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**Družbena varnost in varnost državljanov - Napotki za upravljanje varnosti v zvezi z nevarnimi snovmi (CBRNE) v zdravstvenih ustanovah**

Societal and citizen security - Guidance for the security of hazardous materials (CBRNE) in healthcare facilities

Schutz und Sicherheit der Bürger - Leitfaden für die Sicherheit von Gefahrstoffen (CBRNE) entlang ihres Lebenszyklus in Gesundheitseinrichtungen

Sécurité sociétale - Document d'orientation pour les établissements de soins de santé relatif à la sécurité des substances NRBC tout au long de leur cycle de vie

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**Ta slovenski standard je istoveten z: CEN/TS 17159:2018**

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**ICS:**

11.020.99	Drugi standardi v zvezi z zdravstvom na splošno	Other standards related to health care in general
13.300	Varstvo pred nevarnimi izdelki	Protection against dangerous goods
13.310	Varstvo pred kriminalom	Protection against crime

**SIST-TS CEN/TS 17159:2018****en,fr,de**

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TECHNICAL SPECIFICATION  
SPÉCIFICATION TECHNIQUE  
TECHNISCHE SPEZIFIKATION

**CEN/TS 17159**

April 2018

ICS 13.300; 13.310; 11.020.99

English Version

**Societal and citizen security - Guidance for the security of  
hazardous materials (CBRNE) in healthcare facilities**

Sécurité sociétale - Document d'orientation pour les établissements de soins de santé relatif à la sécurité des substances NRBCE tout au long de leur cycle de vie

Schutz und Sicherheit der Bürger - Leitfaden für die Sicherheit von Gefahrstoffen (CBRNE) entlang ihres Lebenszyklus in Gesundheitseinrichtungen

This Technical Specification (CEN/TS) was approved by CEN on 10 December 2017 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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**CEN/TS 17159:2018 (E)****European foreword**

This document (CEN/TS 17159:2018) has been prepared by Technical Committee CEN/TC 391 “Societal and citizen security”, the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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## Introduction

Protecting citizens, institutions, infrastructures and assets is one of the four key pillars of the EU's Counter-Terrorism Strategy. One of its aims is to detect and mitigate risks related to the acquirement and misuse of hazardous chemical, biological, radioactive or nuclear (CBRN) materials, such as those referred to in the EU CBRN action plan [1]. There are indications that terrorists would be interested in using some of these CBRN materials for executing attacks. Securing them and preventing unauthorized access to them is therefore key to preventing their misuse. In the action plan, EU member states have planned to enhance the security of CBRN materials.

One of the industries that uses these hazardous materials in their regular processes is the Health Care Industry. Possible risk scenarios for this industry could include the theft of CBRN material from hospitals to perform (complicated) malevolent attacks such as the contamination of major water supply systems, but also the production (and detonation) of an improvised explosive device (IED) containing chemical and/or radiological material in public areas that would cause panic and fear across Europe. Securing these materials in healthcare facilities (HCF) is therefore important.

This document provides guidance for the design and implementation of a *security* management approach and system to deal with security threats involving hazardous CBRNE materials.

Security management of hazardous materials also has a strong relationship with occupational health and safety (OH&S) management. This standard does *not* aim to provide guidance for safety management (i.e. occupational health and safety issues deriving from the improper use of CBRNE material) as these are already managed via different standards and guidelines. This relationship is discussed in 4.1.6.

**NOTE** It is important to emphasize that across the European Union there are several regulatory and legislative limitations for use of security techniques and technologies, so it is important to take these limitations into account. Use of the guidelines can vary based on the health care system in each country of the European Union.

**CEN/TS 17159:2018 (E)****1 Scope**

This Technical Specification provides guidance for managing security of (high risk) chemical, biological, radioactive, nuclear or Explosive materials, such as those covered by the EU CBRN action plan, that are used within healthcare facilities (HCF); it covers the lifecycle of such materials within a HCF's span of control. In this Technical Specification these materials are referred to as 'CBRNE materials'.

It covers the protection of (high risk) CBRNE materials used in healthcare facilities against security threats relating to their deliberate misuse. It covers the protection of people, assets and information related to CBRNE materials.

This Technical Specification also applies to circumstances where healthcare is provided at locations remote from the normal location of the HCF.

This Technical Specification also provides guidance to all stakeholders that are responsible for each step in a lifecycle of CBRNE materials within the HCF such as such as administrator staff, facility management staff, logistics and transport staff, medical staff, waste management staff, domestic staff and security staff as well as visitors and contractors working on the HCF premises.

This Technical Specification can be applied as part of generic management systems such as EN ISO 9001 [2], EN ISO 22301 [3], ISO 22320 [4] and possibly ISO 28001 [14].

It does not apply to occupational health and safety issues deriving from the proper and improper use of such materials.

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**2 Normative references (standards.iteh.ai)**

There are no normative references in this document.

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**3 Terms and definitions**

For the purposes of this document, the following terms and definitions apply.

**3.1****CBRNE material**

chemical, biological, radioactive, nuclear or explosive material that could harm society or individuals through their deliberate release, dissemination, or misuse and for which high levels of security are warranted

[SOURCE: EU CBRN Action Plan [1], adapted]

**3.2****CBRNE security management**

set of interrelated or interacting elements (system) for managing the security of CBRNE materials in organisations in order to prevent their deliberate misuse

**3.3****design basis threat****DBT**

description of the attributes and characteristics of potential insider and/or external adversaries who might attempt unauthorized removal of CBRNE materials or sabotage against which a physical protection system is designed and evaluated

[SOURCE: IAEA Development and Use of the Design Basis Threat [15], amended]

**3.4****explosive**

reactive compound that contains energy, which when released quickly from the compound, can produce an explosion that is usually accompanied by the production of light, heat, sound, and pressure

**3.5****explosive precursor**

chemical substance which can be made into an explosive with relative ease e.g. by mixing or blending with other materials, or by simple chemical processing

[SOURCE: Guidance on the EU Marketing and Use of Explosives Precursors Regulations, [8] ]

**3.6****healthcare facility****HCF**

facility and its organisation, personnel, management and processes which provides health care such as hospitals, psychiatric clinics and nursing homes including pharmacies, storage and laboratories within the healthcare facility's control

Note 1 to entry: HCF refers to singular and plural. HCF's refers to the possessive subject.

**3.7****improvised nuclear device****IND**

improvised device that is designed to cause nuclear material contained within it to produce a nuclear explosion

**3.8****life cycle**

set of consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources, to use and final disposal

[SOURCE: EN ISO 14040:2006, 3.2 [9]]

**3.9****life cycle inventory analysis**

phase of life cycle assessment involving the compilation and quantification of inputs and outputs for a product throughout its life cycle

[SOURCE: EN ISO 14040:2006, 3.3 [9]]

**3.10****nuclear material**

Uranium 235, Uranium 233 and Plutonium 239

Note 1 to entry: Detailed information can be found in IAEA NSS 13, Section 4, Table 1 [10].

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## 3.11

**occupational Health & Safety****OH&S**

conditions and factors that affect, or could affect, the health and safety of employees or other workers (including temporary workers and contractor personnel), visitors, or any other person in the workplace

[SOURCE: OHSAS 18001:2007 [11] ]

## 3.12

**radioactive material**

material designated in national law, regulation or by a regulatory body as being subject to regulatory control because of its radioactivity, or, in the absence of such a designation by a State, any material for which protection is required by the current version of the International Basic Safety Standards

[SOURCE: IAEA NSS Risk Informed Approach for Nuclear Security Measures, No 24-G, [12], modified]

## 3.13

**radioactivity**

phenomenon whereby atoms undergo spontaneous random disintegration, usually accompanied by the emission of radiation

[SOURCE: IAEA Safety Glossary [13]]

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## 3.14

**radiological dispersal device**

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**RDD**

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device designed to disperse, usually with explosives, radioactive material in an uncontrolled way, without the need of nuclear explosion

## 3.15

**risk**

expression of the combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence

[SOURCE: ISO 31000 [21], modified]

## 3.16

**security**

resistance to intentional acts designed to cause harm or damage to or by the supply chain

Note 1 to entry: Harm includes psychological and societal harm.

[SOURCE: ISO 28001:2007, 3.20, [14]]

## 3.17

**security risk**

expression of the combination of the consequences of a threat once enacted and the associated vulnerability to that threat at a specific location

**3.18****security threat**

situation where an adversary has the capability and the intent to violate security of CBRNE materials

**3.19****security threat scenario**

means by which a potential security incident might occur

[SOURCE: ISO 28001:2007, 3.26 [14]]

**3.20****security controlled area**

area which has specific controls to restrict access to authorized persons only

[SOURCE: CEN/TS 16850:2015, 2.1 [8]]

**3.21****security management**

systematic and coordinated activities and practices through which an organization optimally manages its security risks, and the associated potential threats and impacts therefrom

[SOURCE: ISO 28000:2007, 3.3 [5]]

**3.22****security management policy (standards.iteh.ai)**

overall intentions and direction of an organization, related to the security of and the framework for the control of security-related processes and activities that are derived from and are consistent with the organization's policy and regulatory requirements

[SOURCE: ISO 28000:2007, 3.5 [5]]

**3.23****vulnerability**

weakness within the security arrangements which could, at some point, be exploited by a threat

**3.24****visitor**

person authorized to visit restricted areas who is not a visitor for patients during visiting hours or person authorized to visit restricted areas who is not part of the HCF's organization

**4 General guidance****4.1 Context of CBRNE risks in HCF and other facilities within HCF responsibility****4.1.1 General**

To understand the context of security risks in healthcare facilities, associated with CBRNE materials, a brief overview is presented below. Recommendations regarding approaches to security are then presented in subsequent paragraphs.

The major threat from CBRNE materials is that they could be deliberately used for executing criminal and/or terrorist acts. These materials can, for instance, be placed in locations where people would be directly harmed by them or they could be deliberately distributed into the environment through dispersal devices or other means.

**CEN/TS 17159:2018 (E)****4.1.2 High-risk chemical materials/agents**

These are chemicals with the potential to be used to cause death, temporary incapacitation or permanent harm to humans or animals. This includes all such chemicals, regardless of their origin or of their method of production, and regardless of whether they are produced in facilities, in munitions or elsewhere [16].

The wide range of chemicals and materials used in healthcare treatment and associated research implies that HCF are potential sources of high risk chemical materials / agents or their pre-cursors.

HCF should consult their national authority to define what is high/medium/low risk material.

**4.1.3 High-risk biological material**

When speaking of security of biological material the focus lies on pathogens, or parts of them, and toxin-producing organisms [17]. These can be plant, animal, microorganism and human derived.

Toxins are also classified as biological agents. These are naturally occurring poisonous chemicals produced by biological organisms, including plants, animals and microorganisms (although some may be artificially synthesized).

Some of these materials are extremely important for research and development in the domains of medicine, biology and agriculture, but on the other hand can be used as biological weapons. This means that many of them can therefore be used for two purposes. The term used by the international community for these types of materials is 'dual use' [18].

Clearly, HCF and their processes are potential sources of high risk biological materials / agents.

HCF should consult their national authority to define what is high/medium/low risk material.

**4.1.4 High-risk radioactive sources and nuclear materials**

Radioactive materials give rise to two types of radiological hazard. Firstly, the hazard of external exposure to the radiation they emit and secondly, internal exposure if radioactive material enters the body.

Nuclear materials are a special class of radioactive materials which have the potential to be used to construct devices that also generate large amounts of energy as well as highly penetrating radiation, through the process of nuclear fission. HCF are extremely unlikely to be sources of nuclear materials but they may be the source of other radioactive materials that could be used to aid the construction of an IND or used in a RDD.

HCF should consult their national authority to define what is high/medium/low risk material.

**4.1.5 Explosives**

Explosives are not routinely used in HCF, but in the context of this Technical Specification the term Explosives should also be taken to refer to explosive pre-cursor chemicals such as those listed in Annex I or Annex II of [19] (as amended from time to time) on the marketing and use of explosives precursors, in a concentration higher than the corresponding limit value set out therein.

Therefore, such materials are included in the term of high-risk materials/agents for the rest of this document.