prepare a corrective action strategy, assess the risk, decide on the appropriate action to take, implement the action and assess its effectiveness.

Since the power to recall products is such a powerful tool that entails considerable administrative discretion, when transposing the GPSD into regulations, the British added the right for a supplier to appeal a formal recall notice. The supplier under the UK regulations may request the enforcement authority to seek independent written advice from an individual nominated by the Chartered Institute of Arbitrators. The advice focuses on the issues of “whether a product is dangerous and whether recall is appropriate and proportionate to the seriousness of the risk.”\(^\text{22}\)

devices covers electrical defects that may affect the safety of the patient, users
or other persons when correctly installed, maintained and used for the intended
purpose. A Medical Device Vigilance System has been established to facilitate
direct, early and harmonised implementation of corrective actions across Europe.

The manufacturer of a medical device is required to report to the Competent
Authority in a member country of the occurrence, any adverse incident including
electrical ones, and the actions to be taken by the manufacturer to correct the
problem, within 10 days. Corrective action may include, but may not be confined
to: a device recall; the issue of a field safety notice, additional
surveillance/modification of devices in use; modification to future device design,
components or manufacturing process; modification to labelling or instructions
for use. A final report is made to the competent authority when the corrective
action is completed.

The National Competent Authority is required to monitor the actions of the
manufacturer and take further action to withdraw the device from the market if it
is determined that the device may compromise the health or safety of patients,
users or other persons. The authority must also inform the Commission of the
actions taken. Guidelines explaining the responsibilities of manufacturers and
authorities under the Medical Device Vigilance System were developed and
come into force January 2008.

If a CE marking, which is a declaration of conformity with the essential
requirements, is wrongly applied to a device, the manufacturer or his authorized
representative in the Community is obliged to end the infringement. If non-
compliance continues, the Member State must restrict or prohibit the placing on
the market of the device and ensure that it is removed from the market.

A number of Europe’s procedures and guides developed in order to administer
the provisions if the GPSD and the Medical Device Directive for corrective action
provide examples that ESA and its stakeholders may wish to consider when
developing a corrective action guideline for Ontario. These practices include:

- Detailed information on the responsibilities of manufacturers and
  authorities;
- Clear explanation of the factors to consider when assessing a risk;
- Detailed procedures to identify an appropriate corrective action and to
  implement it; and
- Instructions on how to assess the corrective action.

1.4.1.3 Australia

The majority of recalls conducted in Australia are initiated voluntarily by
manufacturers and suppliers when they become aware of a defect in a product
that poses a risk to the public. The Trade Practices Act obligates suppliers to

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European Commission, DG Enterprise and Industry, Guidelines on Medical Devices
Vigilance System, April 2007
notify the Minister for Consumer Affairs that they have initiated a recall within two days of taking action to voluntarily recall a product. This is then administered by the Consumer Safety Unit within Treasury Department who place the notice of the recall on the Recalls Australia website, www.recalls.gov.au, and monitor the progress of the recall by liaising with and sometimes auditing the company.

Under the Trade Practices Act, the Minister responsible for consumer affairs can order a compulsory recall of a product that will or may cause injury if the supplier has not taken satisfactory action to prevent the product from causing injury to any person or refuses to take action. Failure to comply with such an order may result in substantial fines.

A further significant type of recall occurs when the Australian Competition and Consumer Commission have uncovered unsafe goods in the market that do not comply with regulations. In such cases, companies are asked to conduct a recall, and to notify the Minister.

The majority of State electrical safety regulators have mandatory recall powers and regard a voluntary recall as mandatory for the purposes of enquiry and subsequent review. Manufacturers and importers are required to advise the regulator, who issued the certification or approval, of the basis for a recall, including:

- The type of equipment including brand/trade name/s and model number/s;
- The fault and its expected consequence;
- How the fault came to notice;
- Number of units found to have the fault;
- Cause of the fault – e.g. design defect, manufacturing process failure or bad workmanship;
- Total number of units manufactured or imported;
- Number sold to wholesalers and/or retailer;
- Number of units known or suspected to have the fault, and how this number was determined; and
- Details of the name and location of the manufacturer or importer.

In the case of medical devices, those responsible for the device are required to monitor the device on the market and implement corrective action commensurate with the nature and risks involved with the medical device. The manufacturer or importer then is obligated to assume responsibility for recovering the devices and for any corrective action deemed necessary. The Therapeutic Goods Administration’s Recall Co-ordinator assists by advising those responsible of the procedures, notifying agreed third parties and monitoring the overall action. Although most recalls are not mandated, the procedure is underpinned by the Therapeutic Goods Act which contains provisions for ordering recalls, safety alerts or product improvements undertaken by the manufacturer where devices fail to comply with a standard24.

1.5 Issues to be Considered

1.5.1 Electrical Products and Hazards Covered

Obligations under the Electricity Act, 1998 apply to all electrical products and devices governed by the Ontario Electrical Safety Code and adopted under Ontario Regulation 164/99, made under the Act. This includes consumer electrical products, electrical medical devices, and electrical products used in industrial settings and the workplace. Questions arise as to whether or not battery operated products such as hand tools should be covered by the authority to mandate corrective action. Currently, only the battery re-charger is covered. Under the legislation in the United States and the Directives in Europe, reporting of serious incidents involving battery operated products is required not just for incidents involving the re-charger as is the situation under the Ontario Electrical Safety Code. In addition, the question of whether corrective actions should be mandated by ESA or Health Canada for serious electrical incidents involving medical devices needs to be resolved.

In general, both electrical equipment intended for incorporation into other equipment (electrical motors, transformers) and equipment intended to be used directly without being incorporated is covered. This would not apply where the safety of the component depends on how it is integrated into the final product and the overall characteristics of the final product.

In Europe, the Low Voltage Directive covers all types of risks that may be exhibited by an electrical product and the same applies to the legislation administered by CPSC. In the area of medical devices, all types of hazards that could affect the health of an individual are covered. The regulations under the Electricity Act 1998 address those hazards covered by the safety standards that are part of the Ontario Electrical Safety Code.

1.5.2. Responsibility for Corrective Action

In the development of guidelines, one concern that arises is the issue of who should be responsible for carrying out corrective action. The amendment to the Electricity Act 1998 specifies that the authority (ESA) may “issue such orders relating to work to be done, or the removal of things used, in the installation, removal, alteration, repair, protection, connection or disconnection of any of the works...as the Authority considers necessary or advisable for the safety of persons or the protection of property and, in any such order or after having made it, the Authority may order any person to cease and desist from doing anything intended or likely to interfere with the terms of the order.”25 This provision is very broad to allow ESA the ability to order the appropriate party involved in the manufacture, wholesale, importation, distribution, sale, certification or evaluation of an electrical product to carry out any corrective actions that ESA considers to

be necessary to protect the health and safety of the public. In other jurisdictions such as Europe and the United States, the responsibility for identifying and implementing a corrective action falls mainly on the shoulders of producers (manufacturers or importers) and to a lesser extent distributors (distributors and retailers). Distributors are required to cooperate and keep producers informed throughout the corrective action. This approach recognizes the fact that different organizations in the supply chain have different abilities to plan and implement corrective action.

The responsibilities of certification bodies to develop and implement corrective action are specified in Can-P-1527\(^{26}\) which is based on the international ISO Guide 27 entitled “Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.” In order to maintain their accreditation, certification bodies are required to carry out the following corrective actions when a mark is misused or a product is found to be hazardous:

- Notify parties responsible for initiating a recall when it is deemed necessary to protect the public;
- Remove the mark of conformity from the product;
- Require the product to be rebuilt so that it complies with certification requirements or to be replaced; or
- Notify the public of the hazard.\(^{27}\)

The main problem related to this procedural document is the lack of guidance about what is meant by a hazardous product, which is responsible where more than one certification body is involved and the timelines for corrective action. By taking a broad approach and requiring all those in the supply and approval chain to carry out or assist in corrective action, the Ontario Government has increased the chances of reducing the risk to the public at an earlier stage.

In most jurisdictions, voluntary corrective action in response to products posing a danger to the public or workers is encouraged irrespective of whether or not it is possible for the authorities to order corrective action. The same development and implementation strategies as outlined in the guidelines could be followed when a company decides to voluntarily initiate a corrective action.

1.5.3. Criteria to Trigger Corrective Action

One of the factors that determine the ability of a business or organization to comply with a legislative requirement is whether or not they understand what is required\(^ {28}\). It is critical that any guideline explaining the process to follow in order to carry out effective corrective action clearly defines and communicates


\(^{28}\) OECD, *OECD Guiding Principles for Regulatory Quality and Performance*, Adopted April 2005, [http://www.oecd.org/topic/0,2686,en_2649_37421_1_1_1_1_37421,00.html](http://www.oecd.org/topic/0,2686,en_2649_37421_1_1_1_1_37421,00.html)
the criteria that should trigger corrective action. The inclusion of such definitions would minimize confusion among suppliers, certification bodies and field evaluation authorities and respect the legal codes and the Charter of Rights.

With respect to reporting under the new regulations, a report should be made when there is a “serious electrical incident or accident or a defect in the design, construction or functioning of an electrical product or device that affects or is likely to affect the safety of any person or cause damage to property.” Guidelines with respect to risk assessment are being developed to provide clarity to those responsible for electrical products.

In considering whether or not to imitate corrective action, basically those responsible for taking corrective action will need to identify the hazard, assess the risk, determine the best way to address the problem and evaluate the effectiveness of the corrective action. ESA would verify the proposed corrective action to ensure it adequately addresses the risks identified by ESAs risk assessment process.

1.5.4. Administrative Discretion

In a recent report prepared for Health Canada, the power of ordering a recall was described as a powerful tool that often entails considerable exercise of administrative discretion, which must accord with procedural fairness. The unfair use of orders for corrective action could result in a claim of damages for negligent over-enforcement. The trigger for corrective action which will be articulated in the guideline for risk assessment will clearly explain when and what type of corrective action is to be carried out. Such precise guidance will help to limit the administrative discretionary power of officials and thus lead to a system which is uniform and fair.

In addition, to ensure that those who receive orders issued by ESA are accorded fairness in administrative law, a regulation entitled the “Reviews and appeals of orders issued by the Electrical Safety Authority” was passed under the Safety and Consumer Statutes Administration Act, 1996. These regulations provide suppliers with the ability to request a review by the Director or a three member Review Panel.

1.5.5. Cost of Corrective Action

In principle, timely and efficient corrective actions can remove potentially unsafe products from the market place and from use, resulting in reduced injury and death. However, corrective action, particularly recalls, can be a very expensive measure for suppliers to undertake. In addition to the direct costs of undertaking the corrective action, such as notifying ESA, informing distributors and retailers, notifying the public, arranging for the return of products, advertising in the media, and dealing with enquiries, some types of corrective action can remove a
potentially profitable product from the market. Due to the trade between the US and Ontario and the firms selling the same product in both locals, the financial burden could be reduced if the system in Ontario was similar to the already well-established system in the US.

The success of a product recall is critical to business. The impact of a poorly handled product recall can be catastrophic not only to the safety of consumers and workers but also to an organization's reputation. Badly managed product recall processes lead to vastly increased costs, adverse publicity, loss of sales and potentially, closure of business. It is therefore imperative for businesses to gain and maintain the knowledge of how to manage a product recall effectively.

1.5.6. Effectiveness of Corrective Action.

The effectiveness of a recall to remove unsafe products from the distribution chain and hands of the public has been questioned. In a study, produced by the Department of Trade and Industry in the United Kingdom\textsuperscript{31}, the average return rate reported was 37 per cent (although eight recalls achieved rates of less than 10 per cent). The Australian Productivity Commission\textsuperscript{32} in reviewing the product safety system in Australia found the situation to be similar. As might be expected, return rates appear to be lower for low value products and higher for those that the supplier can trace to individuals. In carrying out any corrective action, it is necessary to monitor the level of response to any actions undertaken by keeping track of the number of unsold products returned by retailers, the number of products sold and the number of products returned. This information obtained should be analyzed to determine if further action is required.

1.5.7. Disposal of Faulty Products

The management of waste from disposed electrical and electronic products is becoming a major public policy issue due to concerns about the potentially hazardous material which these products may contain and the number of products that require disposal. Waste from electrical and electronic products may contain lead, cadmium, mercury, and other potentially hazardous materials. In a corrective action, it may be necessary to ask users to dispose of an electrical product, particularly low cost products, or for the firm to dispose of the product itself. It is important to ensure that any information provided to consumers requesting them to dispose of a product clearly outlines a method of disposal that does not cause environmental damage. In addition, any disposal method chosen by a supplier should take environmental issues to account. Any guidelines on corrective action that are published need to discuss the disposal of unsafe electrical products.


\textsuperscript{32} Australian Productivity Commission, Review of the Australian Product Safety System, Discussion Draft, July 2005, p277
1.5.8. Timelines for Corrective Action

The timelines for reporting on an electrical incident and the actions to be taken to address the problem can vary from 24 hours to 10 days. Moreover, in the United States, the time to plan and initiate a recall under CPSC’s Fast Track Recall Program is 20 days. In recognition of the fact that suppliers may not immediately have complete information on the cause of an incident, the associated risk or the extent of distribution of the product, guidance documents for Europe, the United States and medical devices in Canada recommend or require that producers and distributors give the authorities preliminary information about a product risk as soon as they are aware of it. The information could include details to identify the product or lot, a description of the incident and risk presented, available information on the number and location of products and a description of any actions proposed to be taken to address the problem. With this information the authorities may be able to help a manufacturer or importer carry out corrective action and protect the public more effectively. A more complete report or final report is submitted at a later date.

1.5.9. Standardization

The compatibility of the system in Ontario with that in the United States is of particular importance since many of the same electrical products are sold in both the US and Ontario. Companies that sell or distribute the same electrical products in the two venues are more likely to carry out corrective action in Ontario at the same time as in the United States if there are similar requirements. This would help address the problem of Canadian officials not learning of a corrective action until the US has made a decision and announced a recall. In the case of medical devices, the requirements and guidance for corrective action has been standardized with both the US and Europe.
This draft guideline has been developed to facilitate consultation and discussion. The ideas and concepts presented do not represent the official or final view of the Electrical Safety Authority.
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2.1 Introduction

Even the best businesses make occasional mistakes and no company likes having to take action to correct one of its products. But when a risk in a product is identified, it is to everyone’s benefit to move quickly to correct the product or remove it from the market. Effective corrective action not only ensures consumers’ and workers’ safety but enhances a business’s reputation and ensures everyone can have confidence in the safety of the products that they buy or use.

2.1.1 Purpose

Many companies faced with carrying out corrective actions find it difficult to know where to start. This guide is aimed at helping them understand their obligations and responsibilities under Part VIII of the Electricity Act, 1998 and providing them with advice on selecting, planning and implementing effective corrective actions. The guide will also provide suggestions on how to try to prevent the need for corrective action. It applies to manufacturers, wholesalers, importers, distributors, retailers, certification bodies and field approval agencies and to both voluntary and mandatory corrective actions.

This guidance document is designed to supplement the legislation and, if a conflict exists between this guidance document and the Act or regulations under the Act, the Act and regulations take precedence.

2.1.2 Scope

The guide covers all types of corrective actions that may be undertaken by those responsible for eliminating reducing or removing a safety risk arising from electrical products covered by the Ontario Electrical Safety Code including consumer products, electrical medical devices, industrial products and wiring products.

2.2 Preventing the need for corrective action

Unfortunately there is no guarantee that a company will never be faced with having to take corrective action to deal with an electrical product that was found to have caused serious injury or property damage. There are, however, certain steps that can be taken to prevent the need for corrective action.

- Ensure that all stages of production and distribution (design, manufacture, presentation and marketing) are focused on ensuring that only safe products are produced;
- Make sure that all electrical products comply with the relevant legislation, regulations and safety standards;
- Ensure that all products are certified to the appropriate standards;
- Check on all materials and components before production and introduce quality management systems for the production process;
- Set up systems to ensure a company can trace all the components used to make products and to record which products have gone where;
• Clearly mark products with lot numbers in locations that are accessible so that consumers can identify the products easily;
• Ensure that Instructions and/or warnings are easy to read and understand;
• Monitor complaints from consumers, distributors, and retailers so that potential safety problems are picked up at the earliest possible stage; and
• Monitor warranty and insurance claims.

2.3. What are the requirements for corrective action?

For the purposes of augmenting ESA’s ability to deal with product safety concerns, Part VIII of the Electricity Act, 1998 was amended in December of 2006 and proclaimed August 15, 2007 to provide ESA with the authority to order actions to correct noncompliant or harmful electrical products in order to protect the safety of persons and property. Section 113 (11) of that Act states:

“(11) The Authority may issue such orders relating to work to be done, or the removal of things used, in the installation, removal, alteration, repair, protection, connection or disconnection of any of the works, matters and things mentioned in subsection (1) as the Authority considers necessary or advisable for the safety of persons or the protection of property and, in any such order or after having made it, the Authority may order any person to cease and desist from doing anything intended or likely to interfere with the terms of the order.”

With respect to product safety, these orders will obligate manufacturers, wholesalers, distributors, importers, and retailers to establish and implement documented corrective actions for products in order to address safety problems with a product.

All electrical products sold within Ontario must be approved or certified to the safety standards under the Ontario Electrical Safety Code. Canadian Procedural Document, Can-P-1527, published by the Standards Council of Canada, identifies, for those who certify products, the conditions under which corrective action can be taken. These conditions include:

• When the mark of conformity is affixed to a product that is hazardous;
• When the product is not authorized to bear the mark;
• When the product bears an unauthorized form of the mark e.g. counterfeit product; or
• When the product is in violation of the certification agreement.

The document also presents the corrective actions that it can ask the party responsible for the product to take when “there is a misuse of its registered mark of authority or a situation in which a certified product is found to be hazardous” as outlined in section 1.2. and the procedures to follow in initiating and completing corrective action. The

Canadian document follows the responsibilities of certification bodies internationally outlined in ISO Guide 27 entitled “Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.” The risk assessment guideline will provide further information to determine which circumstances would appropriately require corrective action to be undertaken.

2.4. Goals of Corrective Action

In carrying out corrective action, a company should aim to achieve all of the following:

- Ensure hazardous or potentially hazardous products are corrected or removed from the market in a timely and effective manner;
- Minimize the risk of injury to the public and anyone else who might come into contact with the product;
- Comply with the law and limit any potential liability of your company;
- Minimize the cost and inconvenience to the consumer and the company;
- Protect the company’s reputation and brand image – and preferably enhance all of these; and
- Inform ESA when corrective action is initiated, with the results of the corrective action, and actions to prevent further such incidents.

2.5. Who is responsible for corrective action?

The responsibility for initiating, implementing and evaluating corrective action primarily rests on the shoulders of the company who either manufactured the product in Ontario or was responsible for importing it into Ontario either from another country or another part of Canada. In some instances, a retailer or distributor also imports products into Ontario and would be responsible for assessing the risks, monitoring the market and taking corrective action if required. The respective responsibilities will vary depending on circumstances and their ability to identify the hazard, assess the risk, determine the best course of action to take and to implement the action. The manufacturer or importer of a product into Ontario normally would be more knowledgeable about the product and its potential risks. Thus, they are responsible for matters affecting the safety of the product that are either directly or indirectly under their control, for monitoring serious electrical injuries or damage to property, for taking appropriate corrective action, for evaluating it and for reporting these to ESA. A distributor or retailer not involved with importation, however, would not have the same level of expertise and, thus, is responsible for exercising reasonable care within the limits of their capacity to influence the safety of the product, cooperating in the implementation of any corrective measures, collecting information on unsafe products and reporting adverse incidents to the manufacturer or importer and ESA. In Appendix 1, a diagram illustrating the different responsibilities is presented.

There may be situations where the supply chain is complicated. For example, a product or components may be sold under different brand names. Companies should consider having agreements with their suppliers defining their respective responsibilities to eliminate lengthy discussions on differences of opinion that will only delay the corrective action and make it less effective.
Certification bodies, in order to be accredited, are required to undertake certain types of corrective action if their mark is misused or the certified product is hazardous. The contribution of these organizations can be critical to the effectiveness of corrective action due to their expertise in assessing products and associated risks, the assistance they can provide in a corrective action and their responsibility to inform the public of hazardous products.

2.6. Criteria for Corrective Action

Corrective action in other jurisdictions such as Europe, the United States and for Medical Devices at Health Canada is required when a product or device presents a substantial risk of injury to the public. Where the hazards cause slight harm, where exposure is rare and it is possible to avoid, the hazard is classified as low and the corrective action involving outside parties may not be required. Manufacturers and importers are expected to identify the hazard and assess the risks in order to determine the type of action to be followed. The guidance document on risk assessment provides the details on the criteria to be used and how to carry out such a risk assessment.

2.7. Planning Ahead

The time for a company to develop a corrective action process and policy is before it is faced with correcting a faulty product. When it becomes aware that one of its products poses a risk to the public, acting quickly will be vital, and the company will not have the time to think through the process it needs to follow or to establish a team.

A corrective action plan normally includes:

- A policy stating the company’s goals and commitment to corrective action;
- Identification of a team, individual, or outside company with expertise in all aspects of the design, production, quality assurance, purchasing, distribution and marketing of a company’s products;
- Systems to collect and analyse incident reports, customer complaints, warranty claims, results of product tests or quality checks, returned products, or evidence of tampering;
- A means to identify products that are unsafe e.g. serial numbers, lot numbers, bar coding;
- A mechanism to determine where and to whom the products were sold e.g. warranty cards, retailers records;

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• Records of product design and material specifications;
• A list of everyone that needs to be contacted both within and outside the company;
• Procedures to assess any risks and carry out corrective action; and
• A protocol to measure the effectiveness of any corrective action and to determine what if any other measures need to be taken.

2.8. Identifying the hazard and assessing the risk.

In order to choose the most appropriate corrective action to address a problem associated with a product, a supplier will need to identify the hazard and assess the risks. This is where the knowledge and experience of the design, use, incidents, and hazards related to the product are brought together in order to determine the risks associated with the product and to implement any risk reduction measures deemed necessary. The guideline on risk assessment will outline the steps that need to be taken in assessing the risk and determining the best course of corrective action.

The assessment of any risks needs to be carried out by a person or group who are knowledgeable about the product and potential hazards. ESA must be provided with the risk assessment and course of action planned so that it can review the risk assessment and determine if the action proposed is adequate to correct the problem.

2.9. How to carry out a corrective action?

Although manufacturers and importers have the main responsibility for carrying out corrective actions, distributors and retailers have a significant role to play in assisting them. Moreover, certification bodies are obligated to take certain corrective actions if their mark is misused or a product is hazardous. A checklist to follow when carrying out corrective action was prepared by a number of organizations in Europe. A copy of this checklist can be found in Appendix 2 to assist you.

2.9.1. Identify products affected.

Ensure that all products that need to be included in the corrective action are identified. This may involve not only the products directly affected by the incident but also other brands or sizes of the same product. Information to identify each product affected may include the description, style, colour, brand, UPC code, lot number, item number, date of manufacture or date of import.

2.9.2. Determine the type of corrective action needed.

The first step after identifying the nature of the hazard associated with the product is to determine the need for corrective action and what form the corrective action should take in order to protect the public. In addition to the actual hazard or risk posed, other factors to be considered include the total number of products, type of consumer affected, the practicality of any action (e.g. including recalls), June 2004.
distribution network, recovery procedures, resources or corrective action) and its potential success, the advice of those responsible for the legislation, and the perception of the public about the risk. A business also needs to consider the legal consequences of not recalling, or of delaying the recall of a product which you know has a problem.

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 distribution chain;
- Modifying the product in the distribution chain, at retail, the customer’s premises (e.g. in the case of large domestic appliances) or elsewhere;
- Recalling the product from consumers or other users for replacement, modification or refund;
- Sending information and warnings about correct use of the product to users of the product;
- Return of the product by purchases for replacement or refund;
- Asking the consumer to dispose of the product and claim a refund.

With respect to those who certify products, corrective actions could take the form of assisting manufacturers, importers and ESA and the following:

- Notification of parties responsible for initiating a recall when it is deemed necessary to protect the public;
- Removing the mark of conformity from the product;
- Requiring the product to be rebuilt so that it complies with certification requirements or to be replaced; or
- Notifying the public of the hazard. 41

2.9.3. Who does the corrective action need to reach?

The corrective action to be initiated needs to reach anyone who is at risk from the hazard identified. This could mean contacting consumers, retailers and distributors of the product. In determining the method or methods to be used consideration must be given to the level of risk that the product presents. There are three main ways to go about contacting the distributors, retailers, owners and users of the product.

First of all, an organization can contact them directly by letter, telephone or internet if you know or can find out the names and addresses of all the businesses or people who distribute, sell or bought your product. Normally, such information would come from sales invoices, installation records, warranty cards or registration cards. The production of a distribution list identifying accounts who received the product and their addresses can assist. Contacting businesses and customers directly is probably one of the most successful and cost-effective ways of telling them about a corrective action. But as this relies on

knowing their contact details, it’s worth thinking now about how to set up systems to improve distribution and customer records. It will be necessary to instruct distributors and retailers to remove the product from sale immediately and customers to stop use. They will also need to know what will be done or what they need to do in terms of products that will be repaired, replaced, recalled or destroyed.

Secondly, retailers can play an important role as many retailers are collecting information on those who purchase products, particularly large appliances, or take out extended warranties.

Thirdly, when you have little or no knowledge of the owners or users of the products, you can try to reach them through:

- A press release which could be a joint press release with ESA;
- A news conference;
- Notification of distributors, retailers, installers, or other persons who may be involved with the product;
- Purchase of mailing lists of individuals or companies likely to use the product;
- Notification of repair stores;
- In store advertising;
- Advertisements in newspapers or magazines; and
- Company internet sites

The media or information release must contain sufficient details to uniquely identify the product, together with a clear outline of the problem (without causing unnecessary alarm) and must state the appropriate response by the target audience. A toll free telephone number of the company responsible, to allow 24-hour access to further information, should be given.

Where it is necessary to quickly notify consumers of unsafe electrical products on the Ontario market, a public notice should be issued that includes the following information:

- Name and location of the recalling company:
- A detailed description of the product, including name, make, model, distinguishing features, batch or serial number, retail cost, etc and a picture if possible:
- A statement of the hazard and associated risk:
- Dates when the product was available for sale:
- Retail locations where the product was sold:
- The immediate action that the consumer should take:
- Who consumers should contact for further information, including a telephone number, preferably toll-free, and hours of operation.

ESA may also post a notice on its website.
2.9.4. Inform and discuss proposed course of corrective action with ESA and other concerned parties

A company that is planning to undertake corrective action should inform and discuss with the staff of ESA its proposed corrective action plan. The plan must include the company’s agreement that ESA may publicize the terms of the plan in order to inform the public of the nature of the hazard and the actions being taken to correct the hazard. The staff of ESA will review the risk assessment, the appropriateness of the corrective action planned and approve the communication materials that a company plans to use. If ESA is not satisfied that the corrective action proposed will adequately address the risks identified, ESA will carry out its own risk assessment prior to ordering what it feels is the appropriate corrective action.

2.9.5. Carry out the corrective action.

The manufacturer or importer, with the assistance of distributors, retailers and possibly certification bodies, will have to carry out the corrective action decided upon across the province. It will be important to notify retailers and distributors immediately to stop selling or distributing the products. Any repairs, refunds or replacements should be carried out as quickly and efficiently as possible to limit the harm. Arrangements will have to be made to collect or repair the products from distributors, retailers and consumers and mail out replacement parts if appropriate. These unsafe or modified products should be clearly identified so that they do not return to the supply chain. With respect to recalled products, decisions will have to be made on what will be done with these products – disposal or refurbishing.

2.9.6. Monitoring the corrective action and assessing its success.

It is very difficult to measure the overall success of a action to correct a risk associated with a product, because most suppliers will probably never find out what has happened to all of their product. Their records will tell them how many products have been returned or modified, but they will not be informed about older products which had already been discarded, or items (especially cheaper ones) which have been thrown away instead of being returned.

Even bearing these factors in mind, it’s still useful to set a target response rate for a corrective action because it helps to assess whether or not the message about the action was as effective as possible. Instead of aiming for the same rate for all products, it is better to set targets that reflect the type of product, its age, and most importantly how much of a risk it presents. So whereas a low recall rate might be relevant for cheap low-risk items sold several years ago, a business will want to aim for a higher rate for more expensive products.

2.9.7. Report to ESA on effectiveness of corrective action

On a regular basis after corrective action is taken, the manufacturer or importer is to provide reports on the effectiveness of the corrective action that was undertaken to ESA. The reports are to contain the following information
(however, responsible parties are not required to repeat information in the final report that has already been given, unless there is a change to that information):

- The circumstances leading to the corrective action;
- The action taken;
- The extent of distribution of the relevant batch in Ontario;
- The result of the corrective action - quantity of stock returned, corrected, outstanding, etc;
- Confirmation, where practicable, that customers or consumers have received the corrective action notification or letter;
- The method of destruction or disposal of recalled goods; and
- The action proposed to be implemented in future to prevent a recurrence of the problem.

These reports establish the effectiveness of the corrective action. If satisfactory reports are not received, further corrective action may have to be considered.

The evaluation of the corrective action effectiveness should also assist the company in improving its corrective action plan for the future.
Appendix 1. Corrective Action Procedure Checklist

Key considerations for a successful corrective action are acting quickly and communicating effectively. Consumer safety and your company’s reputation may depend on these measures.

1. Plan ahead – before you have a problem
   · Establish a policy and procedure for corrective action
   · Discuss your policy with your trade partners
   · Set up a corrective action team
   · Monitor information about the safety of your products
   · Keep good records to help trace products and identify customers and end users
   · Assemble documents about your product’s design and safety
   · Update contact information for key people and organisations.

2. Decide whether to take action - assess the risk
   · Identify the hazard and its cause
   · Estimate how many products are affected
   · Identify who might be affected
   · Consider what severity of injury could result
   · Assess the likelihood of such an injury
   · Evaluate acceptability of overall risk.

3. If corrective action is needed – what to do?
   Decide whether the corrective action needs to involve:
   · Products in the supply chain and possibly
   · Products in the hands of consumers
   · Decide what corrective actions need to be carried out
   · Agree responsibilities and actions with distributors
   · Inform market surveillance authorities.

If the action involves products in the hands of consumers you need to:
   · Trace the products and their owners
   · Set up a communications programme
   · Draft any corrective action message clearly and simply
   · Decide how to communicate the message
   · Deal with your consumers
   · Communicate with others who need to know
   · Carry out corrective action on the products
   · Deal with products that have been returned
   · Monitor the response to the corrective action and decide if further action is needed.

4. After corrective action – learn from experience
   · Review design standards and improve quality systems to try to avoid future problems

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· Assess the success of your corrective action procedure and make any improvements
· Send comments and thanks to key participants.
Consultation on Guidelines for Corrective Action

Appendix 2.  Product Supply Chain

Product Supply Chain

Producers
Primary suppliers of product into Ontario who have the ability to influence the safety of a product and are responsible for manufacturing or importing the product into Ontario from another Province/ Territory or country

Distributor
Secondary suppliers who have limited ability to influence the safety of consumer products

For practical purposes, ‘producer’ is defined in two ways - either as the first placer of the product on the Ontario market or as someone whose activities may affect the safety of the product.

‘Distributor’, in contrast, is any professional in the supply chain whose activities do not affect the safety of a product. This can include distributors, wholesalers, and retailers. It is noted, however, that a distributor or retailer who is involved in the assembly of a product or is responsible for importing it into Ontario may affect the safety of a product.