AMDEA™
The Association of Manufacturers of Domestic Appliances

Code of Practice

GUIDANCE ON CORRECTIVE ACTION INCLUDING RECALLS AND GENERAL PRODUCT SAFETY REGULATIONS

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Contents

1. Introduction

AMDEA promotes the view that product safety is of utmost importance. Members should ensure that their products are designed, tested and manufactured to be compliant with the safety requirements of the markets in which their products are to be sold.

The purpose of this Code of Practice is to provide a guide for AMDEA Members regarding corrective action requirements in accordance with EU Directives, UK Regulations, British and European Standards. The Code has been prepared taking into account guidance issued by the UK government and the European Commission. It recommends practice above minimum legal requirements in some cases to ensure the highest level of protection.

It should be noted that countries that are not full members of the EU but are at the candidate stage or countries such as Switzerland and other EEA countries could have additional requirements beyond those indicated in this Code.

The requirements will be different for all countries outside the EU and AMDEA Members must ensure that they are aware of, and comply with, all relevant regulations and laws.

The safety requirements for appliances are detailed in international and European standards. These standards are under constant review and revision so as to ensure that they reflect the state of the art as regards protection and technology. AMDEA informs its Members about the changes to these standards, which in turn provide a presumption of conformity with legal safety requirements within the EU.

There are, however, occasions when a design or manufacturing problem raises a concern about the safety of a product and it is necessary to take corrective action. The General Product Safety Regulations 2005 (the UK law implementing the 2001 General Product Safety Directive) and Commission Decision 2010/15/EU (otherwise known as the RAPEX guidelines) provide a source of reference and state the following:

- Producers/distributors have a duty to 'notify' the relevant National Authorities as soon as they suspect they have sold products within the EU that do not comply with the essential requirements of the Low Voltage Directive and/or other applicable Directives concerned with product safety (e.g. the General Product Safety Directive). The relevant National Authorities are those of any country within the EU in which the product has been placed on the market.
- National Authorities have powers to issue safety notices requiring the producer to take action – anything from warning about the risks of using the product to a complete recall taking all products back from the consumer.
- The European Community Rapid Information System (RAPEX) applies when there is more than one country affected. If there is only a single country involved then only the National Authority of that country needs to be notified. If, however, an AMDEA Member's Home Authority is not within the country affected, it is recommended that the Home Authority is still made aware of the notification.

LEGAL OBLIGATION

General Product Safety Directive (2001/95/EC) – Article 5(3):
Producers and distributors of consumer products must inform the competent National Authorities where they know that a product they have placed on the market poses a serious risk to consumers.

2. This Code of Practice

- Sets out organisational arrangements that would enable businesses to monitor incident reports and conclude what action should be taken;
- Defines a method for conducting a market risk assessment;
- Recommends steps necessary for implementing corrective action;
- Recommends areas to review following corrective action; and
- incorporates procedures from the guide 'Product Safety in Europe'

Appendices 5 and 6 explain in a concise way how the General Product Safety Regulations work, the responsibilities of the people in the supply chain, and the powers of Local Authority officials to intervene and require action.

Implementing the recommendations in this Code will help AMDEA Members to have systems in place to deal with product safety problems, to cooperate with National Authorities such as Trading Standards Departments (TSD), and meet their legal obligations. A company which follows this Code will enhance its reputation for dealing with its customers.

This Code of Practice incorporates requirements from the EMARS/PROSAFE Corrective Action Guide.

3. Scope

This Code of Practice covers products marketed by AMDEA Members. AMDEA Members should use this Code to create policies and procedures specific to their own products, company practices and quality management.

This Code of Practice covers all types of corrective action aimed at reducing safety risks from products that have been placed on the market.

It should be noted that this Code has been written with respect to RAPEX guidelines and as such does not include the requirements of countries outside of the EU. Where AMDEA Members place products onto markets outside the EU it is the responsibility of that Member to be aware of, and comply with, the requirements and regulations within that market.

Appendix 2 of this Code details a risk assessment procedure that follows RAPEX guidelines. It should be noted that countries outside the EU may use a different risk assessment method which may give different results.

4. Planning and Preparation

4.1 Plan ahead

In order to ensure effective corrective action, the producer should have a written plan laying down procedures for monitoring product safety and taking all necessary action.

The corrective action plan should enable the producer to:

- Monitor safety complaints;
- Assess any risk identified;
- Identify when it is necessary to notify the National Authorities if there is a product which poses a ‘significant risk’ or ‘serious risk’;
- Take appropriate corrective action where required; and
- Comply with global, European and national legislation concerning the safety of products.

4.2 Things to consider

In order to ensure effective corrective action, producers should have and maintain:

- A way of identifying products, e.g. model number and serial/batch number;
- Records for traceability of materials and components;
- Records for traceability of spare parts;
- Records for traceability through distributors;
- Adequate records regarding products sold including, where possible, a database of owners of its products; and
- Agreements with trade partners on how they will capture and retain data on owners of their product.

5. Monitoring, Data Collection and Risk Assessment

AMDEA Members should establish a safety monitoring team.

It should be responsible for the monitoring, data collection and risk assessment activities in accordance with a defined documentation retention policy.

The team should have expertise in the following functions:

- Design;
- Production;
- Quality assurance;
- Product service and after sales;
- Product safety standards;
- Distribution;
- Internal and external communications;
- Legal; and
- Risk management (including insurance liability considerations).

In small organisations more than one function may be the responsibility of one person or some may be carried out by outside organisations.

Procedures should include systems to collect and analyse the following information:

- Reports of incidents and complaints involving their products directly or via retailers, Fire Brigades etc.;
- Information from service engineers, both the company's own service personnel and independent service agents;
- Reports on returned components and products;
- Guarantee/extended warranty claims;
- Insurance claims or legal actions;
- Reports from trading standards and other external bodies;
- Reports from the company's quality systems; and
- Results of product testing.

The team should have a written procedure for carrying out a risk assessment. When an AMDEA Member becomes aware of a potential product safety issue then a risk assessment must be carried out. The risk assessment will determine whether it is unacceptable and corrective action is needed – and the nature of that action.

The risk assessment needs to be carried out by a small team with experience of the product and statistical ability.

At the beginning of the process, the team shall ensure that the following information is available:

- A clear understanding of the issue[1];
- The root cause of the problem;
- An assessment of what could occur as a result of the problem;
- Details of any incidents/actions that have occurred as a result of the problem;
- Which products are affected;
- The number of products made;
- The number of products in stock;
- An estimate of the number of products still in use that may have the problem;
- Spare part lead-times for potential corrective action.

Using this data and any other relevant facts the team should review the hazard and potential risks. If appropriate, they should conduct a formal risk assessment. Appendix 2 contains a risk assessment procedure, but it is only an aid to assist the team, which must make its own decision. The conclusion of the risk assessment may be that:

- No action is necessary; or
- That the risk can be removed through internal action alone; or
- That market intervention is also necessary.

6. Establishing Corrective Action

AMDEA Members should establish a team for corrective. This team may include people/disciplines from the team described in Section 5 (Monitoring, Data Collection and Risk Assessment) plus the following, as appropriate to the circumstances:

- Purchasing;
- Sales and marketing;
- Distribution;
- External communications; and
- Internal communications.

Internal corrective actions could be:

- Changing the design of products;
- Modification of the manufacturing process;
- Improved quality control; and
- Changes to instructions or warnings.

Market intervention corrective actions could be:

- Information and warnings about correct use of products for consumers;

[1] It is not always possible to identify the root cause of a failure at the start of an investigation. If this is the case then AMDEA Members should not delay the process but should establish the most likely cause and proceed on that basis. If clarification subsequently becomes available then the process should be updated accordingly.

- Withdrawing products from the distribution chain;
- Modifying products at the customer's premises or elsewhere; and/or
- Recalling products from consumers for replacement or refund.

7. Corrective Action Implementation

This Code of Practice only deals with the identification, assessment and actions required for safety related issues from a regulatory viewpoint. It does not include any assessment of the commercial risk or any impact on reputation. AMDEA Members may choose to take actions above and beyond the recommended actions for business reasons.

7.1 Defining the level of risk

The risk conclusion may be one of the following and should give an indication of the action required:

A. Serious risk

Indicates that the level of risk is unacceptable and cannot be justified. Notification should be made within a maximum of **THREE DAYS** from the date on which you concluded that the product presents a **'serious risk'**.

European Commission guidance for the notification of dangerous goods, **Section 4.3 states:**

When there is a serious risk companies are required to inform the Authority(ies) immediately and in no case later than three days after they have obtained notifiable information.

In an emergency situation, such as when immediate action is taken by a company, the company should inform the Authorities immediately and by the fastest means.

What actions to take will depend on the type of product involved and a range of other factors. As such, a definitive list cannot be provided but could include some or all of the following, depending on whether product is still in production or not:

- Stop production;
- Immediate modification to product or process;
- Stop supply and withdraw from distribution;
- Rework in field;
- Recall.

B. High risk

Indicates that the level of risk must immediately be reduced. The following possible actions should be considered:

- Stop production;
- Immediate modification to product or process;
- Stop supply and withdraw from distribution;
- Rework in field.

Likely[2] notification **– you have a maximum of 10 DAYS from the date on which you concluded that the product presents a 'high risk'.**

It is worth noting that the RAPEX process is only applicable for risks that have been assessed as serious. If a risk is assessed as high and is also notifiable then the notification can be either via the Business Application (see Appendix 5) or directly to each affected state individually.

C. Medium risk

Indicates that the risk is not high but should be reduced as soon as practicable. The following possible actions should be considered:

- Modification to product or process;
- Amending instructions to consumers;
- Placing a warning on new product;
- Notification is not required.

D. Low risk

Indicates that the risk is not significant:

- Action unlikely;
- Notification is not required.

NOTE: Even though notification is not required this does not prevent any AMDEA Member from taking any form of action for commercial purposes.

When discussing risk and actions there may be comparisons with other products and the relative risk that these may present. The following part of EU Regulation (EC) No 765/2008 demonstrates that each risk assessment is independent.

The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

8. Notification Process

When a risk has been assessed as serious (or high) then there is an obligation to notify the relevant National Authority of every country where the product has been on sale. For cases within the UK this will be Trading Standards. The updated list of national Market Surveillance Authorities is available on the European Commission (DG Health and Consumers) website:
http://ec.europa.eu/consumers/safety/rapex/docs/article5_3authorities_completelist.pdf

[2] Official guidance uses the word 'likely' for notification of high risks rather than being mandatory. For clarity, AMDEA recommends that Members contact Trading Standards for high risks to discuss the situation and agree whether to notify.

The official notification method is ‘Business Application’. This is an online process by which companies can notify not only their Home Authority but also the Authorities of any other countries where the risk is also present.

The Business Application website is:
https://webgate.ec.europa.eu/gpsd-ba/index.do;jsessionid=NvQSW4N7nT2yPjBQVBlW4WW3GWFMWRvGbGZ4gCpMd5ryJVPRvz5p!1307198953.
Please also see Appendix 5 for more information.

As an alternative to Business Application, the Home Authority can use the RAPEX process to alert other Authorities if the product has been sold in more than one EU Member State. If AMDEA Members take this option they should obtain assurance from Trading Standards that the notifications have taken place.

Before completing a Business Application, AMDEA Members are encouraged to contact Trading Standards to discuss and agree the proposed actions. For cases where the risk has been assessed as high, the discussion can include whether a notification is appropriate.

9. Monitor Progress

When corrective action has started, AMDEA Members should have systems to record how many customers contact them and the number of products that could be handled.

This information should be analysed and monitored for a period of time and the risk assessment repeated to determine what further action is needed.

It is recommended that, as a minimum, the following records are kept:

- The number of appliances affected;
- The number of customer details held at the start of the action;
- The method(s) of communications used;
- A rolling tally of confirmed contacts with references to how they have been contacted;
- The number of completed corrective actions;
- The number of customers who have refused the corrective action;
- All processes and meeting minutes.

10. Completion of Corrective Action

The goal for AMDEA Members is to trace all defective products. However, in practice this may not be possible to achieve, e.g. if the original customer has sold on their appliance but has not kept a record of the new owner.

In cases where the corrective action is being carried out and a notification has taken place the appropriate National Authorities will normally need to accept and monitor the customer tracing process, product tracing rates and corrective action rates.

At some stage periodic analysis performed according to Section 8 will show that, as agreed with the appropriate National Authorities, the operation can be reduced in scale, but as a minimum monitoring should continue with service engineers instructed to be on the lookout for any remaining affected products.

It is important to assess the effectiveness of the corrective action. An appropriate analysis should be conducted to show that the risk has been eliminated, or reduced to a level acceptable to both the Member and the appropriate National Authority. Post corrective action product failures or customer reporting needs to be monitored to ensure that the corrective action has not created any new or unexpected risk.

11. Learning from Experience

When any corrective action has been carried out, those involved should take time to review what happened. The review should cover the reason for the action, the processes involved and the effectiveness of the action. The purpose of the review is to evaluate the robustness of the process and where any weaknesses are identified to ensure that these are improved upon.

11.1 Stop it happening again

Once the active stage is over, you need to identify if the problem was caused by a failure in any parts of your process and, if it was, to put things right to prevent a repetition.

The kinds of areas you should look at are:

- How you applied safety standards;
- Other safety design principles;
- The manufacturing process;
- Quality assurance;
- Product safety management systems.

If you were not directly in control of the design and manufacture of the appliance you need to ensure that the fault is traced to the correct part of the supply (or design) chain and that the supplier has gone through this process and put the resulting documentation on your file. If the fault has been traced to production or quality, then you should agree with and store the resulting control documentation.

Where the fault lies with the design of the product this should be reported back to the design function and also form part of the normal safety review to eliminate the fault from future products.

11.2 Review your corrective action procedure

Compile a report of the results of all the activities undertaken and:

- Assess their speed and effectiveness, including numbers of consumers or dealers dealt with compared with targets;
- Examine the quality of the interaction between team members;
- Evaluate each technique used, especially for external and internal communications;

- Discuss and agree within the team any changes required in policy, procedures and training;
- Report to your retail customers and your suppliers on the success of the corrective action and any improvements you have put in place – particularly any that affect them.

APPENDIX 1: Risk Assessment Procedure

What is risk?

In the field of product safety, risk is generally acknowledged to be a combination of a hazard and the probability that injury will occur. Risk describes neither the hazard, nor the probability, but both at the same time.

The term 'hazard' can be subject to different interpretations depending on the product and how, where and when it is used. So for this risk assessment process the hazard is further defined by the injury type and severity (see examples in Appendix 3).

Risk assessment

The following guidance is based on the framework found in Commission Decision 2010/15/EU (the 'RAPEX guidelines'), which is accessible online at:
http://europa.eu/sanco/rag/help/Journal.pdf

The aim of the guidance is to assist AMDEA Members in assessing the level of a risk and deciding whether a notification to National Authorities is necessary. The guidance in this Appendix is not exhaustive and AMDEA Members should judge each individual case taking into account the criteria set out in the guidance as well as their own experience and practices, other relevant considerations and appropriate methods.

A consumer product may present one or more hazards depending on the product and how, when, where, how long it is used for, etc. If one or more hazards are present it may be necessary to carry out separate risk assessments for each type of hazard to determine the highest overall gravity of outcome.

When several hazards, several injury scenarios or differing severities of injuries or probabilities have been identified, each of those should be carried through the entire risk assessment procedure in order to determine the risk for each. As a result, the product may have several risk levels. The overall risk of the product is then the highest risk level identified, because action on the highest risk level is normally the most effective way of risk reduction. Only in special cases may a less-than-highest risk be considered particularly important, since it may require specific risk management measures.

The potential of a hazard to materialise as an effect on health/safety will depend on the degree to which the consumer is exposed to that hazard. The exposure has to be assessed over the lifetime of the product and should include not only the intended usage but also foreseeable misuse. In addition, the exposure to certain hazards may in some cases involve more than one person at a time.

When determining the level of the risk presented by a product, consideration should be given also to the ability of the exposed consumer to prevent or react to the hazardous situation. This will depend on the evidence of the hazard, the warnings given, and the vulnerability of the consumer.

Taking into account the above considerations, the following approach may assist companies when deciding whether a specific hazardous situation caused by a consumer product requires corrective action and/or notification to the Competent Authorities.

It is recommended that assessments be carried out by a small team who have knowledge and experience of the product and its hazards. This team may have to make subjective judgements if objective data is not available and it is hoped this procedure will help them to make consistent and reasoned judgements about actual or potential risks.

This risk assessment process follows the following path:

- Identification of the hazard;
- Identification of the persons at risk;
- Creation of a step-by-step scenario by which the person becomes exposed to the hazard;
- Identification of the severity of the injury or fire;
- Calculation of the overall probability;
- Identification of the risk;
- Action guidance.

Identification of the product hazard

Hazard is the intrinsic property of the product in the way that it is being used that may affect the safety of a person, domestic animal and/or property. Consistent with the EU legislation, this Code of Practice assesses risk in relation to injury. An injury can result after a product has consequentially led to other property becoming unsafe.

Hazard may include environmental considerations such as when and where the product is being used.

It can appear in different forms and for products placed on the market by AMDEA Members the most likely hazards that will need to be assessed are:

- Mechanical hazards, such as sharp edges that can cut fingers, or tight openings in which someone can trap their fingers;
- Electrical hazards, such as from live electrical parts that can cause an electric shock;
- Heat or fire hazards, such as a heater fan that overheats, catches fire and causes burns;
- Thermal hazards, such as a hot surface that can cause a burn;
- Chemical hazards such as poisoning or skin damage;
- Biohazards such as mould, bacteria, Legionella, contamination of surfaces, etc.

NOTE: The above list is **not** exhaustive and is given for guidance only; it is the responsibility of AMDEA Members to consider the potential hazards of their own products.

Identification of the person at risk

The operator of any product will almost always be at risk from any hazard but for a risk analysis to be complete it must consider everyone that may be affected.

Although not exhaustive, as each product will be different, the following factors may help in the identification of those at risk:

- Is the product attended or unattended? – A fire in an unattended product could happen at any time and be undetected; therefore any person in the home would be at risk. Products that require charging should be considered unattended.
- Is it likely that the product would be left plugged in when not in use? – Consider how children could foreseeably interact with such products. It is worth remembering that not all sockets are switched like those in the UK.
- Does the hazard exist when the product is not in use? – An unstable product or a sharp edge would be accessible to vulnerable people at all times.
- Does the hazard extend beyond the product? – A part flying off could injure a bystander.
- Use of the product by a vulnerable person.

Scenario leading to injury

In order to assess the probability of an injury there has to be an analysis of the scenario in which the hazard is created, the person becomes exposed to the hazard and that the person becomes injured.

As paths to injury can be relatively complex, rather than making a single step with a high degree of uncertainty, the path is broken up into individual smaller steps which can be assessed individually and hence give greater confidence that the assessment of the overall scenario is correct.

Most injury scenarios consist of the following three main steps:

1. The product has a ‘defect’ or can lead to a ‘dangerous situation’ during its foreseeable lifetime;
2. The ‘defect’ or ‘dangerous situation’ results in an accident;
3. The accident results in an injury.

However, each of these three steps can be broken down into smaller elements giving greater confidence of the overall result.

When creating the scenarios it is important to consider not only the method and purpose for which the product is intended to be used but also reasonably foreseeable misuse.

Scenarios may well have to take into account different behaviours and reactions not only for competent adults but also for vulnerable and very vulnerable people.

Consider whether a vulnerable or very vulnerable person would identify a risk and how they might react, noting that vulnerable and very vulnerable people will have slower reaction times than might be expected.

Whilst AMDEA Members will normally provide some form of instruction, the assessment must also include reasonably foreseeable use or misuse of the product.

The assessment should take into account the whole of the life cycle of the product including distribution, sale, unpacking, installation use, maintenance and disposal.

Other factors that need to be considered are the effectiveness of warnings and safeguards – would these be read, understood and acted on?

Where multiple hazards, scenarios or persons at risk have been identified a risk assessment should be carried out for each combination.

NOTE: Risks levels are not cumulative and each assessment is independent.

Dynamic risks

Some risks, such as a sharp edge, would exist throughout the life of the product and so the probability of the injury occurring should reflect this. Other risks may vary in the time that they exist and also in severity. Examples of these 'dynamic risks' might include:

- A product in which a small number were fitted with an incorrectly rated component fitted that fails when first plugged in. Any product used more than once would have no hazard.
- A product where exposure to the hazard only occurs on assembly, once assembled there is no risk.
- A product where a failure mode occurs only after a certain life, this could be a screw coming loose or a part wearing prematurely.
- The existence of hazards at certain points during ownership of a product, such as cleaning a filter.

In cases such as these there may need to be multiple assessments to define the different levels of risk that occur as the product is owned or used. Risks that will occur in the future may allow a wider range of corrective actions to take place than would be possible in a reactive situation.

Where dynamic situations exist the timescales involved with the sales and distribution chain will also need to be taken into account.

Product volume

The risk assessment looks at the risk arising from any individual product. The identified risk to any given person is completely independent of how many products have been produced or that may be left in the field.

It does not matter how many products are affected, the requirement to report remains the same. However, the details of the corrective action may vary depending on the number of affected products and should form part of the discussions with the appropriate Authorities.

Tolerance of the results

A multi-step scenario method has been adopted to establish the probability in order to increase the accuracy of the assessment. However, it is inevitable that there will be doubt about some of the figures used unless there is established field data to rely on. Where this is the case, higher and lower figures should be estimated and the effect on the 'overall probability' tested. If the result changes the level of action required and the range of figures cannot be closed by testing or data then it is advised that the higher figure should be used but that this should be included in any communications with the appropriate Authority.

Risk level and action guide

The RAPEX guidelines include the following table which combines the probability with the severity of injury to establish the overall risk level.

Probability of injury during the foreseeable lifetime of the product		**Severity of injury or fire**			
		1	2	3	4
S	> 50%	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
	< 1/1 000 000	L	L	L	L

The risk levels are defined as follows:

S – Serious risk	Rapid action and notification required
H – High risk	Action required and notification likely
M – Medium risk	Some action, notification not required
L – Low risk	Action unlikely and no notification

These risk levels provide members with the actions as laid out in the RAPEX guidelines. However, AMDEA considers that in order to promote higher levels of product safety members might wish to view these as a basic requirement and err on the side of caution, potentially taking action where it is not indicated by the guidelines.

As such, there are three proposals which AMDEA members may wish to consider. The first two are an aid to the assessment process itself and the third looks at actions for high severity cases:

1. The introduction of a severity ranking of 0 to cater for injury or fire levels below that indicated in Appendix 3. This provides a mechanism to record risk assessments where there is no resulting injury or fire. A severity ranking of 0 would not require any corrective action but may still lead to a change for commercial reasons.

2. The inclusion of fire severity ratings. The assigned severity ratings 0-5 are based on the same definitions as for injury, with the link being the equivalent level of injury (including inhalation of toxic smoke) that could be expected from a fire of that ranking.

3. A consideration to surpass RAPEX guidelines for low probabilities of severities 3 and 4 and for example to take action should a risk of fatality be assessed as under a million to one. AMDEA Members may wish to go beyond the RAPEX guidelines and so assign a higher risk level, appropriate for that product and the circumstances of its use. AMDEA Members could, therefore, take corrective actions even though the RAPEX guidelines do not indicate that this is necessary.

NOTE: This Code of Practice does not advocate that AMDEA Members assign risk levels below what is in the RAPEX guidelines.

The RAPEX guidelines use a fraction based value system of 1/100 etc. for the overall probability of injury.

Some AMDEA Members may prefer to use a decimal system as shown below, the results will be the same as the fraction based system and this has been included to allow for personal/company preference.

Probability of injury during the foreseeable lifetime of the product		**Severity of injury or fire**				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

Injury severity rankings

The following table is a quick reference guide for injury severity rankings – the official RAPEX rankings can be found in Appendix 3.

Injury severity reference	Fire / smoke severity reference	Ranking
No injury	No fire and no damage	0
Minor injury – No professional first aid	No fire, potential for minor injury	1
Medium – Injury requiring assistance from a medical professional	No external flames, small amounts of smoke	2
Serious – Injury requiring stay in hospital	No external flames, large amounts of smoke	3
Very serious – Potential for death	External flames, large amounts of smoke	4

How to carry out a risk assessment

The first step is to identify the product fault and the hazard(s) associated with that fault. Where there is more than one hazard conduct assessments for each one.

It is important to define and record which product(s) are affected, where the products have been sold, sales figures, whether there are any records of injury claims and manufacturing or service records relating to the failure mode.

Example. *A toaster has an internal wire which connects the outside casing to an earth. The connection to the earth can come loose and the free wire end can touch a live part making the metal casing live. The hazards would be electrical shock and burn. The toaster is still manufactured and sold in the UK and Europe. There have been no claims of shock or injury. The earth is 100% checked on the production line. Service and repair of toasters over six months old shows corrosion of the screw connection to the earth in 80% of cases. The fault is due to an incorrect washer material causing bi-metallic corrosion.*

Once the hazard has been identified, the next step is to review the severity ratings (see Appendix 3) and to see the range that might apply. It is important that an assessment is made for each severity because it is not always the most severe injury that creates the highest level of risk.

Example continued. In this example, the fault would be exposure to a mains supply in which case the severity could range from nothing (below the threshold of perception) through to electrocution with severity 4.

The next step is to establish who is at risk. It is important to consider whether the hazard exists at all times or only under certain conditions. At each condition it is necessary to assess all the ways in which someone could be exposed to the hazard. This will include deliberate use, unintentional contact, cleaning, moving or playing with the product.

Example continued. *It would be expected that a toaster might be plugged into the mains at all times and that the socket would not be switched off. It could be reasonably expected that a toaster would be positioned on a work surface away from the reach of very young children. It would, however, be within the reach of older children and adults of all abilities. In this design of toaster both the live and neutral are disconnected when the toaster is not activated but the fault is internal and there*

is no effect on the performance of the toaster. Therefore anyone who touches the toaster whilst it is cooking toast is at risk.

At this stage the first section of the risk assessment can be completed.

General description of hazard	Electric shock hazard from the casing of a domestic electrical toaster	
Product(s) under assessment	Nice 'N' Brown UK and EU	
Have any cases of this hazard been reported?	**Y**	Loose wires have been found but no shocks reported
Are Vulnerable or Very Vulnerable persons at risk? Explain reasoning	Although the risk only exists when the appliance is in operation, the hazard is not visible so vulnerable adults and older children would be at risk.	
Risk assessment completed by	John Smith	
Risk assessment reviewed and approved by	HiTeq Ltd safety committee	
Date completed or updated dd/mm/yy	14/02/2011	

Once the hazard, severity and person at risk have been established, the scenario by which they become exposed to the hazard has to be detailed. Each separate step should be noted, this may be a relatively simple list or it could be complex depending on the individual situation. A different scenario will be required to achieve each severity rating.

Example continued. *In this case, the first thing that has to occur is that the earth wire comes loose. The wire then has to touch the live terminal; the metal casing of the toaster can now be live. A person touching the casing would receive an electrical shock and the severity of the shock would depend upon the effectiveness of the path to ground (or neutral). A person exposed to a live part whilst touching an earthed object would be expected to have a bigger shock than a person who is otherwise electrically isolated.*

As the level of electrical shock can vary it will be necessary to work through several risk assessments. In this case it is easier to assign a severity rating and then work through a scenario which would create that rating.

Once a scenario has been established a probability has to be established for each step. The format of the probability is unimportant and can be assigned in whichever way is easiest. E.g. 1/10, 0.1 or 10%. It is important to assign each probability as accurately as possible, ideally the value would be evidence based from records or testing. This will not always be possible so experience or judgement may have to be used and where this is the case it is normally better for the value to be discussed or reviewed by more than one person – always remember that where user interactions are included, the probability will be based on that person and not that of the person making the assessment.

The reasoning behind each probability value should be noted down both for peer review and as a record.

Once a probability has been assigned for each step of the scenario, the overall probability can be calculated by multiplying all of the individual probabilities together.

By reviewing overall probability and the severity rating in the ‘risk level and action guide’ the result for this scenario is ‘medium’ which does not require notification. However, since there is a range of possible severities the process should be repeated for each.

Hazard Scenario	Hazard type and location	Severity of hazard	Probability of Hazard		Overall probability	Risk	Explanatory notes
The earth connection breaks and the wire comes loose. The loose wire touches the live connection. The user touches the casing whilst the toaster is in use. The user is not earthed.	Electrical shock on the finger or hand of user	1	The earth connection breaks and the wire comes loose.	0.95	0.045	Medium	From the service records when considered over the life of the product it is almost certain that the wire will break
			The loose wire touches the live connection.	0.05			Due to the heating cycles of the toaster it is probable that the wire will droop downward. The size of the live conductor is approx. 10% of the area the wire could fall into but it is in the centre. Over the life of the product the wire could move and touch the live conductor so a value of 0.5 or 50% has been allocated.
			The user touches the casing whilst the toaster is in use.	1			Whilst the metal might get hot and discourage touching, there will almost certainly be some form of contact.
			The user is not earthed.	0.95			In most situations it would be expected that the user would have a poor or negligible contact to earth.

In the above table a medium risk is calculated. This calculation is also shown in the below tables, which are the AMDEA versions of the risk level tables (fraction and decimal) found in the RAPEX guidelines. In each case the medium risk is circled.

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	> 1/2	L	H	S	S	S
	> 1/10 to < 1/100	L	M	S	S	S
	> 1/100 to < 1/1000	L	M	S	S	S
	> 1/1 000 to < 1/10 000	L	L	H	S	S
	> 1/10 000 to < 1/100 000	L	L	M	H	S
	> 1/100 000 to < 1 000 000	L	L	L	M	H
	> 1/1 000 000 to < 1/10 000 000	L	L	L	L	M
	> 1/10 000 000	L	L	L	L	L

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	S	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

In the second scenario, most of the individual steps are identical in both description and probability. In this scenario the severity rating has been placed at the highest, 4, and the final risk result is 'serious' – rapid action and notification are required. A severity of 3 would have the same result and a severity of 2 would also require similar action.

Hazard Scenario	Hazard type and location	Severity of hazard	Probability of Hazard		Overall probability	Risk	Explanatory notes
The earth connection breaks and the wire comes loose. The loose wire touches the live connection. The user touches the casing whilst the toaster is in use. The user is earthed.	Electrical shock on the finger or hand of user	4	The earth connection breaks and the wire comes loose.	0.95	0.0024	Serious	From the service records when considered over the life of the product it is almost certain that the wire will break
			The loose wire touches the live connection.	0.05			Due to the heating cycles of the toaster it is probable that the wire will droop downward. The size of the live conductor is approx. 10% of the area the wire could fall into but it is in the centre. Over the life of the product the wire could move and touch the live conductor so a value of 0.5 or 50% has been allocated.
			The user touches the casing whilst the toaster is in use.	1			Whilst the metal might get hot and discourage touching, there will almost certainly be some form of contact.
			The user is earthed.	0.05			In most situations it would be expected that the user would have a poor or negligible contact to

Hazard Scenario	Hazard type and location	Severity of hazard	Probability of Hazard		Overall probability	Risk	Explanatory notes
							earth. However in a kitchen there may be wet surfaces, taps, stainless steel worktops or sink units which could provide a low resistance path to earth.

In this particular example once the casing earth has been lost there is a risk that a different fault could also result in the casing becoming live but since the assessment of the loose wire has arrived at notification there is no need to assess any other risks. If the assessment had led to no action required then all other risks would need to be assessed separately.

The below tables illustrate the positioning of the risk using the AMDEA risk level tables (fraction and decimal) for a second time.

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	> 1/2	L	H	S	S	S
	> 1/10 to < 1/100	L	M	S	S	S
	> 1/100 to < 1/1000	L	M	S	S	S
	> 1/1 000 to < 1/10 000	L	L	H	S	S
	> 1/10 000 to < 1/100 000	L	L	M	H	S
	> 1/100 000 to < 1 000 000	L	L	L	M	H
	> 1/1 000 000 to < 1/10 000 000	L	L	L	L	M
	> 1/10 000 000	L	L	L	L	L

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

APPENDIX 2: Severity Ratings

In order to establish a meaningful risk assessment the severity of the potential injury or fire has to be established.

The RAPEX guidelines advise four separate and increasing criteria with the following definitions:

1. Injury or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible.

2. Injury or consequence for which a visit to A&E may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete.

3. Injury or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.

4. Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10% of disability.

The following severity ratings for fire and injury are provided for guidance for the most predictable type of injuries, where an injury type is not included the rating should be made according to the four definitions shown above. It should be noted that for injuries the ratings are for guidance rather than being prescriptive. National and cultural differences may apply but any deviation must be justifiable should the change result in a lower overall risk be assigned.

Type of injury	**Severity of injury**			
	1	**2**	**3**	**4**
Laceration, cut	Superficial	External (deep) (> 10 cm long on body) (> 5 cm long on face) requiring stitches Tendon or into joint White of eye or cornea	Optic nerve Neck artery Trachea Internal organs	Bronchial tube Oesophagus Aorta Spinal cord (low) Deep laceration of internal organs Severed high spinal cord Brain (severe lesion/dysfunction)
Bruising (abrasion/ contusion, swelling, oedema)	Superficial ≤25 cm2 on face ≤50 cm2 on body	Major > 25 cm2 on face > 50 cm2 on body	Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest	Brain stem Spinal cord causing paralysis
Concussion	—	Very short	Prolonged	Coma

Type of injury	Severity of injury			
	1	2	3	4
		unconsciousness (minutes)	unconsciousness	
Entrapment/ pinching	Minor pinching	—	(Use as appropriate the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable.)	(Same outcome as for suffocation/ strangulation.)
Sprain, strain, musculoskeletal disorder	Extremities Joints Spine (no dislocation or fracture)	Knee ligaments strain	Ligament or tendon rupture/tear Muscle tear Whiplash	—
Dislocation	—	Extremities (finger, toe, hand, foot) Elbow Jaw Loosening of tooth	Ankle Wrist Shoulder Hip Knee Spine	Spinal column
Fracture	—	Extremities (finger, toe, hand, foot) Wrist Arm Rib Sternum Nose Tooth Jaw Bones around eye	Ankle Leg (femur and lower leg) Hip Thigh Skull Spine (minor compression fracture) Jaw (severe) Larynx Multiple rib fractures Blood or air in chest	Neck Spinal column
Crushing	—	—	Extremities (fingers, toe, hand, foot) Elbow Ankle Wrist Forearm Leg Shoulder Trachea Larynx Pelvis	Spinal cord Mid-low neck Chest (massive crushing) Brain stem
Amputation	—	—	Finger(s) Toe(s) Hand Foot (Part of) Arm Leg Eye	Both extremities
Piercing, puncturing	Limited depth, only skin involved	Deeper than skin Abdominal wall (no organ involvement)	Eye Internal organs Chest wall	Aorta Heart Bronchial tube Deep injuries in organs (liver, kidney, bowel, etc.)
Ingestion	—	—	Internal organ injury	Permanent damage to internal

Type of injury	Severity of injury			
	1	2	3	4
			(Refer also to internal airway obstruction where the ingested object gets stuck high in the oesophagus.)	organ
Internal airway obstruction	—	—	Oxygen flow to brain blocked without permanent consequences	Oxygen flow to brain blocked with permanent consequences
Suffocation/ Strangulation	—	—	Oxygen flow to brain blocked without permanent consequences	Fatal suffocation/ strangulation
Submersion/ Drowning	—	—	—	Fatal drowning
Burn/Scald (by heat, cold, or chemical substance)	1o, up to 100 % of body surface 2o, < 6 % of body surface	2o, 6-15 % of body surface	2o, 16-35 % of body surface, or 3o, up to 35 % of body surface Inhalation burn	2o or 3o, > 35 % of body surface Inhalation burn requiring respiratory assistance
Electric shock	(See also under burns as electric current can cause burns.)	Local effects (temporary cramp or muscle paralysis)	—	Electrocution
Neurological disorders	—	—	Triggered epileptic seizure	—
Eye injury, foreign body in eye	Temporary pain in eye without need for treatment	Temporary loss of sight	Partial loss of sight Permanent loss of sight (one eye)	Permanent loss of sight (both eyes)
Hearing injury, foreign body in ear	Temporary pain in ear without need for treatment	Temporary impairment of hearing	Partial loss of hearing Complete loss of hearing (one ear)	Complete loss of hearing (both ears)
Poisoning from substances (ingestion, inhalation, dermal)	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system	Irreversible damage to nerve system Fatality
Irritation, dermatitis, inflammation or corrosive effect of substances (inhalation, dermal)	Local slight irritation	Reversible eye damage Reversible systemic effects Inflammatory effects	Lungs, respiratory insufficiency, chemical pneumonia Irreversible systemic effects Partial loss of sight Corrosive effects	Lungs, requiring respiratory assistance Asphyxia
Allergic reaction or sensitisation	Mild or local allergic reaction	Allergic reaction, widespread allergic contact dermatitis	Strong sensitisation, provoking allergies to multiple substances	Anaphylactic reaction, shock Fatality
Long-term damage from	Diarrhoea, vomiting, local	Reversible damage to	Damage to nervous system,	Cancer (leukaemia)

Type of injury	Severity of injury			
	1	2	3	4
contact with substances or from exposure to radiation	symptoms	internal organs, e.g. liver, kidney, slight haemolytic anaemia	e.g. Organic Psycho Syndrome (OPS; also called Chronic Toxic Encephalopathy, also known as 'painters' disease'). Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nervous system	Effects on reproduction Effects on offspring CNS depression
Microbiological infection		Reversible damage	Irreversible effects	Infection requiring prolonged hospitalisation, antibiotics-resistant organisms Fatality

For fire, the severity ratings are based on the same definitions as for injury – with the link being the level of injury that could be expected from the fire.

Unlike assessments for injury, for fire the persons completing the risk assessment may have limited experience of how a fire might propagate through an appliance or spread beyond the appliance to the surrounding materials.

It is recommended that AMDEA Members carry out testing to determine what effect ignition sources may have on the appliance and how any subsequent fire might spread or consider the use of a third party expert to help with the assessment.

Whilst flames are an obvious burn hazard, smoke must also be considered. Large amounts of smoke can blind, disorientate and choke; it may also cause changes in behaviour to both vulnerable and non-vulnerable people. The risk assessment must take into account potential changes in response when a person is exposed to flames and smoke.

The other major difference between a product based risk and fire is that the fire and smoke will extend beyond the product and around the home. Consideration therefore has to be made for where the product is situated and where the people at risk may be.

For unattended products, products on stand-by and products on charge, then the possibility of people being asleep or otherwise being unable to respond should also be included in the assessment.

Severity of fire	Definition	Explanation
0	No actual fire or damage but potential for smell of overheating. Smoke and fumes possible.	No fire and no damage. Examples would be benign component failure or the typical end of life failure of an AC brushed motor.

Severity of fire	Definition	Explanation
1	Elevated surface temperatures. No flames, ejection of sparks or hot particles. Parts only melted or discoloured. Smoke and fumes possible. Self-extinguishing.	No risk of serious injury, possibility of minor skin burn or blister.
2	Fire contained within the product. No external flames but transitory sparking or ejection of particles may occur. Smoke release from the product but no damage to the property. Self-extinguishing.	An example might be an appliance with a metal enclosure inside which a plastic component actually catches fire. The level of smoke released might cause evacuation and a small degree of inhalation. If testing or evaluation indicates a large amount of smoke then severity 3 should be considered. Sparks and ejected particles should be tested to determine the likelihood of igniting anything outside of the appliance
3	Fire contained within the product, smoke released. Hot external surfaces. Smoke damage to property and surface scorching likely	Fire involves multiple components or sub-assemblies but is contained within the appliance.
4	Sustained flames external to the appliance, smoke release or explosion.	

Where an AMDEA Member does have specific knowledge of the product under consideration they can apply that knowledge and will be able to confidently apply severity ratings different to that shown above. Whichever rating is applied then records should be kept to support the decision.

Example *– A product has a connector that is at risk from corrosion and potentially could generate enough heat to ignite built up dust. If this had never occurred then the probabilities might be relatively unknown and so the resulting assessments would need to cover a wide range of severities and assign similar probabilities. However, if the failure had occurred many times and the resulting dust fires had always been contained within the machine then the Member would be able to assign greater probabilities to lower severity outcomes.*

APPENDIX 3: Worked Risk Assessment Examples

EXAMPLE 1

The example below has three different scenarios for a fault that can occur at any time due to customer action. Once the hazard is created the probability remains constant for the life of the product.

General description of hazard	Electric shock hazard from customers damaging cable insulation by running over the cable with a vacuum cleaner brushbar	
Product(s) under assessment	Floorvac Model 1A	
Have any cases of this hazard been reported?	**Y**	Common on older style upright vacuums
Are Vulnerable or Very Vulnerable persons at risk? Explain reasoning	Normally an attended risk but 'vulnerable' or 'very vulnerable' may be at risk if the machine is left plugged in with exposed conductor	
Risk assessment completed by	John Smith	
Risk assessment reviewed and approved by	Floorvac Ltd safety committee	
Date completed or updated dd/mm/yy	14/07/2010	

Hazard Scenario	**Hazard type and location**	**Severity of hazard**	**Probability of Hazard**		**Overall probability**	**Risk**	**Explanatory notes**
Customer runs over mains cable with vacuum cleaner, the cable insulation is damaged sufficiently to expose conductor material, the customer does not recognise the hazard, the customer touches a	Electrical shock on the finger or hand of user	1	Cust runs over cable	0.9	0.0016	low	Considered over the life of the product
			Insulation damaged to expose conductor	0.02			The cable needs to be in a specific orientation to be picked up even though the time to damage can be quite short
			Cust does not see or recognise hazard	0.1			
			Cust touches the live conductor	0.9			Entirely to be expected. Whether or not the machine was plugged in or not has not been included since they have not recognised whether

Hazard Scenario	Hazard type and location	Severity of hazard	Probability of Hazard		Overall probability	Risk	Explanatory notes
live conductor.							there is a hazard
Customer runs over mains cable with vacuum cleaner, the cable insulation is damaged sufficiently to expose conductor material, the customer does not recognise the hazard, the customer touches a live conductor, cust has good connection to earth	Electrical shock on the finger or hand of user	4	Cust runs over cable	0.9	0.00000016	low	Considered over the life of the product
			Insulation damaged to expose conductor	0.02			The cable needs to be in a specific orientation to be picked up even though the time to damage can be quite short
			Cust does not see or recognise hazard	0.1			
			Cust touches the live conductor	0.9			Entirely to be expected. Whether or not the machine was plugged in or not has not been included since they have not recognised whether there is a hazard
			Cust has good connection to earth	1/10 000 or 0.0001			Very unlikely to be touching cable and earthed item. The size of the cable contact is also very small
Customer runs over mains cable with vacuum cleaner, the cable insulation is damaged sufficiently to expose conductor material, the customer does not recognise the hazard, the machine is left plugged into a live socket, a vulnerable	Electrical shock on the finger or hand of user	1	Cust runs over cable	0.9	0.000034	low	Considered over the life of the product
			Insulation damaged to expose conductor	0.02			The cable needs to be in a specific orientation to be picked up even though the time to damage can be quite short
			Cust does not see or recognise hazard	0.1			
			Machine left plugged into live socket	0.95			Most users would leave the machine plugged in at some point
			Vulnerable person touches the live conductor	0.02			The damaged area is usually small and vulnerable people would usually be supervised

Hazard Scenario	Hazard type and location	Severity of hazard	Probability of Hazard		Overall probability	Risk	Explanatory notes
person picks up the cable and touches the exposed conductor.							

In the example above, for each of the three scenarios the risk is calculated as low meaning that action and notification is not required. The risks calculated in each of the three scenarios are, for illustrative purposes, also depicted in the AMDEA risk level tables found below.

Scenario 1: severity 1, overall probability 0.001 6, risk is low

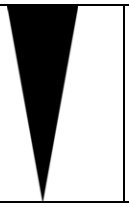
Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

Scenario 2: severity 4, overall probability 0.000 000 16, risk is determined as low

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

Scenario 3: severity 1, overall probability 0.000 034, risk is low

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M

	< 0.000 001	L	L	L	L	L

EXAMPLE 2

The second example is for a domestic heater, an appliance which would often be used unattended.

General description of hazard	The product poses a risk of fire because in case of operation with a reduced air supply the heating element does not switch off.	
Product(s) under assessment	Techno Star fan heater	
Have any cases of this hazard been reported?	**Y/N**	Unknown
Are Vulnerable or Very Vulnerable persons at risk? Explain reasoning	Yes as this is an unattended appliance	
Risk assessment completed by	Customer safety group of Advance appliances Ltd, Brand owner of Techno Star	
Date completed or updated dd/mm/yy	4th March 2011	

Hazard Scenario	**Hazard type and location**	**Severity of hazard**	**Probability of Hazard**		**Overall probability**	**Risk**	**Explanatory notes**
The fan is in heater mode, either the inlet or outlet are restricted, heating element melts housing and exposes hot parts, hot parts ignite material external to the appliance	Fire from unattended product	4	Fan is in heater mode	19/20	0.0002	Serious	Basic function of the machine
			Flow is restricted	1/100			Curtain, cloth or material
			Fan case melts away	1/2			Time and material dependant. Details not known for this case
			Flammable material on product	1/2			
The fan is in heater mode,	Electric shock and burn to	2	Fan is in heater mode	19/20	0.00009	Low	Basic function of the machine

Hazard Scenario	Hazard type and location	Severity of hazard	Probability of Hazard		Overall probability	Risk	Explanatory notes
either the inlet or outlet are restricted, heating element melts housing and exposes live hot parts, customer touches live parts	hand or finger		Flow is restricted	1/100			Curtain, cloth or material
			Fan case melts away	1/2			Time and material dependant. Details not known for this case
			Person touches live part	1/50			Relatively obvious hazard to non-vulnerable persons and uninviting situation to vulnerable and very vulnerable. Hot, probable smoke and smell
The fan is in heater mode, either the inlet or outlet are restricted, the air or radiant heat are sufficient to ignite a covering or nearby material	Fire from unattended product	4	Fan is in heater mode	19/20	0.00002	Serious	Basic function of the machine
			Flow is restricted	1/100			Curtain, cloth or material
			Temperatures are sufficient to cause ignition	1/5			Dependant on temperature setting and flow. Details not known for this case
			Flammable material within range	1/10			Relatively obvious hazard to non-vulnerable persons and uninviting situation to vulnerable and very vulnerable. Hot, probable smoke and smell

With this example, the risks are calculated as serious, low and serious. Once again, the three scenarios are also illustrated in AMDEA risk level tables, which are shown below.

Scenario 1: severity 4, overall probability 0.000 2, risk is serious

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

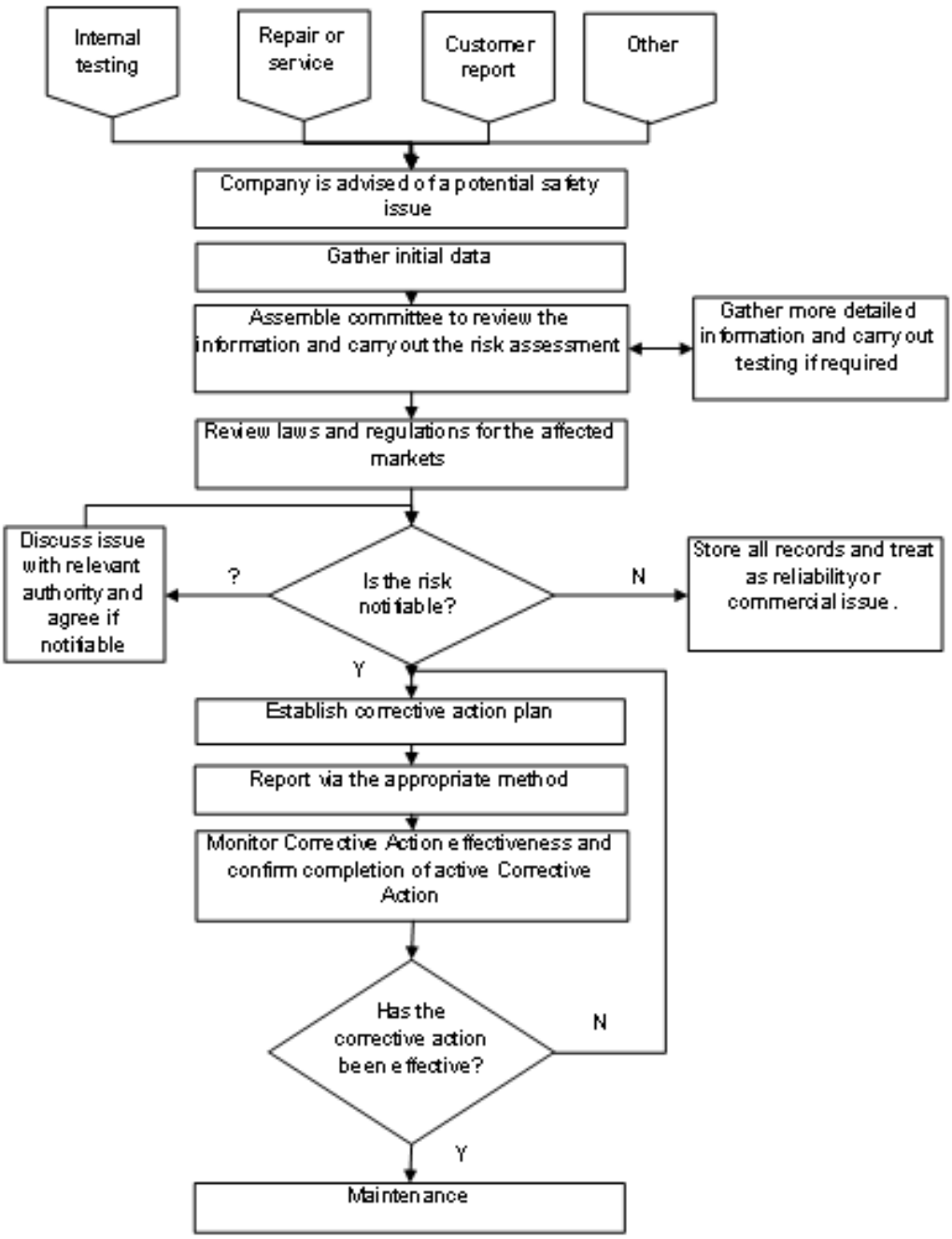
Scenario 2: severity 2, overall probability is 0.000 09, risk is low

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

Scenario 3: severity 4, overall probability 0.000 02, risk is serious

Probability of injury during the foreseeable lifetime of the product		Severity of injury or fire				
		0	1	2	3	4
	1 – 0.5	L	H	S	S	S
	0.5 – 0.1	L	M	S	S	S
	0.1 – 0.01	L	M	S	S	S
	0.01 – 0.001	L	L	H	S	S
	0.001 – 0.000 1	L	L	M	H	S
	0.000 1 – 0.000 01	L	L	L	M	H
	0.000 01 – 0.000 001	L	L	L	L	M
	< 0.000 001	L	L	L	L	L

APPENDIX 4: Process Flowchart



APPENDIX 5: Further Information on Business Application

The following is taken from the European Commission (DG Health and Consumers) website:

Business Application has been established in order to simplify practical aspects of the obligation of producers and distributors under Article 5(3) of the General Product Safety Directive to notify the Competent Authorities of Member States and EFTA/EEA countries (Member States) about a dangerous product they have placed on the market.

Business Application consists of two parts: 1) the notification form and 2) the online database.

- The notification form is intended for producers and distributors. They should complete and submit this form to inform the Competent Authorities of Member States via the Business Application that a product they have placed on the market is dangerous. All notifications will be sent to and stored in the online database.
- The online database is intended exclusively for the Authorities of Member States responsible for receiving notifications on dangerous consumer products submitted by producers and distributors. In the database, the National Authorities can view and process notifications sent by businesses.

It is recommended that AMDEA Members read the guidelines and manual before completing and sending the notification to the Competent Authorities of Member States through Business Application.

Business Application is accessible at: http://tinyurl.com/3jsr4v9

APPENDIX 6: References

References are listed below in order of first citation in the Code of Practice:

General Product Safety Regulations 2005, UK Statutory Instrument No. 1803
[AMDEA Doc. Ref. 1985A09]

Commission Decision 2010/15/EU 'laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)'
http://tinyurl.com/3uu5bkm
[AMDEA Doc. Ref. 1148A10]

Directive 2001/95/EC 'of the European Parliament and of the Council of 3 December 2001 on general product safety'
[AMDEA Doc. Ref. 2064A09]

'Product Safety in Europe: A Guide to Corrective Action including Recalls', PROSAFE *et al.*, 2004
[AMDEA Doc. Ref. 1787A04]

Regulation (EC) No 765/2008 'of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products' (This is more commonly known as 'RAMS' or the 'RAMS Regulation')
[AMDEA Doc. Ref. 3327A09]

EN 60335-1 'Household and similar electrical appliances - Safety - Part 1: General requirements' [New edition due to be published late 2011, based on the IEC 5th Edition, for draft material please consult **AMDEA Doc. Ref. 2738A10**]