Risk management and the R-map

***Matsumoto Koji*, Products Safety Advisor in Products Safety Technology Centre, Japan presented a seminar at the China Quality Association and the Japan Science and Technology League in June 2010. His address, entitled 'Product safety management and risk plot (R-Map) method', has been translated by Chong Zhao and we bring it to your attention.**

Revolving door causes death

At 11:30 am on March 26, 2004, the revolving door of the Roppongi Building in Tokyo killed a 6-year-old boy, Mizoguchi. The boy's head was stuck firmly between the door and the column.

This incident had a tremendous impact within Japan, and the media set about investigating revolving door accidents. Their results showed that accidents caused by revolving doors were far more serious than people realised.

Revolving doors were chosen in many modern Japanese buildings to ensure the stability of air pressure and temperature. Between 1994 and 2004, approximately 500 large automatic revolving doors were installed in buildings, causing hundreds of accidents and even, in one case, a death.

The newspaper, 'Asahi Shimbun', published the following data on April 20, 2004 – injuries and deaths caused by large automatic revolving doors included: 1 death (in the Roppongi Building); 23 serious injuries (fractures of the foot or waist); 110 moderate and mild injuries (collision, laceration, and bruises); and 137 accidents with no reported injury.

The Roppongi Building has 45 large automatic revolving doors and within its first year after opening there were 32 crushing and collision accidents, 10 of which required paramedic first aid.

Do these doors need to be recalled, repaired or should the safety risk be ignored? Of the 45 revolving doors in the Roppongi building, should any such problem be rectified?

A Japanese public opinion poll showed that 60% of respondents think that the country's large automatic revolving doors (500 in total) should be recalled, and 40% commented that they should be improved. But for the Roppongi building, almost 100% of the respondents wanted the doors recalled.

The Government made a mandatory recall for all revolving doors in the Roppongi building, preventing the said building from reopening until the revolving doors had been changed to sliding doors. This put an end to revolving door accidents in the building.

However, was a total recall necessary for one accidental death? Couldn't the matter have just been rectified? What else should the government do to allay the public's concerns?

Using the risk plot method: R-map

The Japanese government purchased a risk plot method (R-Map) in order to create a common, visible platform to help bridge the communication gap. This method creates a common language for disclosure of information and leads to consensus. For example, one of the key benefits of an R-map is that it can make the government's decision-making more convincing, gives companies a clear reason why their products are being recalled, and brings the public on side.

The R-Map was first set in 2004 by the Japan Science and Technology Development Alliance. This risk management approach is a visible tool based on the life cycle of products and services, enabling risk assessment to be conducted, and gives an early warning of a possible recall. The R-map uses different aspects of development, design, manufacturing, sales, use and disposal.

> R-map is a visible tool based on the life cycle of products and services

It has been adopted by Japanese and international manufacturers of home appliances, office equipment, medical equipment and parts. Since 2008, some government administrative agencies have begun to use it to monitor 8000 kinds of industrial products. It is being used as a reference for public safety early warning management and it also encourages organisations to reduce risks continually in a competitive environment.

Currently, there are many risk management tools on the market, such as Risk matrix, Pre-Hazard Analysis / risk analysis of the production process (PHA), Fault Tree Analysis (FTA), Failure Mode and Effects Analysis (FMEA), Hazard and Operability / Operation Analysis (HAZOP), Hazard Analysis and Critical Control Point (HACCP), etc.

Developed in Asia, the R-Map has drawn interest from throughout the world and is being promoted by the Japanese government. During the next five years it is anticipated that it will be more widely accredited and used within the international market place.

R-Map: the method

According to the risk management standard, ISO / IEC Guide 51:1999, safety is achieved by reducing risk to a tolerable level. Tolerable risk is determined by the search for an optimal balance between the ideal of absolute safety and the demands to be met by a product, process or service, and factors such as benefit to the user, suitability for purpose, cost effectiveness, and conventions of the society. There can be no absolute safety: some risk will remain, defined in this Guide as residual risk. Therefore a product, process or service can only be relatively safe.

If there is any risk which hasn't been identified in the stage of product development, we can try to collect and analyse the usage data after release of the products to market. This data can then be fed back to the development stage, thereby providing product safety usage information so the necessary control measures can be taken.

R-Map works for risk management in four steps (see Figure 1).

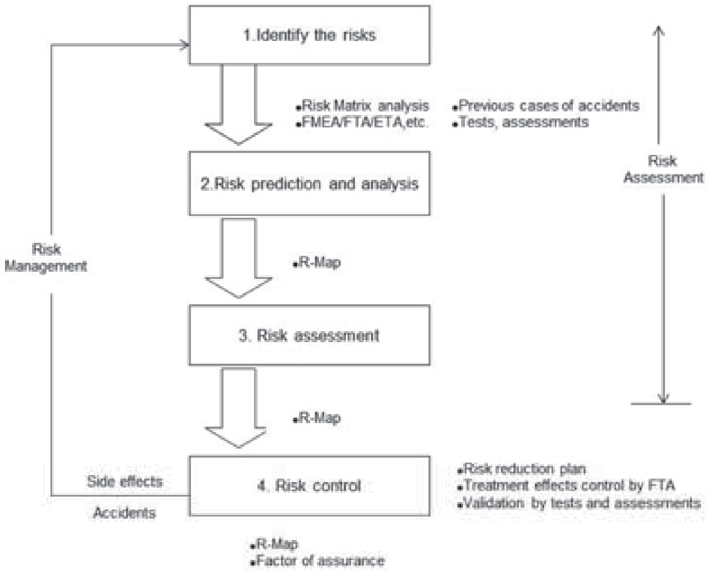


Figure 1: The application of R-Map

Occurrence Frequency								
	5	frequently	C	B3	A1	A2	A3	Area A
	4	occasionally	C	B2	B3	A1	A2	
	3	sporadically	C	B1	B2	B3	A1	
	2	rarely	C	C	B1	B2	B3	Area B
	1	very little	C	C	C	B1	B2	
	0	hardly	C	C	C	C	C	Area C
			no hurt	mild	critical	serious	fatal	
			0	I	II	III	IV	

Figure 2: R-Map schematic diagram.

1. R-Map is divided into three areas (see Figure 2)

Area A is the intolerable risk area. If this risk happens during the product development stage, countermeasures should be taken immediately. If there is risk which cannot be reduced then the product should not be developed any further. If the product has already been released into the marketplace, it should be publicly recalled (and repaired).

Area B is the 'As Low as Reasonably Practicable' (ALARP) area. Products developed and produced in this area must not have any risk, except where the technology has beneficial side-effects. The ALARP principle is that the residual risk shall be as low as reasonably practicable; only if risk reduction is not feasible or the cost involved in reducing the risk is disproportionate to the benefit gained, will the risk be tolerable.

Area C is the safety area. In this area, compared with other tolerable risks, there is relatively low risk of harm and frequency. In this area risk can be ignored.

2. The four characteristics of R-Map method

1. *Integrated with international safety standards.* The R-map considers the ISO/IEC Guide5 as the highest requirement and emphasizes practicality in the development process.
2. *There are some universal approaches.* The research achievements of different industries can be applied to any type of product, especially consumer products and production equipment. Its application in component, material and the automobile industries is currently under investigation. For the food, medicine, atomic energy, aviation and other industries, its applicability has not yet been considered.
3. *A common criterion of evaluation is established.* This criterion is established according to the development, manufacturing, sales, use, scrap and other stages. It can also be used throughout the product life cycle. Therefore, based on the PDCA cycle, we can use the R-Map for continuous improvement to the risk management process.
4. *A type of safety identification risk assessment method.* In the development stage, the risk can be identified and reduced until it reaches an acceptable level (safety area).

3. The degree of hazard

- Fatal: death, fire and buildings burned;
- serious: serious injuries, hospitalization and fire;
- critical: ambulatory clinical treatment, products on fire and burned;
- mild: mild injuries and burns.

4. The frequency of risks

It is important to maintain an annual zero frequency of accidents for each product to ensure a tolerable risk to the public. This means that no matter how harmful it is, 'the highest tolerance of risks to society' is the most important. The frequency values will be different, depending on the industry and age of the product. For example:

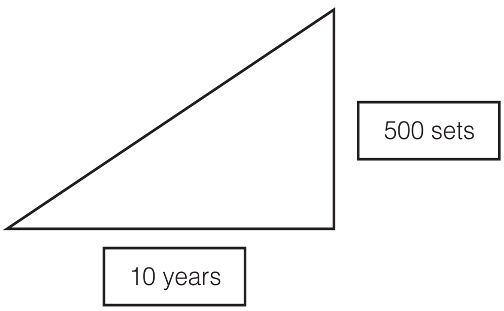
- *Chemical Industry:* 10^{-5} (part/facility year) (Uehara 1985), the current safety level target is reduced by an order of magnitude.
- *Image diagnostic medical devices:* 10^{-6} (piece/set year). Inside the X-ray image diagnostic equipment, there are high-voltage components in order to produce X-rays. In addition, the X-ray itself has a hazardous energy and should be used under the risk effect standards.
- *Elevators, escalators and large automatic revolving doors:* 10^{-6} (piece/set year). This value was developed from the accident statistics and the R-Map made from the results of the public survey.
- *Automotive:* 10^{-7} (piece/set year). This value was developed from the R-Map made from vehicle recalls.
- *Daily life consumer products:* 10^{-8} (piece/set year). The approximate value was calculated from the analysis of several home electrical appliance recall cases. Since then, the Ministry of Economy and NITE took this value as the reference data for recalls. However, the value for electric car seats and electric bicycles was estimated at around 10-7.
- *Important safety components:* less than 10^{-8} (piece/set year). Important safety components (parts) found in cars and home electrical appliances shall have more stringent safety requirements than the requirements of the products themselves. The product failure safety design should be considered that even if the parts do not meet the requirements (in fact most of them do not), they will not cause safety accidents. It's very necessary to consider the basic safety for the whole system.

R-Map application: automatic revolving doors

Back to the automatic revolving door incident of the Roppongi Building, where survey data was used to create the R-Map based on:

The total unit number of functioning large automatic revolving doors in Japan over a ten-year period was calculated as:

500*10/2 = 2500 (set•year) (increasing year by year from SOP to a large number of products running)



IV death (the first time in Japan) occurrence frequency: 1/2500 = 4.0*10-4 (piece/set•year).

III (foot or lumbar fracture) 23 cases, the occurrence frequency: 23/2500 = 9.2 *10-3 (piece/set•year).

II 110 cases of moderate and

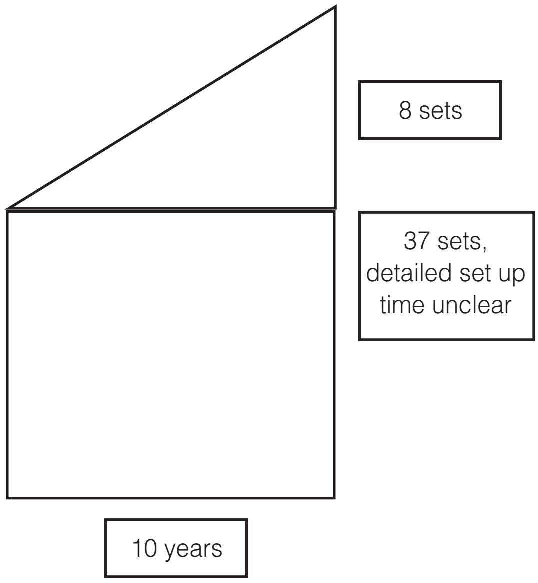
I mild injuries (collision, laceration, bruise), the occurrence frequency: 110/2500 = 4.4*10-2 (piece/set•year).

0 without hurt: 137 cases, the occurrence frequency: 137/2500 = 5.5 *10-2 (piece/set•year).

There were 8 sets of doors of the same model in the Roppongi building, and 37 sets of similar models, making a total of 45 sets of doors. The accumulated operating sets can be calculated as follows: (37 set + 45 set)*1 year/2 = 41 set•year.

IV one death, the occurrence frequency is: 1/41 = 2.4 *10-2 (piece/set•year).

II 10 cases of moderate injuries (Emergency Rescue), the occurrence frequency: 10/41 = 2.4 *10-1 (piece/set•year).



I 22 cases of mild injuries (no emergency rescue needed, crush or conflict), the occurrence of frequency: 22/41 = 5.4 *10-1(piece/set year).

Based on the R-Map Figure 3 was developed and the revolving doors of the Roppongi Building were identified at the A3 area, and the revolving doors of Japan were at the A1 area in the R-Map. This means that all of them should be recalled. The assessment results of the risk plot are consistent with the public poll results, while the risk plot assessment can make a better projection.

After the accident, on March 30 of that year, the Japanese Metropolitan Police Department conducted a search of the estate management building (Mori Building), and Sanwa Shutter industry – manufacturers of the revolving doors – as they were under suspicion of professional negligence.

A thorough investigation was made of the 'blind' range of sensors installed on top of the revolving door, such as how long it takes from the sensor behaving abnormally to the revolving door coming to a stop, how many such incidents up to that date, etc.

One of the reasons they chose automatic revolving doors for the Roppongi Building was the number of visitors: from April 2003 until September 2003 there were a total of 26 million visitors to the building. This was too many people for two sliding automatic doors as they would always be open. So to save energy, the company selected automatic revolving doors, thus improving the speed of rotation.

The revolving doors have a good seal performance, but this new type of construction equipment still had many technical difficulties and shortcomings. For example, when people

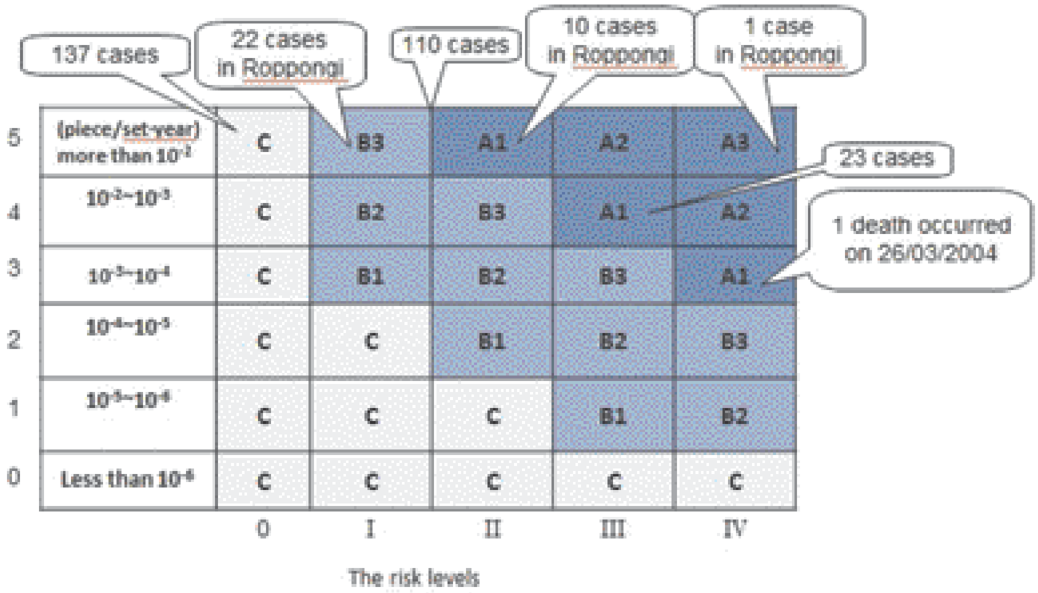


Figure 3: Auto revolving door accidents.

or obstacles are crushed by the doors, the doors cannot be stopped or reversed immediately, and there is no buffer device.

In the Roppongi Building, the doors' infrared sensor manual adjustment was located at the top (higher than 130 cm) and bottom (lower than 15 cm) of the doors, so there were some blind corners (the height of the dead child was 117 cm). In addition, the revolving door in that accident was imported from Europe and was modified before use in Japan.

R-Map identified five requirements to prevent injury

Because of the mall's wind resistance and other requirements, the raw material of the revolving doors was changed from aluminium to stainless steel, which made the doors weigh 3 times more, but the braking and other systems were not upgraded at the same time. After the accident occurred and the sensor sent an alert, the 2.7 ton door continued its rotation for 25~30 cm. For all these reasons, this led to the tragedy.

After the accident, the Roppongi Building replaced all the revolving doors with automatic sliding doors. All the automatic revolving doors in Japan should meet the requirements of 'The Guide about Prevention of Auto Revolving Door Accident' issued in June 2004 and JISA4721 safety guidance issued in 2005, apart from the recall position outlined in the Japanese administrative guide.

According to the R-Map, Table 1 shows the risk reduction levels and five requirements. Alongside these five points of the R-Map, and in addition to replacing automatic revolving doors with sliding doors, there were a further four major measures to prevent injuries: first, reduce the rotation speed from 80 ~ 65 m/sec to 35 m/sec; second, install a safety rail; third, improve the probe-end, non-contact human sensor and braking system; and finally, conduct operation management and equipment inspection. By these four actions, safety protection combined with the other requirements, much of the risk would be eradicated or minimised.

The issue for public safety management is: How to prevent a recurrence of the tragedy in the Roppongi Building. The first level is to ensure the reliability of the technology. The second level is the framework of the safety management; that is, safety-related data and information collection, the system of regular safety conditions review and internal full-time safety management personnel training. The third level is the basic principle for the safety, which means safety management is the responsibility of top management.

For the management of product safety, there are many examples of risk reduction, such as home lawn mowers exported from Japan to the USA. Although the instruction manual requires the users to wear gloves and protective glasses when they are using the mowers, a few accidents have occurred when stones flicked into the user's eyes. As many users have chosen not to wear or use safety gear in hot weather, the injuries could not therefore be completely eliminated. So Japanese mower manufacturers began to change the design of single-edged blade to double-edged blades, and added facilities for deceleration and used other protective ways to reduce the risks.

At the early stage of exporting Japanese electronic products to China, there have been some accidents where the fuse in the current protection device melted and the circuit breakers led to fires. Why wasn't the safety fuse protective? After an investigation, it was found that there was voltage instability in some districts in China. The voltage could jump instantaneously to 400 volts (nominal voltage is 220 volts), before the fuse was completely melted. The circuit breakers burned because of the heat accumulation. Canon, Matsushita Electric and other Japanese companies did a large-scale research, and compared the samples (accidents in 100 sets per year) from China, Europe, America and Southeast Asia, etc. The risk was about 1% according to the different usage environments in the parts of the world they had studied and so they changed the design. This was also a classic case in the study of the Japanese R-Map.

Recall hammers in Europe

One important research use of the R-Map is the Rapid Alert System (RAPEX) for EU non-food consumer products. RAPEX is a rapid alert system used to inform the risk of non-food consumer goods, and is set up according to the

Table 1: Risk reduction levels and requirements.

Risk reduction levels	Contents	Specific measures
1. Risk elimination	Eliminate the risk from the product itself, to prevent that risk from appearing again.	Make sure the impacts of movement, location, thermal, mechanical, electrical, chemical, electromagnetic, sound, magnetic energy, radioactive substances, hazardous substances, microorganisms and sharp edges are controlled to beneath the level which can be damaging to the human body.
2.Risk reduction	• Reduce the risk of the product itself; • Reduce the probability of its being dangerous, or the degree of likely harm, or reduce both.	A. Reduce the probability of occurrence • A system design which won't be an immediate danger even if an error occurs (safety protective devices, prolixity[sic], multiple). • Reduce the probability of misuse (misuse prevention devices, mischief prevention devices). • Isolation (entry forbidden, separated protective and operational parts, interlock). • Management of safety rates, rated value reduction, use of inflammable materials, important parts and important process. B. Reduce the level of damage and injury • Reduce the energy use/production. • Reduce the working energy (ground fault protection, filters).
3. Safety devices/ protective devices	Automatic avoidance and protection before a hazard or danger occurs, or reduce the transmission and amount.	• Detection of a dangerous condition in the early stage and cut-off (over-current protective devices, a variety of detection devices and other safety protective devices). • Protective devices, protective glasses, protective clothing.
4. Alarm	Automatic detection of dangerous conditions, send advice of risks and safety instructions to the operators.	• Work on finding the abnormal state through the alarm device. • Recognize the dangers and install avoidance from dangerous operations (reduce the speed, emergency stop devices, emergency stop switch).
5. Instruction manual and notice sign	• Pre-provision of information about the residual risk. • Education and training.	The notice sign and warning to the users, management and supervisors. Also include education and training.

2001 amendment of 'EU General Product Safety Guides' which came into effect in January 2004. It is mainly for the EU Member States and the European Commission to inform them of the situation regarding dangerous products found in the EU market place.

In the 'Risk Evaluation Guides of non-food consumer goods' set by the European Commission, there is a classic case regarding a flat-head metal hammer with a black plastic handle. It will be used here as an example for the Japanese R-Map method.

R-Map used in the Rapid Alert System (RAPEX) for EU non-food consumer products

In this case, the risk of defects related to the loose fix between the hammer rod and the handle (1/5 piece/ set•durability period). When normal force was used, once the handle was broken (1/2), the material of the hammer was easily damaged under the dynamic impact (1/10).

For example, suppose a hammer was being used to hit a nail into a wall and the hammer broke because it was not strong enough (made of an inappropriate material), and a fragment flew into the user's eye and led to blindness. The injury could be described as 'eye injury, foreign matters in one eye: permanent loss of vision (one eye).' Let's illustrate how to estimate the probability of each step and calculate the overall probability according to the hammer which was broken at the time of fixing nails.

Step one: Because the material of the hammer was not strong enough it broke when banging a nail into the wall. The fragility of the material could be detected by tests. Based on the report of the fragility level, the probability of the hammer breaking in a lifetime was 1/10.

Step two: The probability of a user being hit by a fragment was about 1/10, because a person's upper body was exposed to the debris, and the flight area of the debris was around 1/10 of the hemisphere area in front of the wall. If a user stands close to the wall, his body may occupy a larger place of the hemisphere, and thus the probability of injury will be greater.

Step three: The probability of a user's head being hit by a fragment was about 1/3, as the ratio of the head and upper body was estimated to be around 1/3.

Step four: The probability of a user's eyes being hit by a fragment was about 1/20, as the area of the eyes was about 1/20 of the head.

The probability of the user's eyes being hit could be calculated by multiplying the probabilities in the above steps: i.e., 1/10 * 1/10 * 1/3 * 1/20 = 1/6000.

After estimating the overall probability of an injury, we assumed the lifetime of the hammer was about 10 years. So, shall we recall the hammer or do nothing for this model of hammer? The results were the same for the risk map (see Figure 4) and the European Union decision. The risk sat

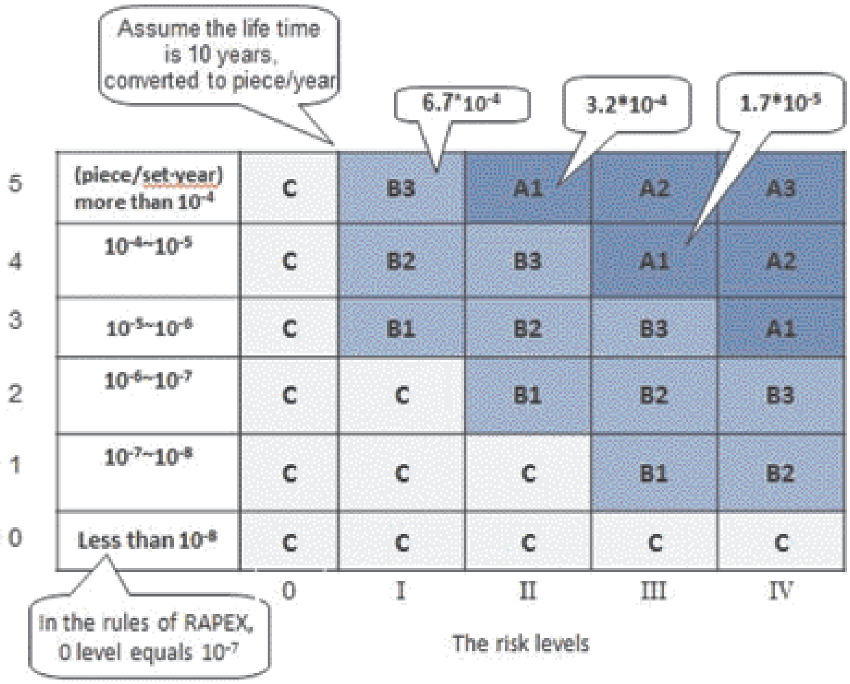


Figure 4: The case of broken metal hammer.

between recall and critical areas, but the final decision of the EU was to recall all these hammers because of their threat of functional loss to the human body.

A poll about this case was conducted among industrial product safety-related officials in the Ministry of Economy, Trade and Industry, in Japan. Most of the people surveyed thought we should recall the product and fewer than 10% thought improvement was sufficient.

Although the R-Map could not be one hundred percent efficacious on any of the products, this visualization tool allows us to understand intuitively the facts and the real situation. And the basis for making the decisions could be changed, based on the public survey and the numbers calculated by risk tool. In addition, this method is mainly used for after-event control and a judgment based on the data after an accident. However, for new product development – where the probability and consequences of an accident are unknown – its five risk levels can be useful when considering safety-designed measures to reduce risk.

Please note: The author has not reviewed the English translation of his presentation, and it has been edited by Lyn Nikoloff.