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The Evolution of the Normative Regulation in Hospital Safety and Security

Despite the Covid-19 epidemic, relatively little is said about hospital safety and security these days, in fact, the concept, along with its complexity, is not precisely defined. In 2016, the concept of critical infrastructures and thus the operator's security approach appeared in the Hungarian health care system. This required a more complex approach than before on the part of the security organisations. It is absolutely necessary to manage the human resources organisation, the operation of the facilities, the various service areas and the so-called classical security and safety areas such as property, fire, environment, disaster management and labour safety areas of the institutions in one management system. These are the areas where complex interpretation can be encountered in every case during Operator Security Planning. In my study, I review the evolution of the normative regulation of these areas and their impact on the security operators' activities in hospitals from the period of the regime change to the present day, until the emergence of the complex operator security approach.

Keywords: hospital safety and security, operator security planning, hospital disaster planning, critical infrastructures, legal environment

Introduction

Based on Council Directive 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection, Act CLXVI of 2012 on the identification, designation and protection of essential systems and facilities was published in Hungary in 2012. After that, the requirements related to critical infrastructures in the healthcare sub-sector were published in Government Decree 246/2015 (IX.8.) on the identification, designation and protection of critical health systems and facilities in 2016.

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With operator security planning, a complex planning approach also appeared, which provided the opportunity to comprehensively analyse the so-called classical safety and security areas (until then was managed separately) and integrate them into the plan.

The current regulation is the pinnacle of the legal regulatory evolution of critical infrastructure, however, individual security areas and their hospital security aspects have continuously developed over the past twenty or thirty years.

In my study, I present the evolution of the legal environment, with a comprehensive analysis of the relevant legislation, an examination of their influence on each other, and the presentation of operational practical examples.

Labour safety

After a long period of codification, Act XCIII of 1993 on labour protection entered into force on 1 January 1994. The aim of the law is to ensure personal, material and organisational conditions for safe work without endangering human health, to prevent work accidents and occupational diseases by defining the rights and obligations of the state, employers and employees.

Since 2003, the concept of occupational safety and health commissioning has been included in the law, which plays a prominent role in the commissioning of dangerous technology or work equipment in health care.

In 2004, the law was supplemented with the conceptual system of occupational safety and health representative, workplace occupational safety and health committee, and parity occupational safety and health board. A higher level of employees' representation can be ensured with these in the occupational health and safety area.

In 2022, as a result of the Covid-19 epidemic, the basic occupational health and safety rules for remote work were also determined. As a result of the epidemic, not only the so-called back office area, but also in patient care, the concept of remote work appeared in the field of telemedicine, and some other areas, such as in the case of finding analysis.

Pursuant to the Labour Protection Act, all employers must have a risk assessment, i.e. they must evaluate the risks that threaten the safety and health of employees, and must take measures to reduce them. In addition to the general workplace risk assessment required by the Labour Protection Act, the employer is required by separate legislation to carry out additional risk assessments depending on his activities. The emergence of these risk assessments also clearly illustrates the development of the occupational safety and health normative environment.

Table 1: Types of risk assessments and their health care relevance

Type	Legal regulation	Review period	Its relevance in healthcare
Workplace risk analysis	Act XCIII of 1993 on labour protection	Every 3 years	General, covering all workplaces
Occupational carcinogen risk assessment of materials	Act XCIII of 1993 on labour protection Decree 26/2000 (IX.30.) of the Ministry of Healthcare on protection against occupational carcinogens and the prevention of health damage caused by them	Every 2 years	Risks of dangerous goods and mixtures used during therapeutic and diagnostic care, dissection, preservation, disinfection
Biological risk assessment	Decree 61/1999 (XII.1.) of the Ministry of Healthcare on the protection of the health of workers exposed to biological factors	Every year	Biological pathogenic factors occurring during health care
Chemical risk assessment	Act XXV of 2000 on chemical safety Decree 5/2020 (II.6.) of the Ministry of Innovation and Technology on the protection of the health and safety of workers exposed to chemical pathogenic factors	In case of change	Dangerous goods and preparations used in healthcare, but also cleaning agents
Artificial optical radiation risk assessment	Decree 22/2010 (V.7.) of the Ministry of Healthcare on the minimum health and safety requirements for the exposure of workers to artificial optical radiation	Every 3 years	Lighting fixtures, IR, UV and laser radiation risks
Biological and sharp or pointed instruments assessment of the risks resulting from its use	Decree 61/1999 (XII.1.) of the Ministry of Healthcare on the protection of the health of workers exposed to biological factors Decree 51/2013 (VII.15.) of the Ministry of Human Resources on the requirements for the prevention of injuries caused by sharp or pointed tools used in the context of healthcare services, the management of risks arising from the use of such tools, and the information and training of persons performing healthcare activities	Every year	The risks of sometimes contaminated sharp, pointy tools (e.g. needles, scalpels) used during health care

Source: Compiled by the author.

According to the legislation, the employer must register and investigate all accidents at work.

The characteristics of the accidents at work records at Semmelweis University, as one of Hungary's largest healthcare providers, are shown below.

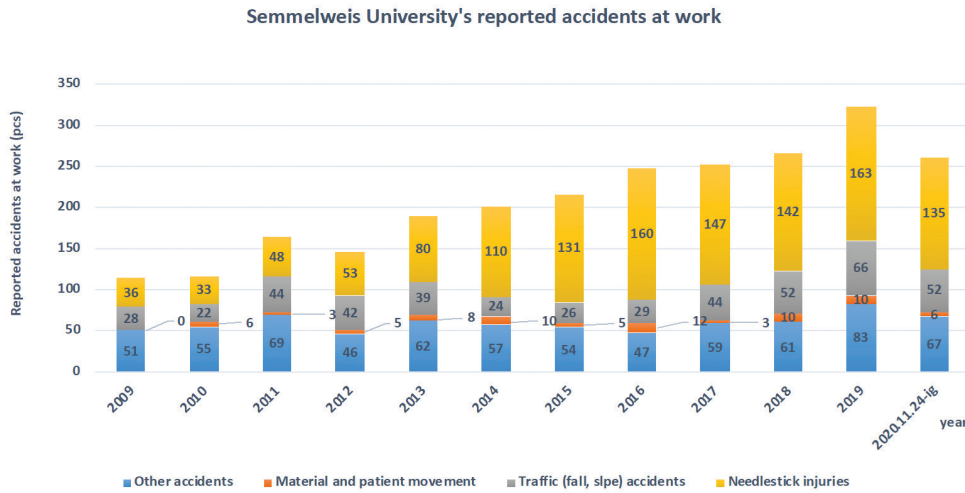

Figure 1: The number and distribution of accidents at work reported at Semmelweis University by type
Source: Semmelweis University Directorate of Safety and Security.

According to the statistics, which correlate with the statistics of other institutions in Hungary, there is a significant preponderance of Needlestick Injuries.

"Based on international literature data, approximately one million workers are injured by needlestick injuries in Europe every year. EPInet (Exposure Prevention Network) reports that in an average hospital, there are 30 accidents caused by sharp objects per 100 beds."[2]

It can be seen that the risk assessments regarding the risks of sharp, pointed instruments and the action plans prepared as part of them are not sufficient to deal with the problem. In this case, greater emphasis must be placed on education and resources must be provided for the purchase of hard-walled needle collectors and possibly needle destruction devices. The labour safety conditions and discipline typical of health care institutions must be improved.

The study commissioned by the Ministry of National Economy, *Comparative Analysis of Occupational Safety Strategies, Research* summarises the experiences of labour safety inspections:

"Healthcare facilities – especially clinics, hospitals, homes – are institutions that employ many workers. The limited financial and human resources are primarily focused on patient care, and the conditions necessary for safe work are not fully met. The technical condition of a significant part of the health institutions that have not been reconstructed is unsatisfactory, and the occupational safety condition of the service units is in most cases inadequate. Minimal resources and personnel are used for maintenance and repair."[3]

[2] Mészáros 2019: 99.
[3] Varga et al. 2015.

Property protection

In the socialist system before the regime change, private property did not actually exist – or in very small numbers – so we cannot even speak of a private security industry.

At the time of the regime change, hospital property protection was characterised by doormen and law enforcement persons employed by the organisation. The normative basis for this was laid down in Government Decree 14/1960 (III.24.) on the organisation of Industrial Law Enforcement Bodies.

Decree 6/1988 (II.12.) of the Council of Ministers on the law enforcement activities of inter-governmental bodies further sophisticated and repealed the earlier decree, thus also affecting hospital security, as it laid down additional rules regarding the property protection activities of hospitals as inter-governmental bodies. This legislation has already established labour safety and fire protection, as well as industrial safety tasks for the industrial law enforcement bodies, and requires the development of vocational training and further training principles for the employees of the organisation in agreement with the Ministry of the Interior.

Private security companies appeared on the market as a result of the privatisation waves after the regime change and the increasing private ownership. However, the legal regulation waited until the publication of Government Decree 87/1995 (VII.14.) on the transitional rules of the personal and property protection carried out in the framework of the enterprise, as well as on private investigative activities. At that time, the transitional decree already tied personal and property protection activities to a police license and contract, as well as defined certain sub-activities. At the same time, the industrial policing character of these organisations ceased, and the labour and fire protection functions were removed from the scope of activities.

Meanwhile, thanks to the changed risks and the development of the property protection market that originally responded to this, a wave of outsourcing started with regard to security guarding. Although hospitals are still state-owned, their protection has increasingly been provided by private security companies.

In 2005, Act CXXXIII of 2005 on personal and property protection, as well as the rules of private investigation activity, entered into force. The law partially regulates the measure possibilities of security guards, their expected professional qualifications, and the obligations related to the police license of security guards and private security companies. It links security guarding activities to a license issued on the basis of the security guard course, but it also does not require more education for the manager of the private security company, which is a significant step back compared to the conditions at the time of the regime change. The so-called industrial law enforcement bodies, so e.g. property protection organisations of hospitals remain unregulated.

In 2015, a mandatory minimum overhead charge was introduced in property protection – for institutions operating from public funds. In 2015, the amount of this minimum overhead charge was in many cases double the usual prices at that time, which generated a significant demand for additional resources in the case of hospitals, as well. As a result of this, a wave of insourcing started and in several health institutions they started to employ their own doormen again, which raises further problems.

The Property Protection Act does not apply to doormen, as the job is not tied to a security guard license, so they do not have more rights in terms of personal and property protection than an average citizen.

Addressing this issue is essential at the legislative level. The data protection and employment issues of hospital asset protection must be reviewed, and the actors of the private security industry must be included in a unified system, taking into account the need for industrial law enforcement activities.

Environmental protection

In addition to the use of renewable energy sources, the sustainable planning and operation of facilities, and the reduction of exposure to air pollution point sources (e.g. laminar boxes), hospital environmental protection manifests itself mostly in waste management. Based on WHO data, 85% of hospital waste is municipal waste, and 15% is hazardous waste. Hazardous waste can be divided into two main groups:

- medical (infectious) hazardous waste requiring special treatment
- hazardous waste due to its chemical/physical properties

Occupational health and safety issues also arise in connection with the collection of infectious hazardous waste. As can be seen from the accidents at work statistics, the number of needlestick injuries is significantly higher than other types of accidents at work, which can also lead to occupational health diseases.

"A person who experiences one needle stick injury from a needle used on an infected source patient has risks of 30%, 1.8%, and 0.3% respectively of becoming infected with HBV, HCV and HIV."[4]

Hungary joined the ADR agreement in 1979 (Accord européen relatif au transport international des marchandieses Dangereuses par Route [European Agreement on the International Transport of Dangerous Goods by Road]). The rules of ADR cover not only the road transport of dangerous goods, but also the waste resulting from their use, as well as the preparation of the transport, temporary storage and packaging. Accordingly, related regulations and tasks appear on the sender's side, i.e. in the hospitals as well.

In 1981, Decree 56/1981 (XI.18.) of the Council of Ministers on the control of the generation of hazardous waste and activities related to their disposal, a list of hazardous waste was published for the first time in Hungary, which grouped hazardous waste according to technological origin.

Government Decree 102/1996 (VII.12.) on the rules for the collection, disposal and transport of hazardous waste came into force in 1996. An annex to the Regulation also forms a list of hazardous waste, which classified hazardous waste into three classes in terms of hazard. Considering that the principle of organising the list differed from the organising principle of the list applied in the European Union, after

[4] WHO 2018.

the accession of Hungary to the European Union, the list was modified during the legal harmonisation. It was replaced by a list in Decree 16/2001 of the Ministry of Environmental Protection.

Decree 1/2002 (I.11.) of the Ministry of Healthcare on the management of waste generated in healthcare institutions came into force in 2002, which regulated the registration, labelling and disinfection procedures for hazardous waste generated (also) in hospitals, prescribed the designation of an institutional waste manager, as well as declared the rules for temporary storage.

Government Decree 98/2001 (VI.15.) on the conditions for carrying out activities related to hazardous waste was developed in 2001, which introduced the concept of "delivery" and "accompanying" tickets. In this way, hazardous waste can be tracked in the waste chain from generation, through transportation, to destruction/disposal through a multi-copy documentation, where each copy is returned to the originator of the waste, who can thus fully fulfil its own responsibility.

The latest sectoral regulation is Decree 12/2017 (VI.12.) of the Ministry of Human Resources on waste management activities related to waste generated by healthcare providers, published on the basis of Act CLXXXV of 2012 on waste. This decree also defines the transportation within the premises and the disinfection procedure for the equipment used for transport.

It can therefore be said that medical waste management is a legally properly regulated and continuously developing field, in which Hungary is constantly harmonising international conventions and standards. Despite this, according to statistics, the hazardous waste generated in the health sector leads to a disproportionately high number of accidents at work and occupational health diseases, the prevention of which is the joint task of the labour safety and environmental protection field through education and the introduction of new technologies.

Disaster management

"The adoption of EU rules on critical infrastructure protection (hereinafter: CIP) began in the mid-2000s. Hungary has developed its own legal regulations in accordance with EU regulations. With the adoption of the newest disaster management act, the Hungarian disaster management system became a unified organization consisting of three pillars, namely the industrial safety, the civil protection and the fire protection. The critical infrastructure protection is one of the main tasks of the industrial safety pillar. The minister of interior is in charge of the coordination of the disaster management tasks and the tasks of critical infrastructure protection on government level."[5]

The complex disaster prevention system was established in 2012 by Act CXXVIII of 2011 on the amendment of certain laws related to disaster prevention. In view of this, in the following I will analyse the relevant hospital safety areas in three parts of this three pillars, such as:

[5] Sibalin et al. 2020: 1–6.

- fire protection
- hospital disaster planning
- critical infrastructures

Fire protection

From the point of view of establishment and operation, the most decisive legislation is the National Fire Safety Codes and Standards (NFSCS). The NFSCS establishes the fire protection provisions for the construction of facilities and the use of facilities, machines, tools, materials and technologies.

By issuing Decree 4/1980 (XI.25.) of the Ministry of the Interior on the issuance of the National Fire Safety Codes and Standards, it was the first time that the organisational rules of firefighting and technical rescue were separated at the legal level from the construction and use rules.

The NFSCS was modernised sixteen years later with Decree 35/1996 (XII.29.) of the Ministry of the Interior on the issuance of the National Fire Protection Regulations, with specifications corresponding to the technical standards of the time.

In the course of Hungary's accession to the European Union, it was necessary to eliminate those elements in the legislation, which are otherwise included in binding standards. However, in order to resolve the unregulated situation caused by European standards that had not been adopted until then, these standard elements were included in a separate decree, which raised these elements to legal status. That was Decree 2/2002 (I.23.) of the Ministry of the Interior on establishing the technical requirements of fire protection and civil protection.

After the publication of the standards adopted after the accession, it was necessary to review the legal environment and the technical requirements system. After that a new NFCSS was born, by issuing Decree 9/2008 (II.22.) of the Ministry of Local Government and Regional Development.

Decree 28/2011 (IX.6.) of the Ministry of the Interior on the National Fire Safety Codes and Standards, published during the next review further cleaned up the legislation and removed all chapters for which an effective standard was in force, and precisely separated the rules for establishment and use.

By the issuance of Decree 54/2014 (XII.5.) of the Ministry of the Interior on the National Fire Safety Codes and Standards, the Fire Protection Technical Guidelines (FPTG) were published, which simplified the text of the legislation by issuing them separately. The essence of the separation is that from now on, the NFSCS will determine the required security level on a mandatory basis, and the application of FPTGs is voluntary, but it actually offers solution options accepted by the Authority.

The latest update of the NFSCS entered into force on 22 January 2020 and was further refined, i.e. it defines only basic rules and all the necessary information is transferred to FPTGs.

In addition to the development of the NFSCS, the FPTGs are also constantly developing. An example is the FPTG called Evacuation, which has been developed four times since its first release on 5 March 2015. Within this, in the first version,

the chapter on the safe evacuation of persons with limited ability to escape only formulated a proposal for the evacuation of disabled people in general. In the latest version, valid since 13 June 2022, it already deals in detail with the evacuation of patients in various inpatient care units, as well as the latest NFCSS and FPTG further detail the concept of persons restricted in their escape.

The development of the guidelines in this direction is of great help during the planning and renovation of hospitals, since several inpatient care functions (e.g. Intensive Care Units, Perinatal Intensive Care Units) cannot be safely evacuated within the evacuation times planned according to general evacuation principles. Given that these evacuation techniques are closely related to other fire protection measures and systems, it is recommended to issue a separate FPMG with a hospital theme.

Hospital disaster planning

According to § 2 of Act II of 1972 on health care, which was in effect at the time of the regime change, the preparation of health bodies and ensuring their operation in case of extraordinary circumstances (epidemic, flood, etc.) is a sectoral task. Instruction 11/1982 (Eü. K. 8.) of the Ministry of Healthcare on the development of disaster plans for medical and preventive institutions entered into force in 1982 based on the Health Act.

This was the first normative measure requiring the development of disaster plans for hospitals.

The first healthcare act after the regime change was Act CLIV of 1997 on healthcare. The Act already dedicates a separate chapter to health crisis care. The law defines the concept of a health crisis situation, the cases of the order and the person making the order, and lists the organisational and planning tasks of the health crisis situation item by item.

The 2013 amendment of the Act introduced the obligation to implement hospital disaster drills for patient care units.

The detailed requirements of the plans were first laid down in Decree 29/2000 (X.30.) of the Ministry of Healthcare on the content requirements of the disaster plans of health care institutions. The decree defined the detailed rules of planning, and in addition to the basic plan, it defined the preparation of sub-plans for different scenarios and their background activities.

Decree 43/2014 (VIII.19.) of the Ministry of Human Resources on the content requirements of the health crisis plans of health institutions and on the amendment of certain health-related ministerial decrees clarified the rules for the central approval of plans and ordered the preparation of additional sub-plans.

Decree 49/2016 (XII.28.) of the Ministry of Human Resources on sectoral national defence tasks affecting the responsibilities of the Minister of Human Resources required the preparation of additional plans applicable during national defence-type special legal orders for healthcare providers as National Defence Action Plans.

Table 2: Hospital disaster planning tasks

Not in force	In force	
Decree 29/2000 (X.30.) of the Ministry of Healthcare	Decree 43/2014 (VIII.19.) of the Ministry of Human Resources	Decree 49/2016 (XII.28.) of the Ministry of Human Resources
Base plan	Base plan	
Alarm and order plan	Alarm and order plan	
Displacement plan	Displacement plan	
Evacuation plan	Evacuation plan	
Separation plan	Separation plan	
Medical aid site installation plan	Medical aid site installation plan	
Emergency hospital installation plan	Emergency hospital installation plan	
Plan for handling additional tasks	A plan for the performance of additional tasks during periods of peace and special legal order	
Maintenance of patient care plan	A plan to maintain care in the event of damage to the institution or conditions that impede operation	
Health and other material support plan	Health and other material support plan	
Transportation plan	Transportation plan	
Food plan	Food plan	
Communication plan	Communication plan	
	Task performance plan related to the risk mitigation plan	
	The plan for the performance of tasks arising in connection with the implementation of the International Health Regulations	
		National Defence Measures Plan
		Hiding and shelter protection action plan
		Blackout and light masking action plan
		Staff leave plan

Source: Compiled by the author.

The detailed rules for crisis health care are laid down in Government Decree 521/2013 (XII.30.) on health crisis care. Thus, the Decree defines the detailed rules for qualification, announcement, preparation and handling of health crisis situations.

Furthermore, in 2020, due to the needs of the treatment of the pandemic caused by the coronavirus, the regulation was supplemented with, among other things, the rules for secondment of healthcare workers and medical students.

Critical infrastructures

The first legislation on critical infrastructures entered into force in Hungary in 2012. This is Act CLXVI of 2012 on the identification, designation and protection of essential systems and facilities (CIP Act).

The Act defines the concept of a critical infrastructure element, and defines the sectors designated from the point of view of critical infrastructure protection and authorises the Government to designate the sectoral designating authority, the proposing authority, establish the general and sectoral rules for identification and designation, as well as the sectoral and the horizontal criteria.

Table 3: Sectors and sub-sectors defined for the identification and designation of critical infrastructures in Act CLXVI of 2012 on the identification, designation and protection of essential systems and facilities

Sector	**Sub-sector**
Energy	electricity system facilities (except for systems and system components subject to regulations on the nuclear safety and radiation protection, physical protection and safeguard supervision of the nuclear power plant)
	petroleum industry
	natural gas industry
	district heating
Transportation	road traffic
	rail transport
	air traffic
	water traffic
	logistics centres
Agricultural economy	agriculture
	food industry
	distribution networks
Healthcare	active inpatient care and the services necessary for its operation
	rescue management
	health reserves and blood stocks
	high security biological laboratories
	drug wholesale
Social insurance	IT systems and records related to the use of social insurance benefits
Finance	trading, payment, clearing and settlement infrastructures and systems of financial instruments
	bank and credit institution security
	cash supply

Sector	Sub-sector
IT	internet access service and internet infrastructure
	electronic communication services, electronic communication networks
	broadcasting
	postal services
	government electronic information systems
Water	drinking water service
	control of the quality of surface and underground waters
	sewage drainage and cleaning
	protection of water bases
	flood defences, dams
Army	national defence systems and facilities
Public safety protection	infrastructures of law enforcement bodies

Source: Compiled by the author.

Government Decree 65/2013 (III.8.) on the implementation of Act CLXVI of 2012 on the identification, designation and protection of essential systems and facilities defines the rules of designation/withdrawal, the tasks of the security liaison officer and general expectations for its employing, as well as the obligation to prepare the Operator Security Plan.

Government Decree 246/2015 (IX.8.) on the identification, designation and protection of critical health systems and facilities entered into force in 2016 for the healthcare sector. The decree defines the sub-sectors and designation criteria, the sector-specific rules of the identification procedure and designation, as well as the sector requirements imposed on the security liaison officer.

Accordingly, the identification procedures and designations also took place in 2016 in the Hungarian health sector.

In 2020, the CIP Act and its implementation decree was also amended, according to which the critical infrastructure elements were re-identified and re-designated. An important change is that the implementation decree precisely defines the content elements of the Operator Security Plan. The National Directorate General for Disaster Management provides uniform help for this and for the preparation of the risk assessment on its website.

Other relevant legislation in the regulatory system of Hungarian critical infrastructure protection:

In Government Decree 188/2016 (VII.13.) on the amendment of Government Decree 346/2010 (XII.28.) on governmental networks, it is laid down that the critical infrastructure elements must be connected to the Unified Digital Radio Telecommunication System (UDRTS) and an UDRTS device must be operated. In practice, this ensures the possibility that the operator of the critical infrastructure is always able to communicate with the communications centre of the disaster management authority coordinating the protection of the critical infrastructure.

Act L of 2013 on the electronic information security of state and local government bodies specifies that operators of critical infrastructures must also classify their IT security organisations and their IT systems into security levels. It also stipulates that

the highest class and level must be reached by levelling every two years for critical infrastructures.

With the emergence of the concept of critical infrastructures in health care, a new era began in Hungarian hospital security, as well. With the operator's security approach, the entire operational process, including the areas of hospital safety and security mentioned in the above sections, can be implemented in a complex manner, taking into account their effects on each other.

Summary

In summary, it can be said that the development of the normative regulation of hospital security and its so-called classic safety and security areas has been continuous since the regime change. This was influenced by the mass emergence of private property (e.g. property protection), mass access to new techniques and technologies, and, to a large extent, the legal harmonisation and standardisation necessary in connection with Hungary's accession to the European Union.

The most recent and most comprehensive step in the development of the normative environment is the horizontal and sectoral regulation of critical infrastructures. The resulting operator security planning is suitable for complex management of the safety and security areas mentioned in the study, since they are present everywhere during the operation of the hospital, from the organisation of human resources, through the operation of the facility, to the basic processes of the institution.

The 2020 change in legislation related to critical infrastructures and the appearance of risk assessment and operator security planning aids showed significant progress towards a complex, process-based approach to operator security. However, in my opinion, for the full interpretation, follow-up and continuous evaluation of measures, and for the operative intervention during extraordinary events, it is essential to adopt a business continuity approach that provides a standard, process-based approach, i.e. the introduction of Business Continuity Management Systems. The need for this is not only valid for the designated critical infrastructures, as the legal environment presented above defines its requirements for all inpatient care institutions.

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Act CXXXIII of 2005 on personal and property protection, as well as the rules of private investigation activity
Act CXXVIII of 2011 on disaster prevention and the amendment of certain related laws
Act CLXXXV of 2012 on waste
Act CLXVI of 2012 on the identification, designation and protection of essential systems and facilities
Act CLXVI of 2012 on the implementation of Government Decree 65/2013 (III.8.) on the identification, designation and protection of essential systems and facilities
Act L of 2013 on the electronic information security of state and local government bodies
Government Decree 14/1960 (III.24.) on the organisation of industrial law enforcement bodies
Decree 4/1980 (XI.25.) of the Ministry of the Interior on the issuance of the National Fire Safety Codes and Standards
Decree 56/1981 (XI.18.) of the Council of Ministers on the control of the generation of hazardous waste and activities related to their disposal
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Decree 6/1988 (II.12.) of the Council of Ministers on law enforcement activities of inter-governmental bodies
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