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# RISK ASSESSMENT PROCEDURES FOR PRODUCTS WHICH DO NOT FULFILL THE ESSENTIAL REQUIREMENTS OF RTTE DIRECTIVE

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**Abstract:**
The risk assessment concept and risk reduction strategies, for products where safety is of great importance, are defined in the generic standards of the New Approach directives. For radio and telecommunication terminal equipment there is still no general standard which defines the principles for the design of this equipment with an emphasis on assessment and risk reduction. The working version of risk assessment procedure for products which do not fulfill the essential requirements of the Directive for radio and telecommunication terminal equipment (RTTE Directive) has not yet been completed, although the working group ADCO R&TTE have been working intensively on this project in previous years. Based on the new standards for risk assessment in the field of machinery, EN ISO 12100, a complete procedure for risk assessment is proposed in this paper for products which do not fulfill essential requirements of the RTTE Directive.

**Key words:**
RTTE Directive,
generic standards,
EN ISO 12100,
risk assessment,
procedure.

## INTRODUCTION

European Union has developed instruments for removing obstacles to free movement of goods, which ensued from differences in technical regulations of the member states. Among these instruments, the New Approach to Technical Harmonization and Standardization and Global Approach to Certification and Conformity Assessment, take the prominent position [1].

The New Approach Directives were brought with the aim of providing free flow of products which are in accordance with the level of protection determined by the Directives. The Directives were generally developed as protection from possible risks connected with public interests.

Improvement in the product conformity assessment procedure has been accomplished by integrating technical products' safety requirements into the process of designing, where risk levels are preventively analyzed and quantified, for the purpose of determining the scope of necessary safety systems [1]. The New Approach Directives and some harmonized standards state explicitly the risk assessment procedure, and in case the risk assessment is not stated in the directive itself, it may be required by the standard linked to the directive.

There still is no general standard defining principles of designing radio and telecommunication terminal equipment (R&TT equipment), with the emphasis on risk assessment and reduction. On the basis of new standard for risk assessment in the area of machines, EN ISO 12100, as well as the working version of the risk assessment procedure for products that do not meet the basic requirements of the Directive for Radio and Telecommunication Terminal Equipment (RTTE Directive), proposal is given in this paper for complete procedure of risk assessment and reduction for products which are not in conformity with basic requirements of the RTTE Directive.

The RTTE Directive was transposed into the Republic of Serbia's technical legislation by bringing of the Ordinance on Radio Equipment and Terminal Telecommunication Equipment ("Official Gazette RS", No. 11/12). The Ordinance on R&TT equipment came into effect on February 22nd, 2012, and its implementation started on June 1st, 2012.

## RISK ASSESSMENT IN THE NEW APPROACH DIRECTIVES

### Risk analysis aimed at determining safety systems required

EU business practice shows that risk analysis and risk estimation have been widely accepted in the process of products and processes development. Manufacturers or their authorized representatives in EU are obligated to perform risk analysis and estimation for their products with respect to fulfilling basic requirements defined in the directives, as well as to offer, on the basis of such analysis, product design solutions that fully meet such requirements.

Risk assessment is the methodology through which risk levels are quantified with the aim of determining the scope of necessary safety systems, all for the purpose of protecting from possible injuries and damages the operator and all the others who come into contact with the product.

Manufacturer's basic task is to make the product safe. In meeting this requirement, risk analysis is one of the first activities. Risk assessment covers all the phases of the product's life: operative usage, installation and dismantling, transport, disposal. In designing a product, the manufacturer should follow the following principles related to hazards/risks:

- Risk elimination or reduction, to the highest possible extent by the structural design itself;
- Installation of protective measures for residual risks;
- Informing the user of the residual risks (in instructions for use, on the product itself, by training the user or in some other way).

### Risk assessment and harmonized European standards

The standardization concept in the field of risk, conducted by the CEN and CENELEC organizations, has got the hierarchical structure depicted in Fig.1 [2]. Such a concept starts from the fact that a successful risk management system implementation in any organization requires a standard structure which is formed starting from generic/general standards and further on towards the standards defining terminology, then towards standards where risk analysis and assessment processes are established for precisely determined business processes and/or functions, moving then towards the standards in which there are instructions on how to execute the mentioned analyses and estimations, and finally, there are defined tools (procedures, guides, check lists, etc.) used in the procedures of risk analysis and estimation. Fig. 1 depicts the hierarchical structure of international and regional standards which are important for the field of risk management in implementing EU technical legislation, i.e. in implementing the New Approach Directives.

On the top generic level, there is the standard *ISO 31000 – Risk Management, Principles and Guidelines* which provides general instructions and principles for developing and implementing risk management system at any organization [3]. On the next level, there are *ISO/IEC Guide 73:2009 – Risk Management - Vocabulary* and *ISO/IEC Guide 51:1999 – Safety aspects – Guidelines for their inclusion in standards.*

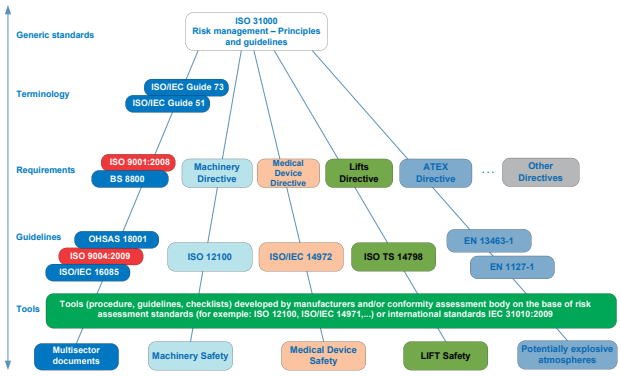


Fig. 1. Hierarchical depiction of standards in the field of risk management which are of interest in implementing EU techical legislation

The existence of such guides is aimed at inducing mutual understanding and consistent approach in job descriptions related to risk management and usage of integral terminology in all the processes related to risk management.

The stated group of standards can be supplemented by the standard *EN ISO 12100:2010 –Safety of machinery - General principles for design - Risk assessment and risk reduction* which provides general methodology that is to be obeyed in designing a machine [4]. Although the purpose of this standard is to upgrade machine designing process, this standard can also be used in designing other technical products to which the New Approach Directives relate to. This standard defines the methodology of risk reduction applicable in all the New Approach Directives.

At the lowest level of the hierarchical structure there are the tools developed as independent standards, such as *ISO/IEC 31010:2009, Risk management – Risk assessment techniques*, which can be implemented in the risk estimation procedure.

### Risk reduction methodology in the New Approach Directives

The best way to realize product safety is to create and realize the inherently safe structure which is accomplished by the design process, adequate manufacturing process, including all the tests and controls and by adequate work processes in which the products are used.

Risk assessment has to be conducted in the phase of product development and designing, so as to enable most efficient realization of all the necessary improvements ensuing from the assessment.

The risk assessment methodology in the New Approach Directives can be explained on the example of risk reduction methodology given in general form in the standard EN ISO 12100: 2010, and depicted in Fig. 2 [4].

The risk reduction methodology is based on several key steps. The manufacturer or his authorized representative determine the risk level for identified hazards, by using the harmonized standards through the procedure of risk assessment, taking into consideration the limitations in which the machine performs its function. In case that it is determined after evaluation activity that identified risk exceeds the acceptable level, measures are called for its reduction.

The manufacturer has to assess the risks of the machines in normal use, as well as during machine's irregular use.

In accordance with the risk reduction methodology depicted in Fig. 2, the manufacturer will first try to reduce the risk by modifying the existing design solution, i.e. he will try to accomplish risk reduction through the so-called "inherently safe structure". If the renewed risk assessment shows that risk level is still high, the manufacturer takes adequate measures such as installing adequate protection aimed at additional risk reduction. It is presumed that despite all previously taken measures, residual risks still subsist, so that manufacturer or his authorized representative is obligated to inform the future user of all these risks, by way of designations on the machine and by instructions for use.

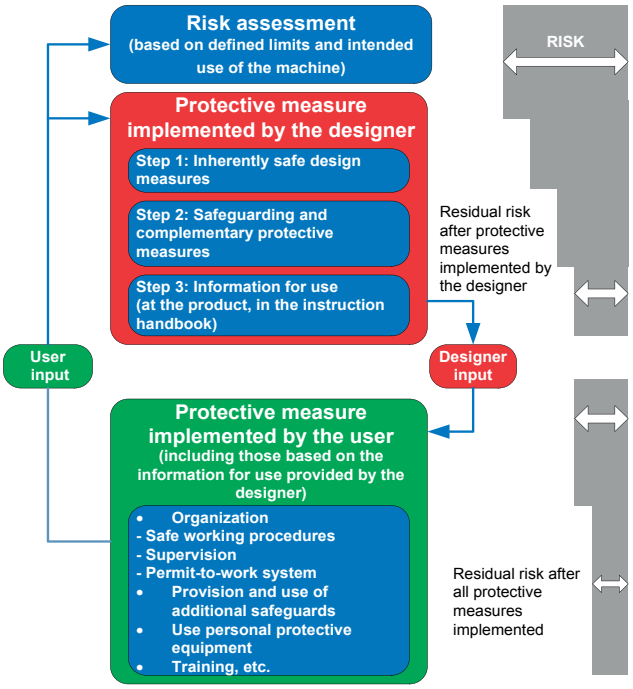


Fig. 2. Risk reduction methodology in the New Approach Directives

According to the methodology shown in Fig. 2, additional risk reduction is expected from the user as well. The user is obligated to additionally reduce the risks on the basis of information received from the manufacturer or his authorized representative. This primarily refers to: establishing of work organization (adequate work procedures, machine operation supervision, clearly and explicitly defined authorizations and responsibilities), use of additional protective measures, use of personal protective means, adequate training of operators, etc.

If all the risks are covered by harmonized standards, then there is no need for additional assessment and risk reduction.

## RTTE DIRECTIVE AND R&TTE EQUIPMENT RISK ASSESSMENT

### General notes on RTTE Directive

Directive 1999/5/EC of the European Parliament and Council dated March 9th, 1999 on radio and telecommunication terminal equipment covers all products which use frequency spectrum (apart from few exceptions) [5]. This directive also refers to terminal equipment connected to public telecommunication networks.

The basic requirements defined by the RTTE Directive refer to the following:

- Health and safety protection of people and other users, including also major requirements related to safety according to Directive 2006/95/EC, but without applying the voltage limits from this directive;
- Electromagnetic compatibility regulated by the Directive 2004/108/EC.

In addition to the stated requirements, the R&TT equipment has to be designed in the way which enables efficient usage of the radio-frequency spectrum, for the purpose of avoiding detrimental interferences.

For certain R&TT equipment individual classes and sub-classes, as well as for the special type appliances, additional requirements can be prescribed related to:

- Networking with other appliances and connecting to adequate interfaces;
- Protecting electronic communication networks from possible misuses, operation interferences, i.e. from significant quality decrease;
- Protecting data on personality and privacy of subscribers and users;
- Ensuring prevention of misuses and fraud;
- Ensuring access to emergency services;
- Relieving usage by the disabled.

### R&TT equipment risk assessment

As with other equipment to which the New Approach Directives relate, safety requirements are integrated into the process of R&TT equipment designing where risk levels are analyzed and quantified for the purpose of determining the scope of necessary safety systems. The R&TT equipment manufacturers are obligated to perform risk analysis and estimation for their products with respect to fulfillment of basic requirements in the RTTE Directives and to offer, on the basis of the estimation, product design solutions which fully meet those requirements.

Conformity to the basic RTTE Directive requirements is achieved by implementing harmonized standards the list of which is published in the Official Journal of the EU.

The risk assessment procedure is not stated explicitly in the RTTE Directive, but risk assessment is required by

the standards which are linked with the directive. There is no a single standard for the R&TT equipment dealing with general principles for designing of this equipment, with the emphasis on risk assessment and risk reduction, as is the case with machines and the EN ISO 12100:2010 standard.

In the case of R&TT equipment, there is a set of harmonized standards dealing with hazards that might occur with this type of equipment. If all hazards are covered by harmonized standards, then it is not necessary to perform risk analysis and assessment for that product. If that is not the case, or if hazards are covered only by a part of a harmonized standard or if harmonized standard does not exist, adequate generic standard must be used for risk assessment, such EN ISO 12100:2010, while risk assessment is implemented in compliance with the procedure defined in that standard.

## Draft version of risk assessment procedure for products which do not fulfill the essential requirements of RTTE Directive

Due to obligation of the EU member states, given in Article 20, paragraphs 1 and 2 of the Regulation 765/2008/EC, the market supervision authorities within the ADCO R&TTE and ADCO EMC organizations have been working on developing adequate risk assessment procedure for the products to which the RTTE and EMC directives relate to.

In Appendix 5 to the document, under the headline *Guidelines for the management of the Community Rapid Information System RAPEX (Commission Decision 2010/15/EU),* a risk assessment method has been set up which should be used by all the EU countries in estimating risk level of user products and in taking the decision whether a product is safe for health of people and whether a RAPEX notification is necessary.

RAPEX guidelines currently focus on injury risk for persons. The New Approach Directives have much broader aspect of the subjects which must not be affected by risk. SOGS-MSG (*Senior Officials Group on Standardization and Conformity Assessment Policy Market Surveillance Group*) has asked the EU Commission to develop a risk assessment procedure applicable to all the 27 New Approach Directives. RATF (*Risk Assessment Task Force*) was formed to analyze the existing procedures and to identify adequate system of general risk estimation. Fig. 3 shows a block diagram of the risk estimation working version procedure for products which do not meet basic RTTE Directive requirements [6]. The depicted procedure is currently being discussed by the RATF.

The basic aim of the risk estimation procedure is to determine risk level in product which is not in conformity with the essential requirements of the RTTE Directive. The risk management phase and communication represent continuation of responsibility of the member states.

If a member state establishes that a product within the RTTE Directive is not in accordance with basic directive's requirements due to irregular implementation of harmonized standards or due to shortcomings in harmonized standards, then the member country immediately informs the Commission in accordance with the procedure, or informs the Commission and other member states in accordance with Article R31 (5) of the Decision 768/2008/EC.

For products that are covered within the RAPEX system and which represent a serious health and safety hazard, member states take prompt intervention measures for protection of consumers and they inform the Commission immediately. Such a system implies quick communication between member states and the Commission aimed at preventing distribution of hazardous products.

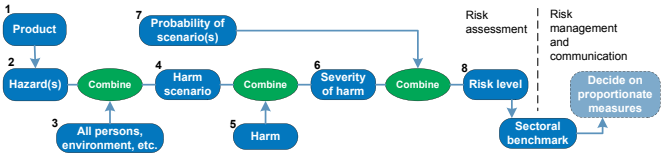


Fig. 3. Draft version of risk assessment for products which do not fulfill the essential requirements of the RTTE Directive [6].

The task group within the ADCO R&TTE is currently considering in what way it is possible to identify nonconforming products which represent a serious risk and in case of which the RAPEX procedure should be initiated.

The first step in risk estimation process, as in the working version of the procedure depicted in Fig. 3, is a comprehensive defining of the product. Although the product defining procedure may seem very simple, this step is of key significance for the entire risk assessment process. In this phase it is necessary to take the whole product into consideration. This may mean that it is necessary to have all product constituent parts defined. Also, it is necessary to identify the product name and brand, as well as its serial number. Instructions and warnings issued by the equipment manufacturer are of key significance for understanding the purpose of the observed product. These data can be of special assistance in identifying potential users, as well as in establishing limits in using the product.

The second step of the observed procedure is identifying those hazards due to the actions of which damages may occur. There is certain number of hazards for each product. The ability to identify and realize all hazards depends on the experience and knowledge of the person assessing the product. In hazards indentifying, the RAPEX hazard classification may be of assistance, as well as reference to adequate harmonized standards. Conformity of products with harmonized standards provides the assumption of conformity with the safety requirements and it can be considered that such a product bears minimum risk.

After identifying a possible hazard, it is also necessary to identify the subject exposed to the observed hazard. The scope of RAPEX Guidelines is limited to injuries to persons, while the New Approach Directives, however, request protection of other subjects as well. Certain amendments to RAPEX Guidelines have been planned, and they will be modified in such a manner as to cover the entire domain of the New Approach Directives.

After defining potential hazards and the subjects exposed to observed hazards, it is necessary to construct the possible scenario which explains in what way the observed hazard affects the observed subject. In this phase of the procedure, such a description does not take into consideration any probability of the event being observed. It is possible to define several scenarios for any product, caused by observing several hazards which may affect more than one subject.

The scenario which describes in what way a hazard affects the observed subject, has got a high influence on the risk level. For example, a non conforming R&TT product can in one scenario completely disturb radio communication of vital significance (e.g. police, emergency, firefighters, air traffic), while in observing some other scenario, the same product will not have any detrimental effect on radio communications.

The fifth step in the observed procedure is to define possible damage, followed by determining the level of the damage, i.e. of the degree of injury. RAPEX Guidelines define only harms to persons, while the New Approach Directives foresee wider scope of subjects.

The most difficult step in the process of risk assessment is the determining of damage occurrence probability. By combining the assessed probability and damage level, the level of risk is determined, which represents a key step in the procedure of product risk assessment. The combination of the assessed damage probability and damage level is represented by the matrix in which the damage level is defined in the horizontal axis, while the occurrence probability is defined in the vertical matrix axis. The risk level is obtained by intersecting the vertical and horizontal axes of the matrix.

## PROPOSAL OF THE PROCEDURE FOR RISK REDUCTION FOR PRODUCTS WHICH DO NOT FULFILL THE ESSENTIAL REQUIREMENTS OF RTTE DIRECTIVE

On the basis of risk assessment procedure draft version, as depicted in Fig. 3 and on the basis of the strategy for machinery risk assessment and reduction defined in standard ISO 12100:2010, Fig. 4 shows a proposal for complete risk assessment and reduction procedure for products which do not fulfill the essential requirements ot the RTTE Directive.

The strategy for risk assessment and reduction for products which do not meet the basic RTTE Directive requirements comprises the following phases:

- Determining R&TT equipment limits, taking into account intended usage as well as foreseeable misuse of the equipment;
- Identifying hazards and associated hazardous situations;
- Risk assessment for each identified hazard and hazardous situation;
- Risk evaluation and taking decisions regarding risk reduction need;
- Eliminating hazards and reduction of the risk associated with that hazard, by protective measures.

Thus, what follows after risk assessment is risk reduction, always when it is necessary. It is sometimes necessary to reiterate this process with the aim of hazards elimination, as long as this is attainable and in order to reduce risks by implementing protective measures. In realizing this process, it is necessary to take into consideration the following factors:

- Equipment safety during all phases of its life cycle;
- Ability of R&TT equipment to perform its function;
- Usability of R&TT equipment;
- Manufacturing, operative costs and R&TT equipment dismantling costs.

## Necessary information for the start of risk assessment

Information that is necessary in R&TT equipment risk assessment is as follows:

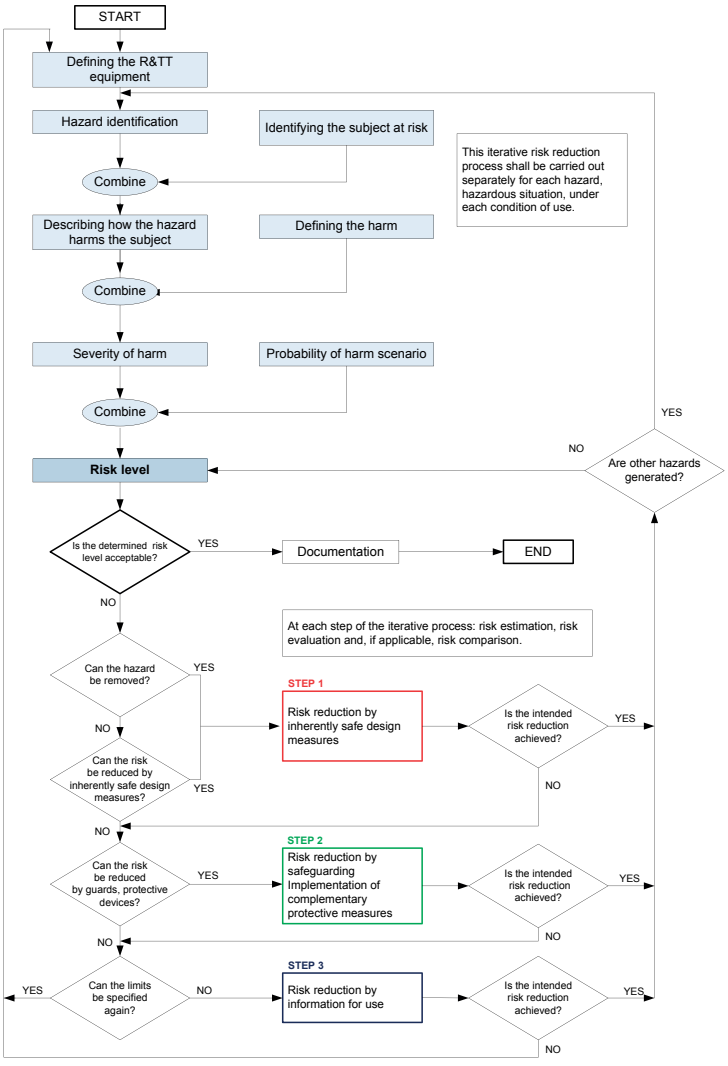


Fig. 4. Proposed procedure for risk assessment and reduction for products which do not meet basic RTTE Directive requirements

- Information associated with the equipment description (technical specification of R&TT equipment, description of potential users, instructions for use);
- Information associated with applicable regulations, relevant standards, recommendations and other documents containing safety data related to R&TT equipment;
- Information associated with experience in use (information on accidents, incidents or faults of the actual R&TT equipment, health hazard data, users' experience with similar type of R&TT equipment);
- Relevant ergonomic principles.

## R&TT equipment defining

Risk analysis starts with the analysis of intended usage, as well as of possible misuse of the equipment. Precise defining of R&TT equipment implies determining of the following factors:

- Use limits (frequency band, maximum effective radiated power, type of antenna, emission class, types of connections, supply/feed type, etc.);
- Different modes of equipment operation as well as the procedure for intervening in case of equipment malfunction;
- Type of equipment use (industrial usage, home usage, personal usage, etc.);
- Type of equipment user;
- Spatial and climate limits in using the equipment;
- Equipment time limits (life limits of equipment or some of its components, recommended servicing intervals, etc.).

## Hazards identification

In order to identify hazards, it is necessary to identify the way of operation of R&TT equipment and the tasks to be performed by persons interacting with the equipment. In identifying hazards, the designer has to take into consideration the following:

- Interaction of people during entire life of R&TT equipment;
- All possible states of R&TT equipment (normal operation and irregular operation of the equipment);
- Non-intended user's behavior or rationally foreseeable misuse of R&TT equipment.

Depending on the type of R&TTE quipment, there are several possible hazards, as well as subjects exposed to the identified hazards. Identified hazards can be of mechanical, electrical, thermal nature. Also, in using some R&TT equipment, hazards can occur from too loud noise, vibrations or electro-magnetic radiation. In using R&TT equipment, frequently identified hazard is the occurrence of harmful interference which can endanger significantly the radio-navigation and radio-communication service operations. A set of hazards can also be identified during irregular usage of R&TT equipment (e.g. prohibited staying close to large antenna facilities, usage of mobile phone during driving, etc.).

## Risk estimation

After identifying hazards, risk estimation is done by determining risk elements for each hazardous situation. Risk associated with certain hazardous situation depends on seriousness of the damage and on probability of its occurrence. The aspects which should be taken into consideration in risk estimation are: persons and/or systems exposed to hazards; type, frequency and duration of exposure to hazards; the ratio of exposure to hazard and its consequences; human factors; protective measures adequacy; possibility of circumventing and avoiding protective measures; ability to maintain protective measures and instructions for use.

## Risk evaluation

After completing risk estimation, it is necessary to perform risk evaluation so as to determine whether it is necessary to reduce risks. With respect to the level, risks can be defined as unacceptable and as acceptable ones. When it is determined that certain risk is unacceptable, it is necessary to perform risk reduction by applying adequate measures. In case when a risk is acceptable, no further risk analysis is needed.

## Risk reduction

Risk reduction can be achieved by reducing hazards or by decreasing damage seriousness from the observed hazard and/or from damage occurrence probability. All protective measures intended for achieving this goal should be applied according to the 3-steps-method, depicted in Fig. 2 and Fig. 4.

As shown in Fig. 4, adequacy of risk reduction is to be determined after applying each of the three steps for risk reduction. In each of the steps, the designer is obligated to check whether additional hazards are introduced or whether other risks are increased in the course of implementing the protective measures. In case additional hazards appear, they are put on the list of identified hazards and adequate protective measures are implemented for them.

## CONCLUSION

During proper use and with implementation of adequate protective measures, R&TT equipment must not jeopardize lives and health of users and other parties. Use of various types of R&TT equipment brings about different types of risks for operators, i.e. for the personnel working directly on them with the aim of performing the activities for which the equipment has been designed, as well as for persons participating in installing, adjusting, cleaning, repairing and transporting of the product.

Definition of the general procedure of risk estimation for products that are not in conformity with basic requirements of RTTE Directive represents the basis for further development of detailed actual risks estimation procedures for different types of R&TT equipment. Further development of the shown procedure contributes to improving safety of R&TT equipment from the point of view of protecting health and safety of people and of other public interests. Use of the standard EN ISO 12100 in risk assessment from the area of machinery represents one of possible solutions in accomplishing the concept of R&TT equipment safety.

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