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Safety of machinery - Ionizing radiation emitted by machinery - Guidance for the application of technical standards in the design of machinery in order to comply with legislative requirements

Sicherheit von Maschinen - Von Maschinen emittierte ionisierende Strahlung - Leitfaden zur Anwendung von technischen Normen bei der Konstruktion von Maschinen um den gesetzlichen Anforderungen zu entsprechen

Sécurité des machines - Rayonnements ionisants émis par les machines - Guide pour l'application des normes techniques dans la conception des machines afin de satisfaire aux exigences réglementaires

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13.110	Varnost strojev	Safety of machinery
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RAPPORT TECHNIQUE  
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**CEN/TR 14715**

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Guidance for the application of technical standards in the design  
of machinery in order to comply with legislative requirements**

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um den gesetzlichen Anforderungen zu entsprechen

This Technical Report was approved by CEN on 3 November 2003. It has been drawn up by the Technical Committee CEN/TC 114.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document CEN/TR 14715:2004 has been prepared by Technical Committee CEN/TC 114 "Safety of machinery", the secretariat of which is held by DIN.

Annexes A and B are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Report: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom

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## CEN/TR 14715:2004 (E)

## Introduction

Machines may emit ionizing radiation either from incorporated radioactive sources or high voltage accelerators (e.g. X-ray machines). Exposure of people to ionizing radiation staying close to the machinery may present a risk to health. To control these health risks, requirements are specified in European and National legislation. The legislation that regulates the design, manufacture and supply of machines is the European Machinery Directive, (98/37/EC). Systems for the protection of workers against the effects of ionizing radiation are specified in a EURATOM Directive (96/29/EURATOM). Detailed technical features are set out in international, European and national standards.

### 1 Scope

The purpose of this report is to give guidance on:

- a) how to comply with the relevant legislative requirements, and
- b) how to take into account the technical recommendations specified in International, European and National Standards

when machines emitting ionizing radiation are designed and built.

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### 2 Relevant legislation

#### 2.1 European Directives

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##### 2.1.1 Machinery Directive 98/37/EC (Currently under revision)

One of the purposes of this Directive is to provide a uniform approach to maintaining or improving the level of safety design of machinery. The Annex 1 to the Machinery Directive lists all the essential health and safety requirements (ESRs) relating to the design and construction of machinery. Of these, ESR 1.5.10 for 'Radiation' states:

*"Machinery must be so designed and constructed that any emission of (Proposed amendment specifies both ionizing and non-ionizing, Revision COM (2000) 899 final 2001-01-26) radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions."*

This document gives guidance on how to comply with ESR 1.5.10 or, if it is not possible during the design or building stage to reduce the emission levels to non-dangerous proportions, how to proceed in order to fulfil the Machinery Directive.

When considering ionizing radiation emissions, there can be no impediment to supply of the machines within the European Union if the requirements of the ESR 1.5.10 [ESR 1.6.11 in proposed Amendment, Revision COM (2000) 899 final 2001-01-26] have been achieved.

##### 2.1.2 Directive 96/29/EURATOM on Basic Safety Standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

The requirements for the health protection of the general public and workers against the dangers of ionizing radiation are laid down in Council Directive 96/29/EURATOM. This Directive is based on the principles put forward by the International Commission for Radiation Protection (ICRP) in their Publication N° 60.

EURATOM Directive contains among others requirements such as:

- a) maximum permissible doses compatible with adequate safety;
- b) maximum permissible levels of exposure and contamination;
- c) fundamental principles governing the health surveillance of workers.

In addition to the requirements for restricting exposure and dose limitation, the Council Directive 96/29/EURATOM also make provisions for the appointment of qualified experts, designation of areas and workers, local rules, monitoring the exposure of employees, medical supervision, notification of work activities, record keeping, etc. There are also requirements for the investigation of high individual exposures and incidents or accidents involving significant contamination or releases of radioactive material.

The EURATOM Directive requires potential users of sources of ionizing radiation either to give a prior report of their intention to the relevant national authority (see article 3 (1) of EURATOM Directive) or to obtain an authorisation from the national competent authority (see article 4 of EURATOM Directive).

As an exception, for sources considered as safe, article 3 (2) of EURATOM Directive allows the use of radioactive substances or electrical apparatus emitting ionizing radiation without reporting or authorisation if specified requirements are fulfilled.

For machines this exception apply if the following conditions are fulfilled:

- a) machines containing radioactive sources which do not exceed defined quantities, in terms of activity or mass activity concentration (see Annex 1 of EURATOM Directive);
- b) machines containing radioactive sources exceeding the quantities or concentration values specified in a), provided that:
  - 1) it is of a type approved by the national competent authority;
  - 2) if the incorporated radioactive source is constructed in the form of a sealed source;
  - 3) it does not cause, in normal operating conditions, a dose rate exceeding  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  at a distance of 0,1 m from any accessible surface of the machine;
  - 4) conditions for disposal have been specified by the national competent authority;
- c) operation of machines containing electrical apparatus provided that:
  - 1) it is of a type approved by the national competent authority;
  - 2) it does not cause, in normal operating conditions, a dose rate exceeding  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  at a distance of 0,1 m from any accessible surface of the apparatus.

If a machine complies with one of the requirements specified under a), b) or c) it can be considered that the machine complies also with the ESR 1.5.10 of Machinery Directive.

## 2.2 National Legislation

European Directives are directed at the Member States (MS), who have to incorporate the requirements into their national legislation. National legislation for the design, construction and supply of machines have to contain identical requirements to those set out in the Machinery Directive. European Directives for the protection of people (e.g. 96/29/EURATOM) specify minimum requirements which may be more restrictively transcribed into national legislation to provide a higher level of protection. Therefore users of machines emitting ionizing radiation will not only have to comply with the national legislation arising from European Directives but also with any increased national requirements to protect people.

**CEN/TR 14715:2004 (E)****3 Standard Technical Specifications**

International, European and National Standards may give useful background material for designers, manufacturers and users of machines emitting ionizing radiation. Standards may also provide technical specifications that are relevant:

- to the measurement of ionizing radiation emissions;
- to describe techniques or give information on the reduction of emissions from machines;
- to provide data on the shielding properties of various materials.

Examples of such standards are listed in Annex A.

**4 Other Sources of Information**

It is recognised that there is a large volume of technical information available in the form of technical reports, recommendations or professional guidelines giving useful background material for designers, manufacturers and users of machines emitting ionizing radiation.

Organisations preparing such documents are for example:

- International Commission for Radiological Protection (ICRP);
- International Atomic Energy Agency (IAEA);
- Organisation for Economic Co-operation and Development/Nuclear Energy Agency (OECD/NEA);
- American Standard for Testing Material (ASTM);
- National organizations in charge of health and safety.

Some relevant documents published by these organisations are given in Annex B.

**5 Methodology for compliance with Machinery Directive - Radiation****5.1 General**

Two types of approaches are possible to comply with Machinery Directive requirements:

- a full compliance with all the ESR 1.5.10;
- If not possible, the machinery must be designed and constructed with the purpose of approaching those objectives (e.g. by using of additional shielding).

**NOTE** If compliance with ESR 1.5.10 cannot be met, in all EURATOM Directive requires additional protection measures. These measures, which purposes are to reduce the exposure of people during operation by management or segregation, may include:

- prohibition of non-essential access to the irradiated areas;
- remote controlled and automatic processes;
- installation of additional shielding by the user at work places;
- use of personal protective equipment;
- limiting time of exposure;
- extending the distances between the machine and the operators.



## 5.2 Full compliance with ESR

To achieve the requirement of the ESR, the design of a machine must restrict emissions to a level that is necessary for the function and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions.

These objectives can be met when a machine complies with one of the requirements specified under a), b) or c) of 2.1.2.

NOTE Machines that comply with the conditions specified in Article 3 of the EURATOM Directive are deemed to comply with ESR 1.5.10.

Using such type-approved machines may provide advantages to the user:

- a) the users will not be required to report to the national authorities their intention to use the machine;
- b) type approval requires that the radioactive substances are in the form of sealed sources, thereby reducing the possibility of releasing contamination;
- c) machines that are type approved may be used with less restrictive controls in the workplace because they present an inherently lower risk to workers and the environment.

To fulfil ESR 1.5.10 manufacturers may need to incorporate features in their products that reduce the emissions from them. Where a technical specification exists for the design of that type or class of products to reduce emissions, it should be used.

## 5.3 Alternative approach to compliance with ESR

### 5.3.1 General

If the requirements of 5.2 cannot be met, the following measures can be applied:

- reduction of emission levels by selection of suitable radiation source (radioactive source or electrical accelerator) or by adding shielding around the process area;
- limiting the access to irradiated area by using either additional guards, mechanical shutters, or other means intended to restrict the exposure of people.

### 5.3.2 Reduction of emission levels

#### 5.3.2.1 Selection of radiation sources

The selection of radiation sources will need to consider the materials to be processed and the intended lifetime of the machine. Balancing the following factors will be the decision of the designer, but the overriding objective is to reduce the emissions to as low as possible while permitting the machine to function as intended.

Factors affecting the choice of radioactive sources will be:

- radionuclide half life;
- emission energy and types (alpha, beta, gamma, neutron);
- activity;
- source design (sealed, according to ISO 2919, see A.1, or unsealed);
- beam geometry (multidirectional or unidirectional);
- safe working life;
- shielding property (effectiveness, weight, volume).

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Factors to be considered when selecting operational settings for electrical accelerators:

- accelerating voltage;
- beam current;
- beam geometry;
- target material;
- shielding property (effectiveness, weight, volume).

**5.3.2.2 Shielding**

The inclusion of shielding in the machine housing will remove or reduce radiation emissions at accessible points around the machine. Design of the shielding has to take account of the materials selected and the construction.

Factors to be taken into account when selecting shielding:

- type of radiation;
- attenuation ability;
- radiation energy;
- secondary emissions;
- physical strength, durability, flammability, resistance to radiation damage;
- chemical form and toxicity;
- weight, volume of material.

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Examples of standards providing detailed technical information about shielding properties of different materials are given in A.2.

**5.3.2.3 Special considerations regarding joints or openings**

Design features such as joints or openings and their covers need special attention. If service penetrations through the shielding materials cannot be avoided, special design requirements to control radiation leakage are to be applied (e.g. zigzag channels, additional overlap shielding, etc.).

Other aspects to be considered include interlocking of movable shields, prevention of leaks and uncontrolled release of radiation, use of enclosed material handling devices, process control systems,

**5.3.2.4 Balancing**

Source selection and shielding design will need to be balanced when making decisions.

**5.3.3 Methods for limiting the access to irradiated area**

To restrict exposure of people, the access to the irradiated area shall be limited. In respect to this objective, the following requirements shall be fulfilled:

- wherever possible, the irradiated area shall be totally enclosed;
- if there is a need for access to the radiation field or beam, then access points should be included in the design. The construction of access points shall not create leakage of radiation above the emission levels specified in the design targets;

- if the process area is not an enclosed volume, barriers, trip devices or guards should be installed to prevent access to this area or to provide additional radiation attenuation. If these guards are only to prevent human access, openings shall be forbidden or their surfaces reduced as far as possible. Interlock system are recommended.

#### 5.3.4 Further actions

The appliance of the previous additional protective measures shall lead to the following conclusion:

- the remaining emission levels do not exceed  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  at a distance of 0,1 m from any accessible surface. In this case, instructions of use shall contain guidance for complying with additional requirements specified by EURATOM Directive (e.g. reporting, authorisation, source disposal);
- the remaining emission levels exceed  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  at a distance of 0,1 m from an accessible surface. In this case, instruction of use shall contain, in addition, provisions for limiting the exposure of people during operation (see clause 5.3.3).

## 6 Measurement of Radiation Emissions

Measurement of radiation emission shall be done in order to confirm adequacy of design and compliance with the requirements listed in 5. Measurement shall be made at accessible points around the machine. Specific techniques for measuring radiation emissions are given in standards listed in A.3.

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## 7 Instructions for Use

Manufacturers must provide sufficient information to enable the machine to be adjusted, operated, serviced and maintained without risks to people from the radiation emissions. Where additional barriers to prevent close approach are needed, criteria for deciding on their selection and location must be included in the instruction manual.

Designers need to take into account the need for sealed sources to be tested for leakage according to standardised methods (see A.1 ISO 9978) at regular intervals. If direct testing of the source is not possible, designers should specify an alternative technique. Information for leakage testing has to be included in the instruction for use.

If additional protective measures for limiting the exposure of people during operation are needed, according to EURATOM Directive (see NOTE under 5.1), these protective measures shall be specify in the instructions for use.