

**REGULATION No. 26**  
**ON THE REQUIREMENTS AND PROCEDURES FOR CONDUCTION OF INSPECTIONS AT**  
**HEALTHCARE FACILITIES PROVIDING SERVICES UNDER THE BLOOD, BLOOD DONATION**  
**AND BLOOD TRANSFUSION ACT (Title amended in SG, Issue 37 of 2007)**

*Issued by the Ministry of Health*

*Promulgated in the State Gazette, Issue 68 of 3 August 2004, amended in SG issue 37 of 8  
May 2007*

Article 1. (Amended in SG, Issue 37 of 2007) This regulation lays down the requirements and procedures for conduction of inspections in healthcare facilities providing services under the Blood, Blood Donation and Blood Transfusion Act.

Article 2. (Amended in SG, Issue 37 of 2007) The inspections conducted at healthcare facilities may be:

1. planned;
2. unplanned;
3. (Repealed in SG, Issue 37 of 2007)

Article 3. (Amended in SG, Issue 37 of 2007) (1) Planned inspections should be carried out on an annual basis according to a plan approved by the Executive Director of the Bulgarian Drug Agency (BDA).

(2) The plan should contain the names of all healthcare facilities which will be inspected during the respective calendar year and the date when the inspection is expected to be started.

(3) The plan should be published on the official webpage of BDA not later than 30 November of the pervious calendar year.

Article 4. (Amended in SG, Issue 37 of 2007) Unplanned inspections should be conducted by order of the Executive Director of BDA, without any prior notification of the healthcare facility.

Article 5. (Amended in SG, Issue 37 of 2007) Unplanned inspections should be conducted in case of serious events or serious adverse reactions, or in case of suspected serious events or serious adverse reactions, within 7 days from their reporting to BDA.

Article 6. (1) (Amended in SG, Issue 37 of 2007) The inspections specified in Article 2 should be conducted by commissions of officials appointed by order of the Executive Director of BDA.

(2) (Repealed in SG, Issue 37 of 2007)

(3) (Amended in SG, Issue 37 of 2007) The order specified in paragraph 1 should contain a description of the subject matter of the inspection and the period in which it will be conducted.

Article 7. (Amended in SG, Issue 37 of 2007) Depending on the types of services provided under the Blood, Blood Donation and Blood Transfusion Act by the healthcare facilities, the subject matter of such inspections may be:

1. (Amended in SG, Issue 37 of 2007) the quality assurance system ensuring the safety of blood and blood components;
2. donor selection;
3. collection of blood and blood components;
4. testing of blood and blood components;
5. processing of blood and blood components;
6. laboratory tests of the donor and the recipient;
7. services related to the release, labelling, storage and issuing of blood and blood components;
8. quality control results;
9. (Amended in SG, Issue 37 of 2007) the functions of the information system and the services related to registration, processing and storage of information in it;
10. records keeping;

11. equipment maintenance;
12. personnel training;
13. (Amended in SG, Issue 37 of 2007) results from external inspections;
14. Haemovigilance system;
15. safety rules during sampling for testing;
16. safety rules during blood transfusion;
17. (Repealed in SG, Issue 37 of 2007);
18. the work done by the commissions for control of the quality, safety and reasonable use of blood and blood components.

Article 8. (Amended in SG, Issue 37 of 2007) During the inspection the persons specified in Article 6, paragraph 1, should be given free access to the inspected healthcare facilities and authorised to access any documentation related to the subject matter of the inspection and to take samples.

Article 9. (1) (Amended in SG, Issue 37 of 2007) The commission should submit to the Executive Director of BDA a written report on the results from the inspection not later than:

1. in planned inspections: not later than 10 days after its completion;
2. in unplanned inspections: not later than 3 days after its completion.

(2) (Amended in SG, Issue 37 of 2007) A copy of this report should be submitted to the head of the inspected healthcare facility.

(3) (Amended in SG, Issue 37 of 2007) The healthcare facility is entitled to submit an objection to the Executive Director of BDA related to the statements made in the report, within 7 days from its delivery.

#### Final provisions

Paragraph 1. (Amended in SG, Issue 37 of 2007) This regulation is issued on the grounds of Article 39, paragraph 6 of the Blood, Blood Donation and Blood Transfusion Act.

#### Additional provisions

TO THE REGULATION AMENDING AND SUPPLEMENTING REGULATION No. 26 OF 2004 ON  
THE REQUIREMENTS AND PROCEDURES FOR CONDUCTION OF INSPECTIONS OF  
HEALTHCARE FACILITIES PROVIDING SERVICES UNDER THE BLOOD, BLOOD DONATION AND  
BLOOD TRANSFUSION ACT

(Promulgated in state Gazette, Issue 37 of 2007)

§11. Throughout the entire regulation, all instances of 'audit', 'the audit', 'audits', 'the audits', and 'audited' will be replaced by 'inspection', 'the inspection', 'inspections', 'the inspections', 'inspected'.

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*I, the undersigned Maria Georgieva Eneva, hereby certify that this is a full, true and accurate translation from Bulgarian into English of the attached document: Regulation No. 26.*

*The translation consists of 4 (four) pages.*

*Translator: Maria Georgieva Eneva*