Version 3.1, 1.12.2013

Joint Market Surveillance Action on GPSD Products 2012
Risk Assessment

Risk Assessment, Tips and Tricks

Introduction
This memo is being prepared by the PROSAFE risk assessment working group to provide guidance to market surveillance officers doing risk assessment.

The idea behind risk assessment
The idea behind a risk assessment is to find out how risky a non-compliant product is to a consumer. This is done by analysing the hypothetical situation where a non-compliant product is put it in the hands of the consumer.

The situation is hypothetical because it presumes that it is possible to identify the non-compliant products, something that is practically impossible for many products (one example being fireworks). It is also presumed that the product is indeed in the hands of a consumer. Something that in practice will only happen during certain parts of the year and only for the group of consumers that have bought the product (one example being furniture for outdoor use that is only used for a few months every year).

When you consider this presumption, it becomes clear that a number of further conditions should not be included in a risk assessment, e.g.:

- The share of defective products. The risk assessment presumes that the user is using a non-compliant product, even if it is only “one in a million” products that does not comply.
- The share of the population that uses the product. The risk assessment only considers the situation where a user actually uses the product.
- The frequency and duration of use. The risk management only consider the situation when the product is actually used and not situations when the product is e.g. stowed away or not used and therefore not dangerous to the consumer.

The share of defective products, the share of the population that uses the product (i.e. the exposure) and the duration and frequency of use should be taken into account in the risk management process when deciding on appropriate measures to handle the risk.

(Frequency and duration may influence the scenarios in a more indirect way: Daily use could make a consumer so familiar with the product that the risk decreases. One can also imagine the opposite; that daily use leads to user fatigue where the user ignores instructions and warnings, thus increasing the risk. Finally, daily or long-term use may accelerate the wear of a product, which could increase the risk. Such issues must be considered when developing the scenarios, estimating probabilities and determining the injury level.)

The situation (the scenario) should analyse an “average consumer”, that is a consumer without extraordinary skills or experience about the product. The analysis should also expect the consumer to behave “normally”, i.e. not overly carefully or overly silly.

Links between risk assessment and risk management
The relations between compliance assessment, risk assessment and risk management are as follows:

1. First, you test if the product meets the safety requirements. Normally, a test laboratory or a market surveillance officer will do this using a (harmonised) standard. (Compliance assessment.)
2. If the product fails to meet one or more requirements, you carry out a risk assessment to see how risky the non-compliant product is.
3. If the product represents an unacceptable level of risk to the consumer, you take appropriate measures to manage the risk - risk management.
   Risk management uses several inputs to decide on the appropriate measure:
   - The risk level identified in the risk assessment.
   - The number of products on the market.
   - The share of non-compliant products.
   - The frequency of use of the product.
   - How easy it is to remove the risk.
   - The consumer type that is at risk.
   - How obvious the risk is for the consumer.

   And other factors as well. Risk level is only one input to the risk management process.

If a business provides statistical data showing that the number of products is huge, the share of non-compliant products is low, and the product is only used in short periods during a year, the authority should consider this information in the risk management process, but not in the risk assessment.

A standard scenario

All risk assessments (of GPSD products) should follow a scenario like "You take a non-compliant product, you put it in the hands of the consumer, and then you see what happens."

Experience shows that most scenarios will fit into a generic "standard scenario":

Step 1: The product is used. (The probability is 100 % as this is one of the presumptions behind the risk assessment. Therefore, this step could also be left out.)

Step 2: The product is non-compliant. (The probability is 100 % as this is another presumption behind the risk assessment. Therefore, this step could also be left out.)

Step 3: The user behaves in a way that triggers the dangerous situation. (With a certain probability lower than 100 %. One example could be that the product is only dangerous if it is used in an unintended way, e.g. an electrical appliance that is used outdoor in rainy weather.)

Step 4: The non-compliance manifests itself. (With a certain probability lower than 100 %. The user may not always be exposed to the hazard. One example being the hammer case where the hammerhead is made from brittle material. If the hammerhead is "almost strong enough", the user will have to use much force to break it.)

Step 5: The user is injured. (With a certain probability lower than 100 %. Even hazardous products do not necessarily cause injuries. One example being a small part that comes off the hammerhead in the hammer case. If it hits the eye there are several outcomes – the eye may be severely damaged so the customer is blinded, the eye may have a superficial scratch that heals by itself, etc. Each of these outcomes have their own probabilities that would add up to 100%. Each outcome would correspond to a separate scenario.)

Each step in a scenario represents one possible further development on the path to the injury. If you consider step 5 as an example, you presume that you are in the situation where a non-compliant product is being used by a consumer (as described in step 1 and 2), the user behaves in a way that triggers the dangerous situation (step 3) and the non-compliance manifests itself (step 4). Several other developments are possible from this situation – the user could suffer from a severe injury, from a lighter injury, from a superficial injury or from no injury at all. The scenario must describe one and only one of these outcomes. When estimating the probability for the selected outcome, one should consider that the probabilities of all the possible outcomes must add up to 100%.

Sometimes the scenario becomes more logical if steps 3 and 4 are swapped.

It may also be useful to split one or more steps into smaller "substeps" to make it easier to estimate the probability.

The table below shows a couple of examples.

How to include protective measures

Protective measures include anything a user may do to reduce or eliminate a risk, e.g. parental supervision of children, use of personal protective equipment, check a product for small parts before giving it to a child, etc.

Such measures should not be included in the scenarios unless it is broadly accepted or even compulsory to apply them when using the product. The generally accepted approach to safety is that products must be designed in a way that makes them safe. If this is impossible, the user must be warned and informed about proper and safe use of the product. If information in itself does not reduce the risk sufficiently, the user is required to use protective measures when using the product. This must be indicated in the warnings and instructions for the product. (In general, it is not necessary to apply protective measures to use consumer products and toys safely. Such products must be safe in themselves and it is not acceptable to require the use of additional protective measures to make their use safe.)

There are some important cases where it is impossible to use consumer products or toys safely without protective measures. Some examples are:

- Experimental (toy) sets for chemistry and related activities as covered by EN 71-4 that requires parental supervision to be safe for the child.
- Powerful tools like chainsaws that requires the user to wear personal protective equipment.
- Motorbikes where the use of a helmet is mandatory in most countries.

If a risk assessment is made for such a product, the scenario should presume that the user would take the common protective measures.

If research, statistics or “common knowledge” indicate that it is reasonably common not to take protective measures, they should be disregarded in the scenario. Examples could be research showing that a high share of installed residual current breakers do not work or statistics showing that many user of chain saws do not wear the recommended protective trousers.

The scenarios should not expect the user to behave extraordinarily carefully or extraordinarily silly, and the results of the risk assessment should support the idea of “safety by design”.

Examples

	Exploding lighter	Breaking hammerhead	Duck with loose beak	Candle with flammable seeds
The non-compliance	5 out of 50 lighters are overfilled	Brittle material in hammer head	Easily detachable beak (small part)	Small flammable seeds in candle
Product hazard	Lighter fuel expands as it heats up. At 75ºC it fills the lighter entirely so it breaks and the gas escapes.	Parts of head break off when hammer is used.	The beak can get stuck in a child's throat if swallowed.	The seeds may catch fire and generate high flames.

	Exploding lighter	Breaking hammerhead	Duck with loose beak	Candle with flammable seeds
Injury scenario	The lighter is left on the dashboard of a car in summer in clear sunlight. The lighter heats up and ruptures so the gas escapes. The gas puts the car on fire.	The hammerhead breaks when a user uses the hammer. Parts fly off and into the user's eye and blinds the user permanently.	A child detaches the beak and puts it in the mouth. The parents don't notice. The small part goes into the child's airways and surgery is necessary.	The candle is burning. The seeds catch fire and generate high flames. Furniture or curtains catch fire. A person in the room inhales toxic fumes and dies.
Step 1: The product is used	100%	100%	100%	100%
Step 2: The product is non-compliant	100%	100%	100%	100%
Step 3: The user behaviour triggers the dangerous situation	The lighter left on the dashboard of a car: 1/10	The user hammers with a force that exceeds the braking force of the material: 10%	A child bites in the beak: 100%	The candle is ignited and left unattended while burning: 100%
Step 4: The non-compliance manifests itself	Fuel temperature increases above 75ºC: 90%	The hammer head breaks: 100%	The beak is detached: 100%	The seeds catch fire: 90%
	Lighter ruptures, gas escapes: 100%			
Step 5: The user is injured	The gas catches fire before escaping from the car: 10%	The broken part hits the user: 1/10	Parents don't notice: 50%	Nearby curtains catch fire: 50%
		The part hits the face: 1/3	Child puts beak in mouth: 100%	Persons are in room (sleeping): 1/1.000
	The car catches fire and burns: 10%	The part hits the eye: 1/20	Beak gets deep into the child's airways: 1/1.000	Persons inhale toxic fumes: 100%
		The user is permanently blinded on one eye: 1/100		Person dies: 50%
Resulting probability	9/10.000 (>1/10.000)	1/600.000 (>1/1.000.000)	1/2.000 (>1/10.000)	9/40.000 (>1/10.000)

Questions and Answers

Q: A test has shown that 2 out of 13 pieces of fireworks (rockets) explode at a too low altitude. Shall I use a probability of 2/13 in the second step ("the product is non-compliant")?

A: No. We always assume that the user has hold of a non-compliant product. In this case, the risk assessment must presume that the probability is 100% for having a non-compliant product. (The share of non-compliant products should be taken into account later on in the risk management, when the appropriate measure is decided.)

Q: I have to do a risk assessment on an overfilled lighter. This particular non-compliance disappears gradually when the user has used some of the gas. How do I take that into account?
A: The risk assessment always works from the presumption that the product is non-compliant, so it should analyse the situation when the non-compliance is present. (The fact that the non-compliance disappears over time and the duration that the non-compliance is present should be taken into account in the risk management phase, when the appropriate measure is decided.)

Q: The product only becomes non-compliant when it gets old and wears out. How do I take that into account?
A: The risk assessment always works from the presumption that the product is non-compliant, so it should analyse the situation when the non-compliance is present. (The fact that the non-compliance only appears when the product wears out should be taken into account in the risk management phase, when the appropriate measure is decided.)

Q: Two toys have small parts. The small part on Toy A comes off at 80N while it requires 10N for Toy B. How is this taken into account in the risk assessments?
A: This difference is seen in the fourth step ("the non-compliance manifests itself"). Imagine that 100 Toy As were given to 100 children. All toys are non-compliant, but only few children will be able to tear off the small part as it requires a force that is close to the value that is considered safe (90N, please see EN 71-1). Therefore, the probability in step 4 for Toy A must be low. If the same experiment is carried out with Toy B, it is much more likely that the small part comes off, so the probability must be higher.

Q: I consider a folding chair where the folding mechanism may cut the user's finger. It is only used outdoors for one or two months a year and it will only be dangerous if the user wants to move the chair. Should I take that into account in step 1 ("the product is used")?
A: No. We always assume that the user is actually using the product, so the probability of step 1 should be 100%. (The outdoor use and the limited annual time of use should be taken into account later on in the risk management, when the appropriate measure is decided.)

Q: I consider a scenario where a small projectile from a toy gun hits a child in the eye and the eye gets a permanent damage. Is the probability 100% for this injury once we know that the projectile hits the eye?
A: No. If a projectile hits an eye there are several possible outcomes: The eye is so heavily damaged that the consumer loses his sight on that eye; the eye is damaged so the consumer's sight decreases; the eye suffers from a superficial scratch; nothing happens; etc. The probabilities of all these outcomes must add up to 100%, so the probability of each individual outcome must be less than 100%.

Annex: Risk Assessment of Protective Products

Introduction

Protective products are any products that consumers use to reduce the risk of a dangerous situation. This includes all kinds of PPE (Personal Protective Equipment), protective electrical equipment like fuses and residual current breakers, helmets for bicycles, motorbikes, riding or skating, car seats for children, etc. etc.

The challenge in assessing the risk of a protective product is that it is seldom dangerous in itself. Rather it exposes the user to a dangerous situation because the user relies on the protective properties of the product. It still means that the product can "represent a serious risk" in the sense of the RAPEX guideline, even though one can argue that the risk is caused by the situation and the use of the product and not the product itself. This is in fact similar to many other risk assessments where the risk only becomes apparent when the consumer uses the product. One example is the hammer case where the hammer in itself is safe, but it becomes dangerous when the user starts to hammer on hard material with it.

Risk assessment of protective products would follow the standard approach: "You take a non-compliant product, you put it in the hands of the consumer, and then you see what happens." It would normally also fit into the 5-step generic standard scenario:

1. The product is used. (The probability is 100 % and the step may be omitted from the scenario.)
2. The product is non-compliant. (The probability is 100 % and the step may be omitted from the scenario.)
3. The user behaves in a way that exposes him to the dangerous situation. (With a certain probability lower than 100 %.)
4. The non-compliance manifests itself. (With a certain probability lower than 100 %.)
5. The user is injured. (With a certain probability lower than 100 %.)

The scenarios should reflect "a common worst case behaviour". They should not expect the user to act overly silly or overly carefully.

The table next pages shows a number of examples of standard scenarios for protective products.

Examples

	Residual current device	Motorbike helmet	Protective mask	Visibility vest	Socket protectors	CO detector
The non-compliance	10% of the RCD's do not interrupt earth currents	The helmet is inadequately fixed to the user's head	The mask is permeable to toxic fumes	The reflecting stripes only have half of the required size.	The socket protector sticks to the pins of electric plugs	The detector can only detect CO in high concentrations
Hazard	The user may get a dangerous electric shock from a faulty appliance connected to AC mains.	The helmet may come off if a motorbike driver falls with his motorbike.	The user will use paint that emits toxic fumes and get intoxicated.	The user will walk in a dark street where car drivers cannot see him and will run him over.	The socket protectors may come off leaving the socket outlet unprotected.	The user may be exposed to dangerous concentrations of CO.
Injury scenario	The user has connected a faulty appliance. He touches it. The RCD does not disconnect the current and he gets a fatal electric shock.	The driver is wearing the helmet while driving on his motorbike. He falls and the helmet is torn off. He gets a severe head injury (coma).	The user is painting the floor in a closed room. He uses paint that emits toxic fumes assured that the mask protects him. He inhales toxic fumes and gets intoxicated.	The user walks in a dark street wearing the vest. A car driver does not notice him in time. The user cannot escape from the road so he is hit by the car and gets severe injuries.	An adult disconnects an appliance and pulls the plug out. He does not notice that the socket protector comes off. A child picks up a small metal pin, sticks it into the socket outlet and suffers a fatal electric shock.	The user has ignited his fireplace. It produces CO because of too little in-feed of fresh air. The user does not notice, is intoxicated and dies.
Step 1: The product is used	100%	100%	100%	100%	100%	100%
Step 2: The product is non-compliant	100%	100%	100%	100%	100%	100%

	Residual current device	Motorbike helmet	Protective mask	Visibility vest	Socket protectors	CO detector
Step 3: The user behaviour triggers the dangerous situation	The user connects a faulty appliance: 0,1% (Guess: 0,1% of all households have at least one faulty appliance.)	The driver falls in a way that requires helmet protection to avoid injuries: 25% (Guess: 25% of all motorbike drivers will experience such falls in their lifetime.)	The user will paint and wear the mask: 100%	The user will walk on a dark street under poor visibility conditions: 100%	The user will pull out the plug and not notice that the protector comes off: 1/10.000 (Guess: Highly unlikely event.)	The user will ignite his fireplace: 100%
Step 4: The non-compliance manifests itself	The user touches the faulty appliance and gets a shock: 100%	The driver will lose the helmet: 20% (Depends upon the particular helmet. Can be verified in a test.)	The user inhales toxic fumes: 100% (Depends upon the characteristics of the mask.)	The car driver does not see the pedestrian in time: 1% (There is some reflexion from the vest.) The user can't escape from the road in time: 10% (Guess.)	The child finds a long thin metallic pin: 10% (Guess. Not common to have lying on the floor.) The child inserts the pin in the socket: 100% (Almost inevitable due to the curiosity of children. Will depend whether installation requirements require socket outlets to be installed above a certain height.)	The fireplace produces and emits CO because if insufficient fresh air: 1/10.000 (Guess: 1 in 10.000 houses may have insufficient fresh air intake if e.g. windows are closed because of cold weather.)

	Residual current device	Motorbike helmet	Protective mask	Visibility vest	Socket protectors	CO detector
Step 5: The user is injured	The user gets a fatal electric shock: 1/1.000 (Guess. Normally you will be able to let go immediately if you accidentally touch an appliance.)	The driver gets a skull fracture: 10% (Guess.)	The user suffers a severe intoxication: 1% (Guess. Normally, you will get a headache or become dizzy firstly. That would cause you to leave the room.)	The user is killed in a fatal crash: 5% (Guess.)	The child will touch live parts in the socket outlet: 50% (Only one pole is energised.) The child will suffer a fatal electric shock: 20% (Guess. A child lying on the floor, sucking the metallic pin makes good electrical contact, which increases the current.)	The user is intoxicated: 25% (Guess. CO makes people sleepy, then fall asleep, so they die in their sleep.)
Resulting probability	1/1.000.000	5/1.000	1/100	5/100.000	1/1.000.000	4/100.000
Injury level	4	3	3	4	4	4
Risk level	Medium risk	Serious risk	Serious risk	Serious risk	Medium risk	Serious risk