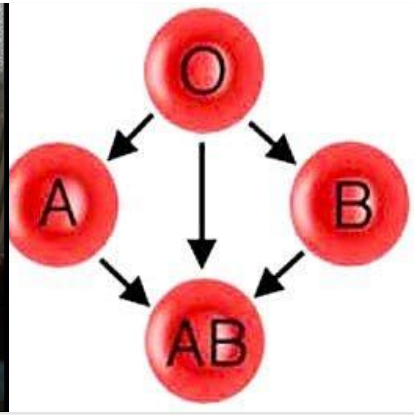
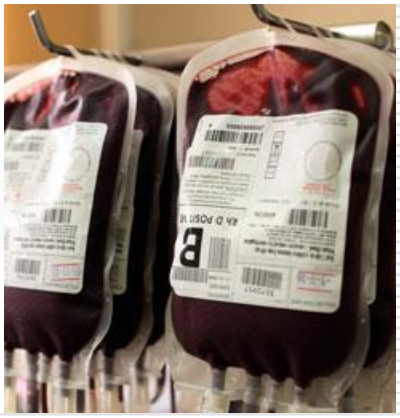
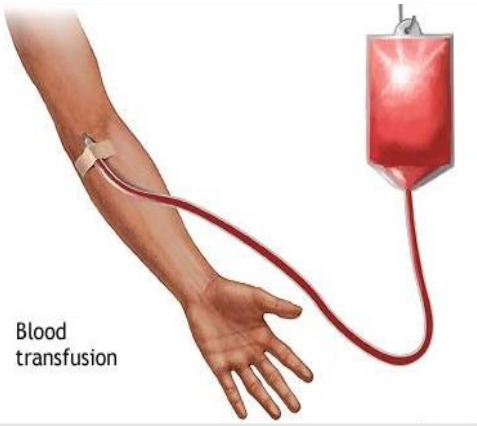
Short description of Bulgarian hemotransfusion system. National regulation. Preparedness of Blood establishments to work in special circumstances .







Several public structures are involved in blood collection in Bulgaria

6 big blood establishments - centers of transfusion hematology: The National center of transfusion hematology (NCTH), 4 Regional centers of transfusion hematology (RCTH) and Center of transfusion hematology at Military Medical Academy (CTH).

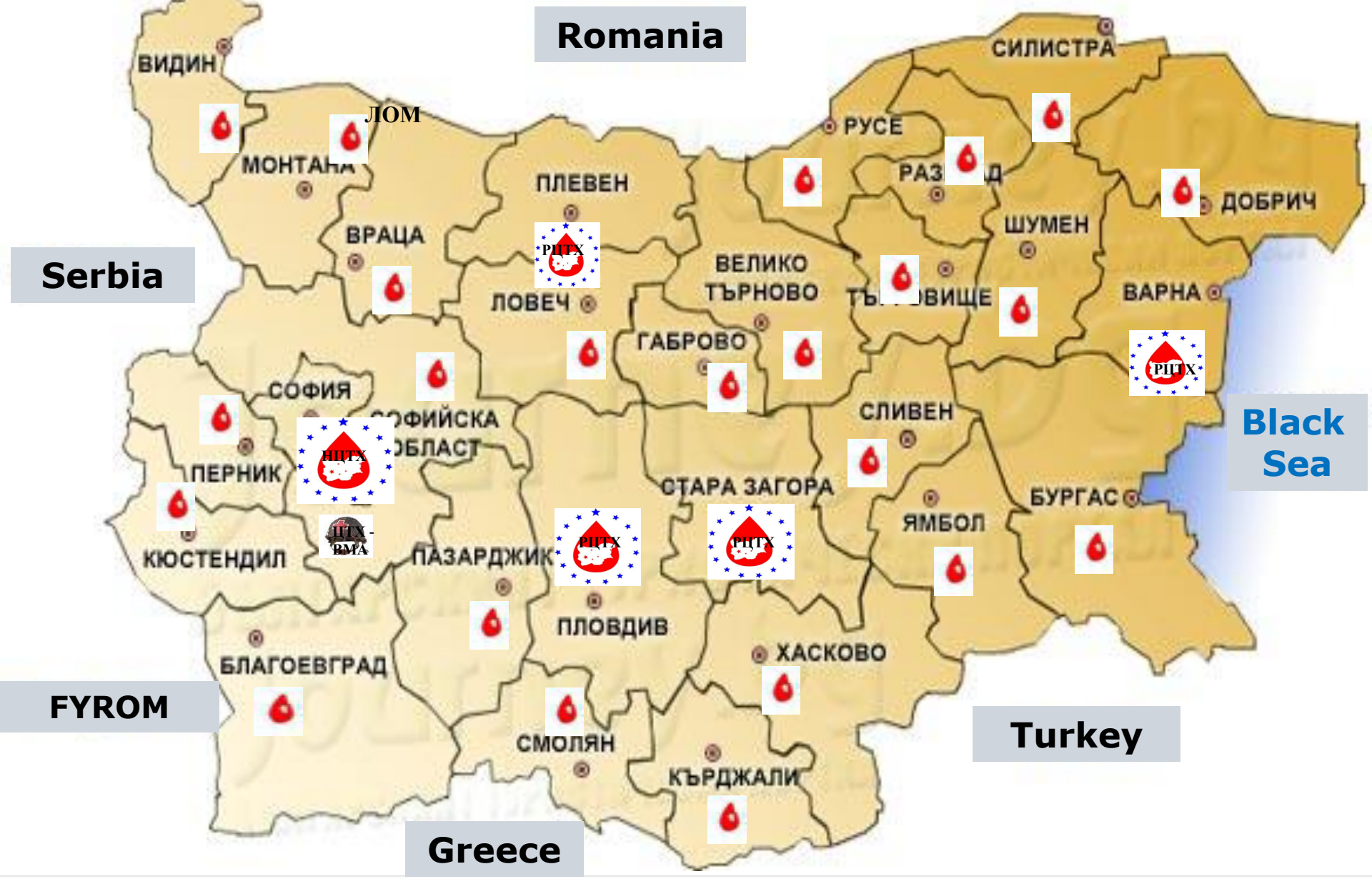
23 hospital based small blood establishments - departments of transfusion hematology (DTH) are engaged in promotion of blood donation and blood collection. The blood collected in DTH is tested and processed in big blood transfusion centers.

Two of the Regional blood establishments are located in the north part of the country and two of them in the south part. The National Centre of Transfusion Hematology (NCTH) is located in the capital city of Bulgaria.

Every blood establishment (including NCTH) supplies a definite area. This area includes different number of district cities where are located Departments of transfusion hematology in multi-profile, district hospitals (small blood establishments). Regional blood establishments collect blood from donors in big cities where they are located - city of Plovdiv, Varna, Pleven and Stara Zagora.

The difference between Regional blood establishments and Departments of transfusion hematology is that only big regional blood establishments perform diagnosis of donated blood for transmissible infections and they have in their structures processing area.

Location of NCTH, RCTH and Departments of transfusion hematology in multi-profile, district hospitals in Bulgaria



Blood banks at hospitals:

(Real name according to Bulgarian legislation is Laboratory of Transfusion Hematology)

Usually blood banks are based in big hospitals that actively perform transfusion of blood components.

They are responsible for:

- Supply with blood and blood components for particular patient and storage it until transfusion.
- Immunohematological analysis of patients and selection or reselection of blood and blood components for patient.
- Distribution of blood and blood components to wards in hospital.
- Optimal use of blood components in wards of the hospital and hemovigilance.

Blood banks are not authorized to collect blood from blood donors.

They receive analyzed and tested blood and blood components from blood establishments (center or department of transfusion hematology).

Hospitals for in-patient care, transfusing blood and blood components:

The number of these hospitals in 2014 is 249 but their number may vary annually because number of hospitals decrease or increase and medical activities in hospitals may change. Hospitals keep records for every unit blood and blood components entered in wards of the hospital. Transfusion must be well documented according requirements of standard of "Transfusion Hematology". Additionally, hospitals for inpatient care, transfusing blood and blood components must establish Commission for control on the quality, safety and rational use of blood and blood components according Art.41 of “Law for blood, blood donation and blood transfusion. This commission is the consulting body for management board of the hospital in the field of hemotransfusion.

Directive 2002/98 EC

(16) Blood establishments should establish and maintain quality systems involving all activities that determine the quality policy objectives and responsibilities and implement them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system, taking into account the principles of good manufacturing practice as well as the EC conformity assessment system.

Quality System

BEs already established a quality system. It contain descriptions of at least the following processes: - quality management, quality assurance, continuous quality improvement, - change control and validation processes; - personnel and organization; - premises and equipment; - documentation; - blood and blood components testing and processing; - storage, issuing and distribution of blood and blood components; - quality monitoring;- quality control; - deviations, complaints, adverse events or reactions, withdrawal of blood, corrective and preventive measures; - self-inspections, audits and quality improvement; - contract management.

The quality system of BEs is documented (SOPs, instructions, job descriptions for working places, which include the specific tasks, authority, responsibilities and accountability etc.). Part of the maintained documentation is listed in SMF (Site Master File - similar to SMF for producers of blood and blood components derived medicines adapted for Blood Establishments according EuBIS project.) which is sent every year by BEs to competent authority. NCA checks quality system documents for updates and reviews during in site inspections and desk-based checks of the mandatory documentation.

Лого	Отделение по трансфузионна хематология при …… ПК…., гр. ……, ул. ……№ …, тел.……, факс:……	
Код на СОП	Стандартна Оперативна Процедура (СОП)	Стр. 1 от 2
Име на сектора използващ СОП-а		

СОП:
Код на документа
Версия (пр. Версия 1.0)

Наименование на СОП (пр. Получаване на ПЗП и др.)

Валиден от:	Датата в която е влязъл в употреба. Краен срок. Трябва да се създаде процедура по документиран контрол, гарантираща редовен преглед на документите.
Заменена версия:	Код и версия на СОП
Промени:	Описание на значимите промени направени спрямо предишната версия на документа. Причините за промените.
Разпространител:	Оригиналът се съхранява при: Отговорник качество Идентификация/ брой копия

Написан от:	**Рецензиран и одобрен от:**		
……име……	……име……/……име……/……име……		
Дата:……	Дата:……	Дата:……	Дата:……
подпис	подпис	подпис	подпис

Код/ версия/ копие на СОП.

	Отделение по трансфузионна хематология при „МБАЛ Силистра" АД гр. Силистра 7500, гр. Силистра, ул. „П. Мутафчиев" № 80, тел. 086/ 818 420, 818 421, факс: 086/ 823 917	
ИХЛ	Стандартна Оперативна Процедура (СОП)	Стр. 1 от 4
Име на сектора използващ СОП-а Имунохематологична лаборатория		

СОП:
ИХЛ-ПР-001
Версия 1.0

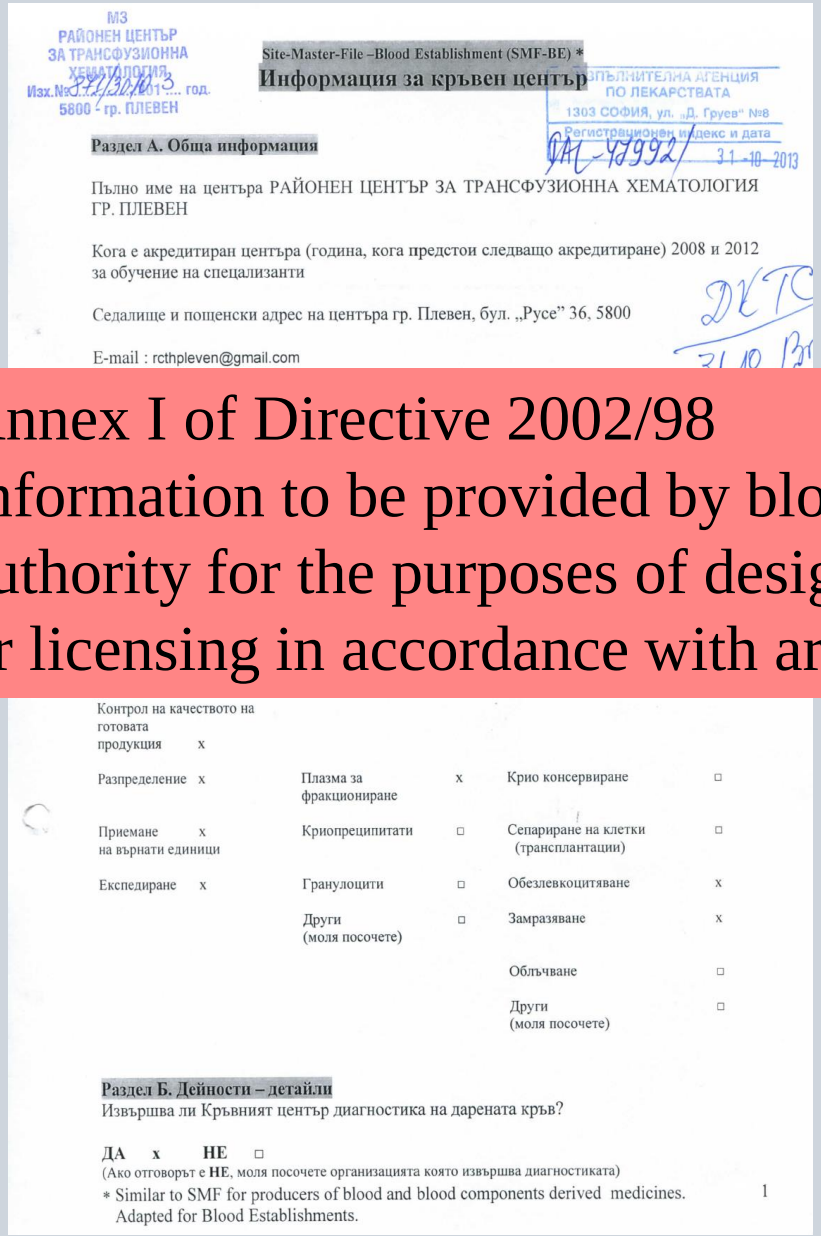
Наименование на СОП: Лабораторна практика в имунохематологична лаборатория

Валиден от:	01.01.2014г.
Заменена версия:	NA
Промени:	NA
Разпространител:	Оригиналът се съхранява при: Н-к ОТХ Идентификация: 2 броя (Копие 1 представлява оригинала) (Копие 2 се намира при персонала работещ по СОП-а)

Написан от:	**Рецензиран и одобрен от:**		
Д-р Панайотова Н-к ОТХ	Д-р Костадинова Изп.Директор „МБАЛ-Силистра" АД		
Дата:01.01.2014 г.	Дата:01.01.2014 г	Дата:……	Дата:……
подпис	подпис	подпис	подпис

ИХЛ-ПР-001/ версия 1.0/ копие 1

SMF(Site Master File-adapted for Blood Establishments according EuBIS project)



МЗ
РАЙОНЕН ЦЕНТЪР
ЗА ТРАНСФУЗИОННА
ХЕМАТОЛОГИЯ
Изх.№ 577/30.10.2013 год.
5800 - гр. ПЛЕВЕН

Site-Master-File –Blood Establishment (SMF-BE) *

Информация за кръвен център

ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА
1303 СОФИЯ, ул. „Д. Груев" №8
Регистрационен индекс и дата
ИА-47992/ 31-10-2013

Раздел А. Обща информация

Пълно име на центъра РАЙОНЕН ЦЕНТЪР ЗА ТРАНСФУЗИОННА ХЕМАТОЛОГИЯ ГР. ПЛЕВЕН

Кога е акредитиран центъра (година, кога предстои следващо акредитиране) 2008 и 2012 за обучение на специализанти

Седалище и пощенски адрес на центъра гр. Плевен, бул. „Русе" 36, 5800

E-mail : rcthpleven@gmail.com

Контрол на качеството на готовата продукция x

Разпределение	x	Плазма за фракциониране	x	Крио консервиране	□
Приемане на върнати единици	x	Криопреципитати	□	Сепариране на клетки (трансплантации)	□
Експедиране	x	Гранулоцити	□	Обезлевкоцитяване	x
		Други (моля посочете)	□	Замразяване	x
				Облъчване	□
				Други (моля посочете)	□

Раздел Б. Дейности – детайли

Извършва ли Кръвният център диагностика на дарената кръв?

ДА x **НЕ** □

(Ако отговорът е **НЕ**, моля посочете организацията която извършва диагностиката)

* Similar to SMF for producers of blood and blood components derived medicines. Adapted for Blood Establishments.

1

Сертифициран ли е кръвният център от външно Сертифициращо тяло, напр. по ISO?

ДА □ **НЕ** x

Раздел Л. Подпис и дата

Дата: 30.10.2013г.

Изготвил: Нач.отд.УККК д-р Данов подпис: .....

Утвърдил: Директор РЦТХ-Плевен д-р Лаков подпис: .....

* Similar to SMF for producers of blood and blood components derived medicines. Adapted for Blood Establishments.

41

Annex I of Directive 2002/98

Information to be provided by blood establishment to the competent authority for the purposes of designation, authorization, accreditation or licensing in accordance with article 5(2)

Directive 2002/98 EC
Article 5
Designation, authorisation, accreditation or licensing of blood establishments

The Ministry of Health is responsible for blood establishments accreditation. Accreditation is carried out according to the "Health Establishments Law" Art. 86 by the Accreditation Council, which is a specialized accreditation body to the Minister of Health.

All blood establishments are accredited. Some of them will be re-accredited this year.

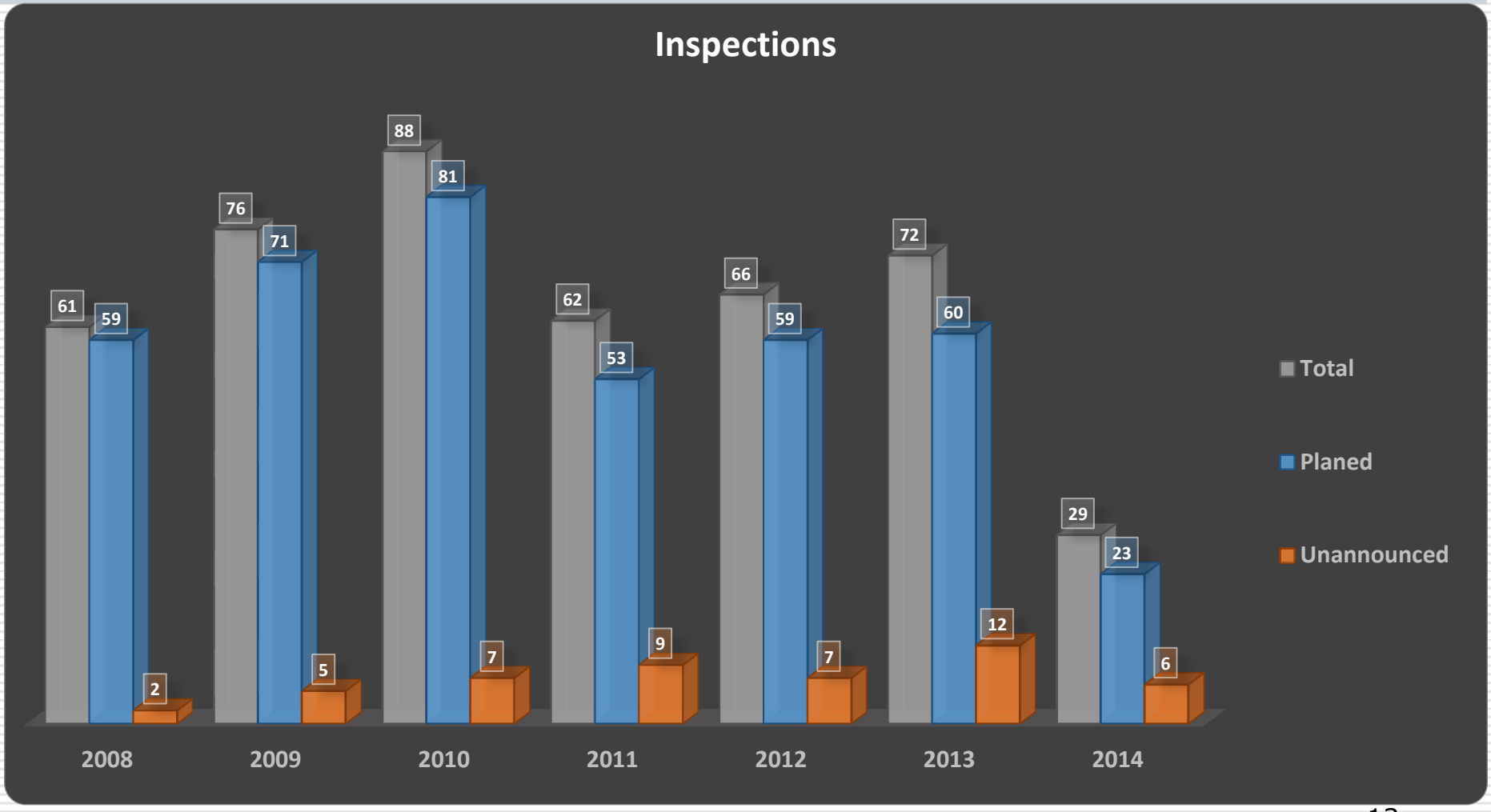
Directive 2002/98 EC
Article 8
Inspection and control

Article 8
Inspection and control measures

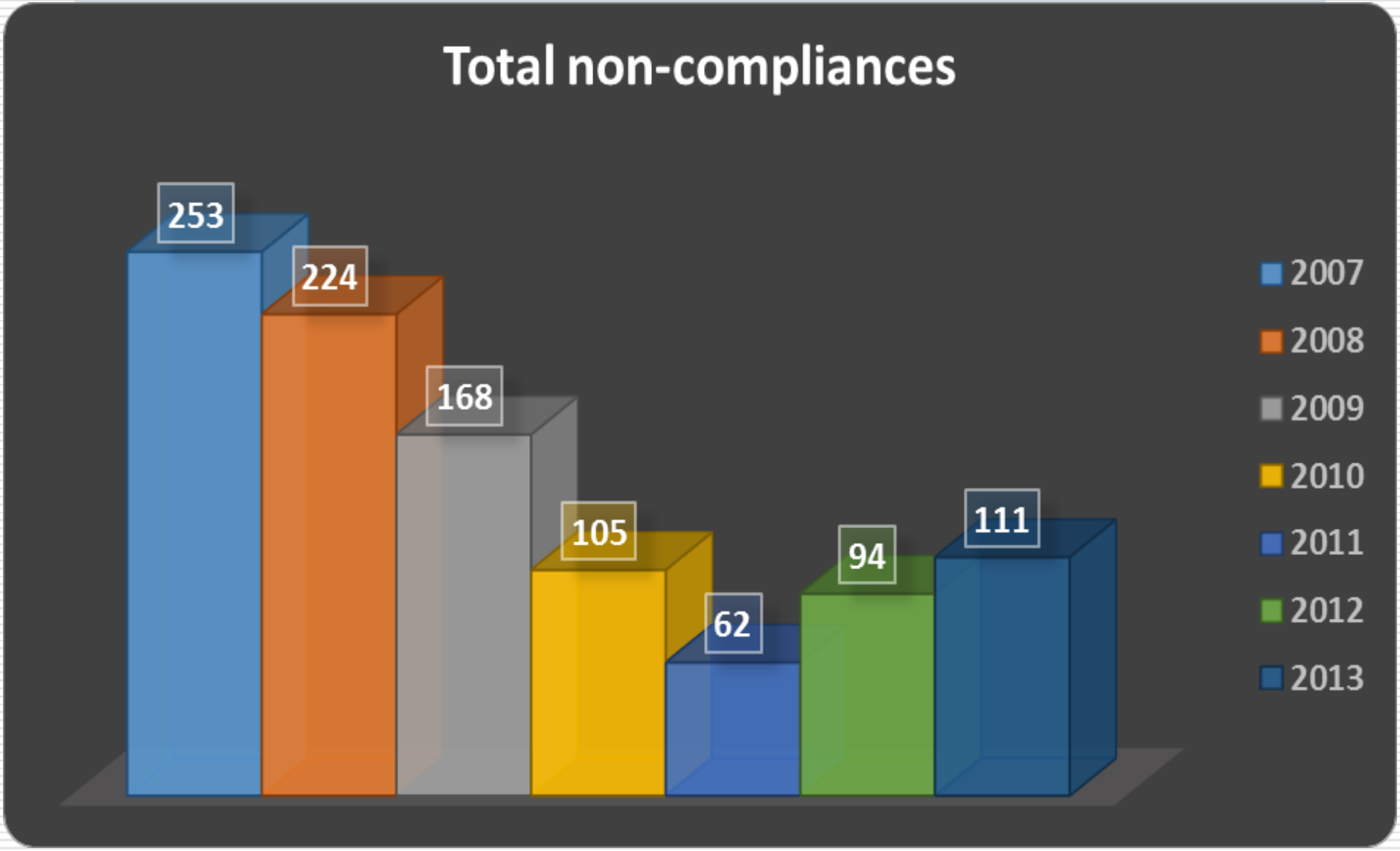
1. Member States shall ensure that the competent authority organise inspections and appropriate control measures in blood establishments to ensure that the requirements of this Directive are complied with.

According to the "Law for blood, blood donation and blood transfusion" Art.38 : The Executive Director of the Bulgarian Drug Agency shall function as a competent authority. Executive Director of the Bulgarian Drug Agency shall execute direct control through officials determined by him. In 2007 the department of " Control of blood transfusion system" was established.

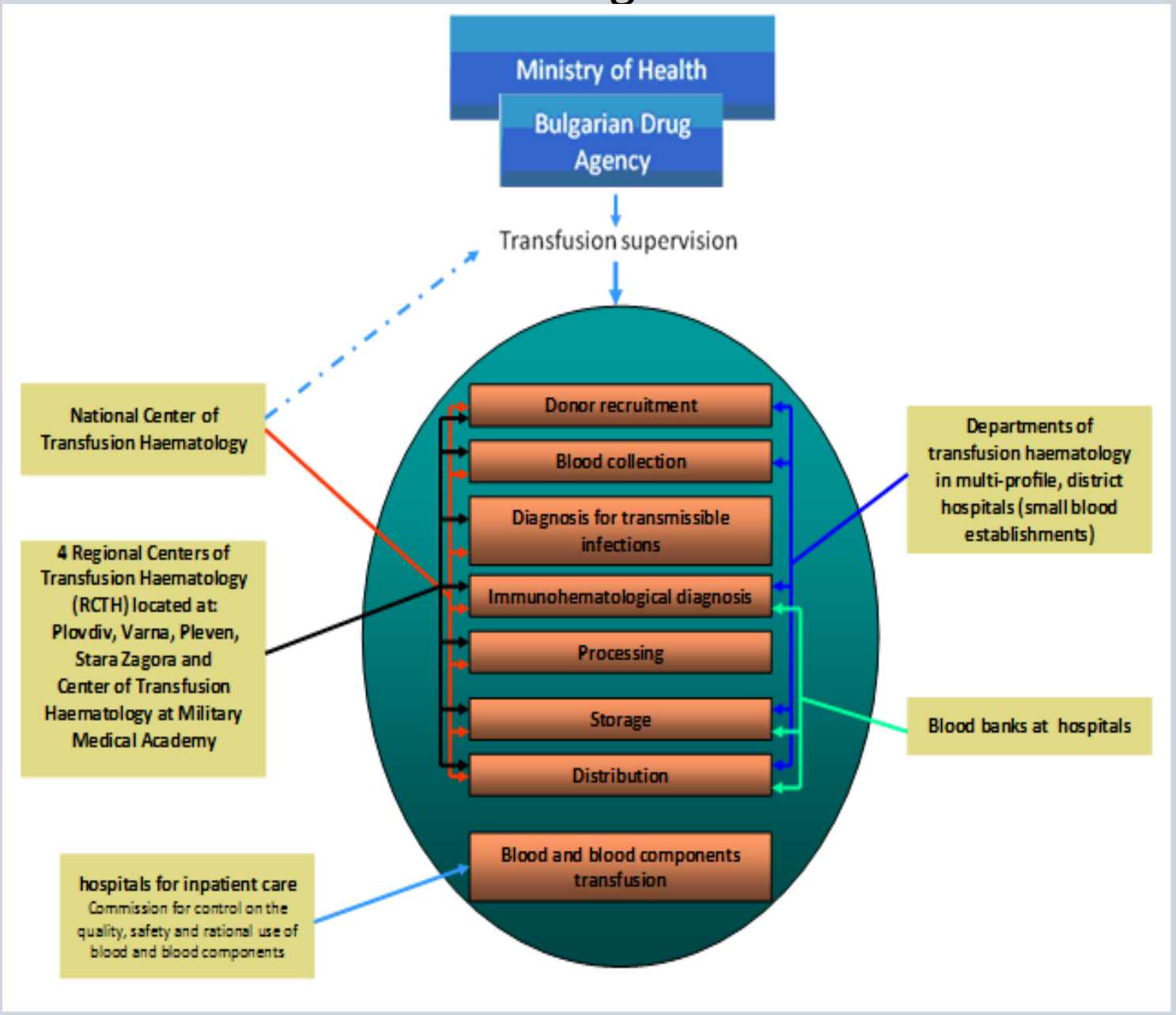
Inspections performed by NCA in BEs and hospitals for inpatient care, transfusing blood and blood components



Tendency in number of non-compliances per year



Interaction between the main actors involved in the blood system in Bulgaria



National regulation

European blood legislation requirements:

Directive 2002/98 EC and its technical annexes
Directive 2004/33 EC - technical requirements
Directive 2005/61 EC – traceability and SAR/SAE
Directive 2005/62 EC – Quality Management

The law "Law for blood, blood donation and blood transfusion" was already established in 2003. The last revision was implemented in July 2012. "Law for blood, blood donation and blood transfusion" is the main legislative document that introduces the basic rules, participants in the processes of blood donation, blood components processing and transfusion, their main features and their interaction.

To apply the various European Directives for Blood, legislator - The Ministry of Health has introduced a number of regulations for complete transposition of their requirements:

- Regulation № 9 establishing medical standard "Transfusion Hematology" May 2006, . Introducing - Directives 2002/98; 2004/33; 2005/61 and 2005/62.

- Regulation № 28 for the conditions for records keeping (a registry type) at The Ministry of Health and Drug Agency according “Law for blood, blood donation and blood transfusion”August 2004 amended. SG. 39 of 15 May 2007. Introducing - Directive 2002/98 - Chapter IV; Article 13- Record keeping

-Regulation № 29 of 19 July 2004 on the conditions and order to draw up, processing, storage and provision of information from register under Art. 36 of “Law for blood, blood donation and blood transfusion” and the form of documents in hemotransfusion chain. SG. 82 of 21 September 2004.

Introducing - Directives 2002/98; 2004/33; 2005/61 and 2005/62 – all chapters (articles) connected to different kind of data and documents that are required. Example: Directive 2005/62 – Annex; 5. Documentation

- Regulation for the conditions and order of inspections at hospitals performing activity under the "Law on blood, blood donation and blood transfusion" SG. 68 of 3 August 2004 amended. SG. 37 of 8 May 2007.

Introducing - Directive 2002/98 - joint text approved (14) and Chapter II; Article 8. In Bulgaria inspections are done at annual basis.

- Regulation № 5 for the conditions and order for free granting medical devices for blood collection, diagnosis, processing and storage of blood and blood components. SG.13 February 2005., amended. SG. 37 of 8 May 2007.

According: Directive 93/42/EC; Directive 93/68/EC; Directive 98/79/EC. For medical device.

- Regulation № 8 for recall, destruction or providing for educational or scientific medical needs of blood and blood components -SG. 24 of 20 March 2007.

Introducing – Directive 2005/62 – Annex; 9. Non – conformance

- Regulation № 18 of 10 June 2004 on the conditions and procedure for the diagnosis, processing and storage of blood and blood components and quality of blood from import.Prom. SG. 58 of 6 July 2004.

Introducing –Directives 2002/98 - Annex IV; 2005/62 – Annex; 2004/33 - Annex IV; Annex V

Import of blood and blood components

The rules and conditions for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries are clearly indicated in the “Law for blood, blood donation and blood transfusion”

Article 8. (1) Blood and blood components shall only be imported in the territory of this country with the permission of the Minister of Health or a Deputy Minister authorized by the Minister in case of emergencies where the available quantities of blood and blood components in the country are not sufficient for the protection of people's health.

(2) The import under Paragraph 1 above shall be allowed in case the blood and blood components have been diagnosticated, processed, labelled and provided by an institution legally recognised by the respective state and shall be accompanied by documentation making possible the identification of every unit of blood or blood components and by information about laboratory testing performed and about the methods of diagnostics and processing.

Export of blood and blood components

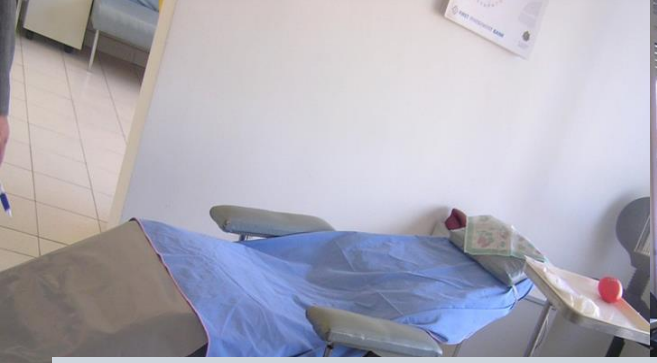
The rules and conditions for the authorisation and control of the export of blood and blood components for transfusion from EU Member States or third countries are clearly indicated in the "Law for blood, blood donation and blood transfusion"

Article 7.(1) Blood and blood components shall only be exported beyond the territory of this country by a decision of the Council of Ministers, where they are meant for:

1. rendering humanitarian aid;

2. production of drugs for this country's needs.

(2) The Minister of Health shall organise the export of blood and blood components in the cases under item 2 of Paragraph 1 above



Preparedness of Blood establishments to work in special circumstances


National multi sectoral and multi-level emergency management in special circumstances.

Legislation:

National Disaster Protection Plan is prepared pursuant to Article 62, paragraph 2, item 2 of the Disaster Protection Act

This Act shall settle providing the protection of the life and health of the population, the conservation of the environment and the property in case of disasters.

According Art 2. of Disaster Protection Act

"Disaster shall be any significant disruption of the normal functioning of society, caused by natural phenomena and/or human activity, leading to negative consequences for the life or health of the population, property, economy and the environment and which the capacity of the system servicing the routine activities related to protection of society would be insufficient to prevent, bring under control and overcome."

Disaster protection shall be provided on a national, district and municipal level

- at **National level**:

A National multi sector emergency management committee is organized as a commission to the Council of ministers. In the National multi sector emergency management committee participate specialists of different ministries (MoI (incl. DG Fire Safety and Civil Protection), MoH, MoD, MoF, MoE – usually at level of deputy minister)

Key risks and threats to the occurrence of non-military (natural) crises in Bulgaria and their impact on medical service| (including blood transfusion service).

The complex natural-geographical structure of Bulgaria makes it vulnerable to various factors affecting the occurrence of non-military crises. The analysis of the principal risks and threats that may lead to the occurrence of non-military crises in Bulgaria shows that they can be caused by natural phenomena such as:

floods

earthquakes

landslides

drought

a major fire

strong winds and tornado

heavy snow, blizzards, ice and avalanches

According Disaster Protection Act

The main principles of disaster protection shall be:

1. right of protection for every person;

2. privilege of the rescue of the human life before the rest activities upon the protection;

3. publicity of the information for the risks of disasters and for the activities of the bodies of the executive power upon the protection in case of disasters;

4. privilege of the preventive measures when ensuring the protection;

5. responsibility for the implementation of the measures of protection;

6. submission of forces and resources for protection stage by stage.

The Minister of Interior shall draw up the National Disaster Protection Plan jointly with representatives of the ministries, departments, The Bulgarian Red Cross and the local government authorities. The National Disaster Protection Plan shall be adopted by the Council of Ministers.

- at **District level**:

The district governor shall organize the drawing up of a district disaster protection plan in coordination with the territorial units of the central executive power and the mayors of municipalities.

The district disaster protection plan shall be approved by an order of the district governor following coordination with the Minister of Interior.

- at **Municipality level**:

The mayor of the municipality shall draw up a municipal disaster protection plan jointly with representatives of departments and legal entities related to disaster protection carrying out their activity within the territory of the municipality.

The municipal disaster protection plan shall be adopted by the municipal council.

Bulgaria consists of 28 districts (oblasti, singular - oblast)

Bulgaria – location of BEs

All districts have on their territories blood establishment

Blood supply management in special circumstances

Ministry of Health plans every year an additional financial support in case of disasters as part of a disaster protection plan.

A reserve of medical devices for blood collection is kept at national level .

In 2011 was set up Team for crisis management in transfusion system under the leadership of the Director of NCTH including directors of all RCTH in the country.

All Blood Establishments have crisis preparedness plans. These plans are coordinated with the other health care structures at district level – regional health inspection, hospitals for inpatient care and with nonmedical structures as district administration, Fire safety and Civil Protection, police, armed forces etc. Director of each BEs is a member of district council in case of disasters.

Blood supply management in special circumstances

The crisis preparedness plan contains different aspects such as: risk communication; power supply in emergency circumstances; organization of mobile teams; change of location; needs of laboratory equipment and supplies used for testing in case of changes from automated systems for diagnostic to manual methods; transport of blood components to the hospitals (including military air transport) ;transport of donated blood to the other BEs with working processing area; etc. The plans of the hospital based small blood establishments are a part of a multi-profile, district hospital's crisis preparedness plan.

Since 2007 all Blood Transfusion Centers in the country are equipped with additional machines for all critical activities i.e. processing centrifuges, automated systems for diagnostic, cooling systems.

All Blood Establishments have operative reserve of medical devices for blood testing.

Blood supply management in special circumstances

All Blood Establishments have operative reserve of medical devices for blood collection .

According to an ordinance of the Minister of Health from 1996 a reserve of blood components (red cells, FFP, platelets) is available in the BEs. The quantity of different blood components from different blood groups in the reserve is evaluated on the basis of the number of inhabitants in the region and the prevalence of the blood groups in the general population.

The renewal of listed reserve is executed according to the shelf life:

- the medical devices for blood collection are renewed at least once per year
- the medical devices for blood testing and the blood components are exchanged continually.

Blood supply management in special circumstances

Factors that allow collaboration between Blood Establishments in exchange of blood components of the same quality and medical devices for collection and testing of blood in special circumstances:

-the existing legal and regulatory framework
-implemented quality system in BEs.
-implemented, Internet based National information system-blood donor register. Interconnections between the BEs is in place.
-uniform forms of documents in hemotransfusion chain for blood and blood products in the country.
-the available blood supplies in country are reported on weekly basis to the Minister of Health trough the Director of NCTH.
-a haemovigilance reporting system is in place in the country-system is uniform and mandatory.
-all BEs are inspected at regular basis by NCA.

Blood supply management in special circumstances

During the last 10 years we didn’t face a situation caused by natural disasters, affecting the blood supply in all the country.

Unfortunately we have had other accidents, caused by activities or actions of the human - road and industrial accidents and a terrorist act.

Thank you for your attention !