



Федеральная служба  
по надзору в сфере  
здравоохранения

# Federal Service on Surveillance in Healthcare

## The Federal Service on Surveillance in Healthcare Activity

**Borzik I.K.**  
**Deputy Head**  
**of the Federal Service on Surveillance in Healthcare**



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# Federal Service on Surveillance in Healthcare (Roszdravnadzor)

**2004**



**Birzhevaya Sq, h. 1**

**By the decree of the President of the Russian Federation dated 9 March 2004 No.314 «About the system and structure of Federal bodies of Executive power» established a system of Federal bodies of Executive power, including Federal ministries, Federal services and Federal agencies**

**2014**

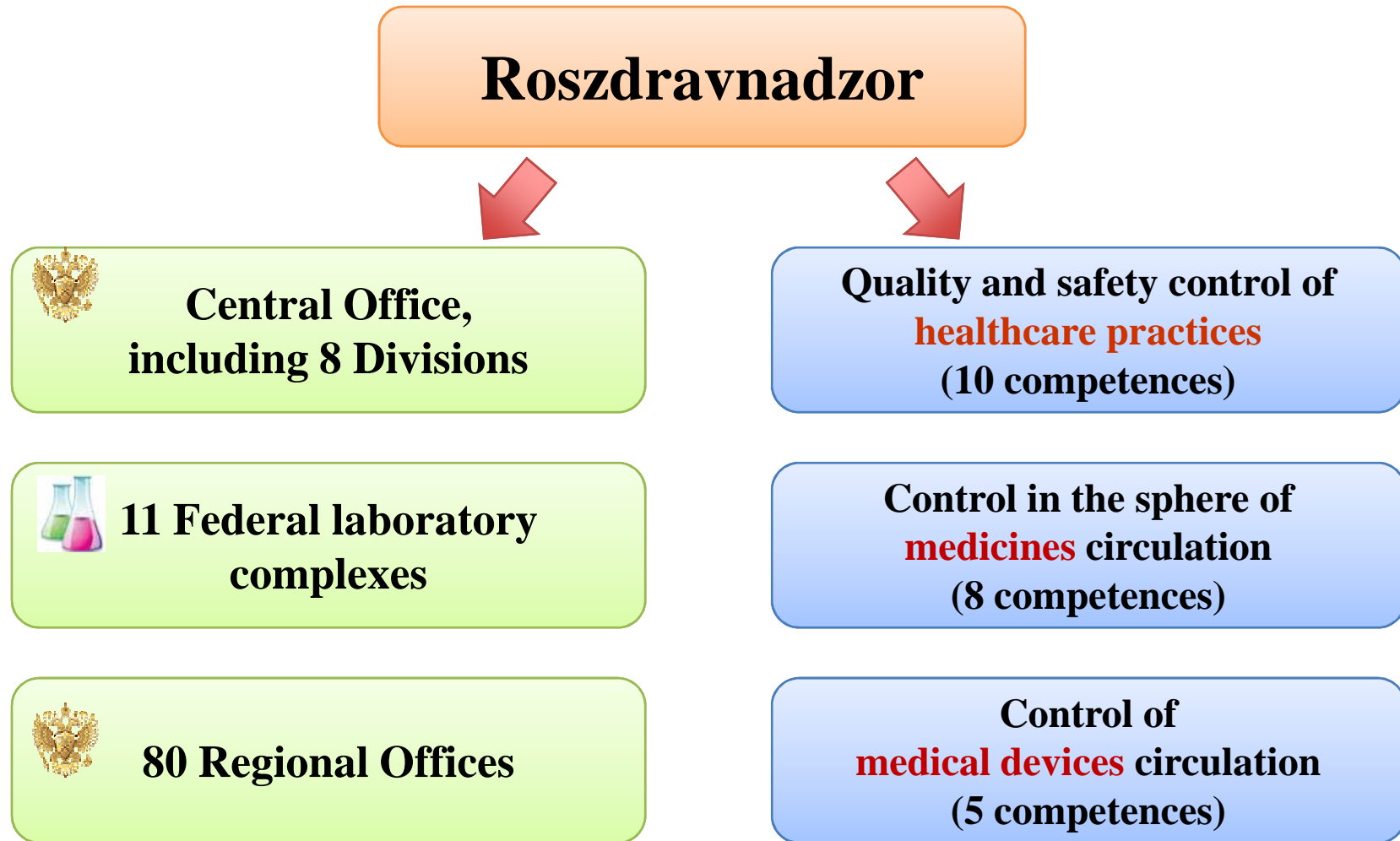


**Slavyanskaya Sq, h. 4, b. 1**



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# Structure and Competence of Roszdravnadzor





# Regional Offices of Roszdravnadzor



**Each subject of the Russian Federation has a territorial body of Federal service on surveillance in healthcare (Roszdravnadzor)**





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# Federal State Budgetary Institution “Information and Methodological Center for Assessment, Recording and Analyzing of Medical Equipment” of Roszdravnadzor



Organizational department

Analytical laboratory

Microbiological laboratory

Pharmacological laboratory

Immunological laboratory  
(Krasnoyarsk, Moscow)

Mobile laboratory





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## Federal State Budgetary Institution “All-Russian Scientific-research and Test Institute for Medical Engineering” of Roszdravnadzor



Testing laboratory of medical supplies and tools

Technical tests laboratory of medical devices

Testing laboratory of mobile complexes for medical purposes

Testing laboratory of instruments and equipment for functional diagnostics and physiotherapy

Testing laboratory of medical devices software

Testing laboratory of instruments and apparatus for radiation diagnosis and therapy

Testing laboratory of electromagnetic compatibility of medical equipment

Testing laboratory of instruments and apparatus for medical laboratory tests

Department of toxicology testing and research materials and medical devices

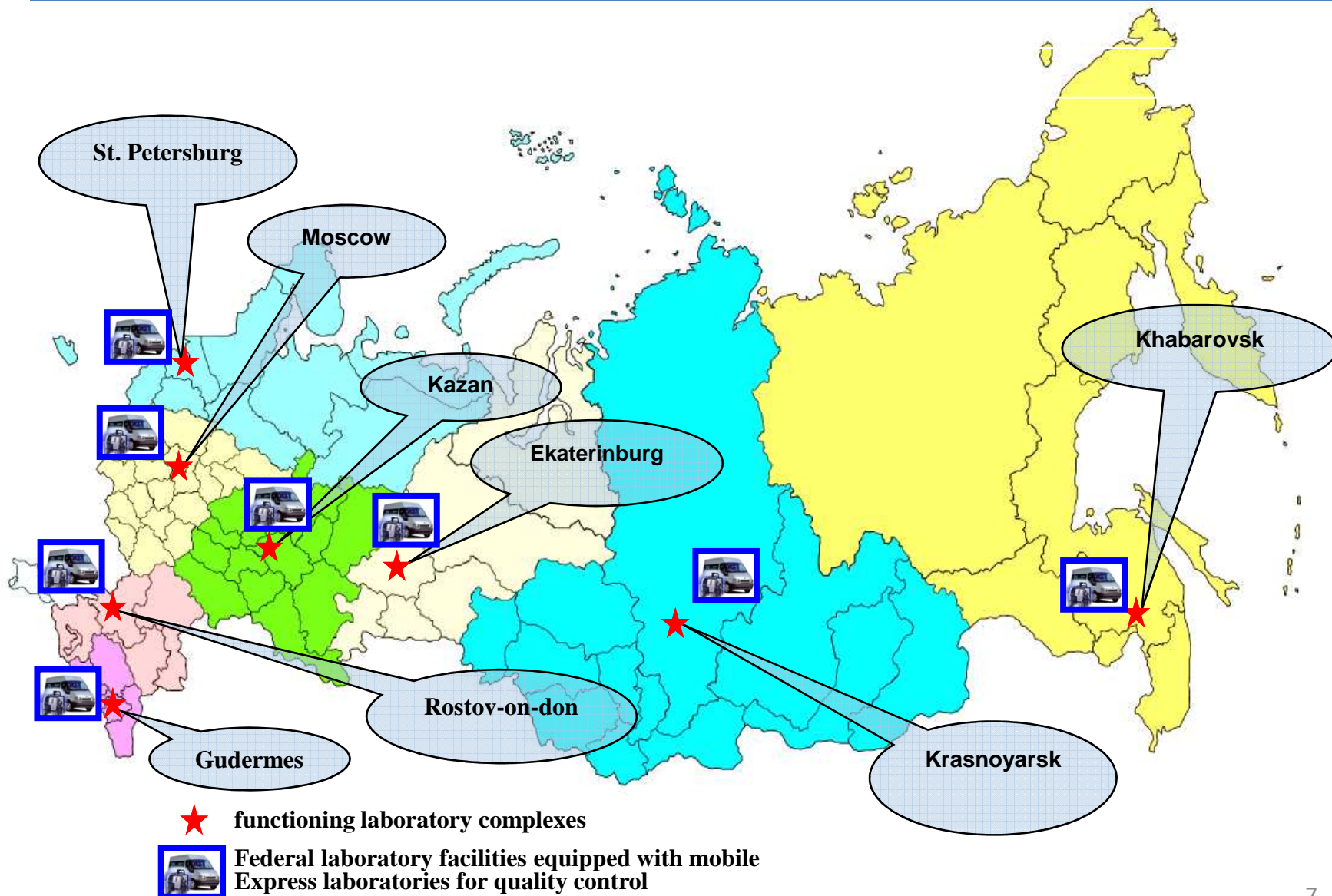
Laboratory of microbiological researching in medical devices





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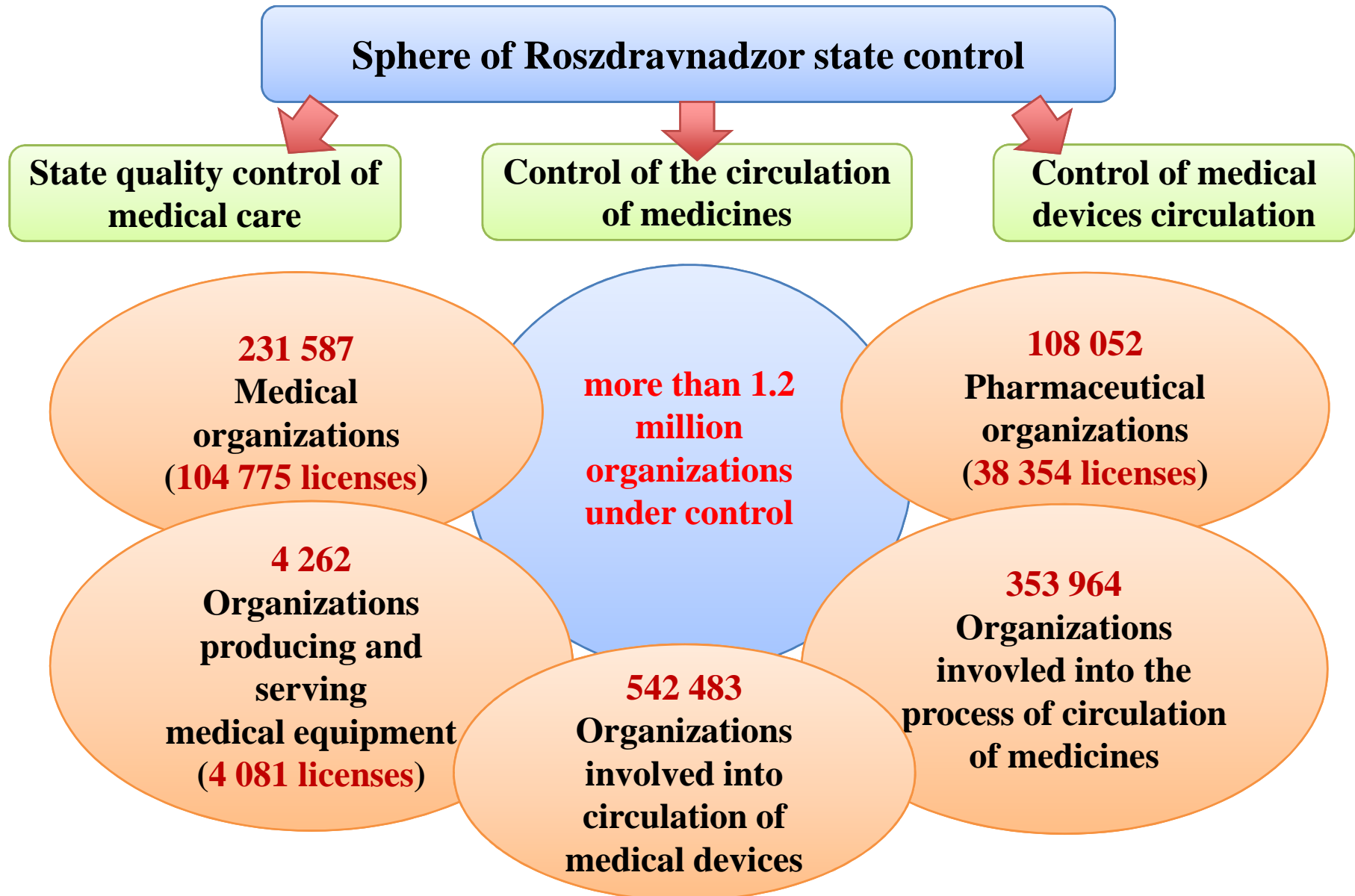
# Federal laboratory facilities for quality control of medicines





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## Control of Observance of Constitutional Guarantees and Rights in the Sphere of Health Protection of Citizens of the Russian Federation







# State Control of Quality and Safety of Medical Practice

## Activity of Roszdravnadzor in the framework of the execution of the function on state control of quality of safety of medical practice

**Licensing of medical activity**

**Observance of the rights of citizens**

**Compliance with orders of medical care and standards of care**

**Compliance procedures of conducting medical examination and surveys**

**Compliance with medical and pharmaceutical workers of the limits on the exercise of their professional activities**

**Test organization and implementation of departmental and internal control quality and safety of medical practice**



# State Control in the Sphere of Medicines circulation

**Pharmaceutical licensing, licensing of narcotic drugs, psychotropic substances and their precursors, the cultivation of narcotic plants**

**The Federal state supervision in the sphere of circulation of medicines (including medicines quality control, control over the conduct of preclinical studies of drugs, clinical trials of drugs, control over the disposal of medicines )**

**Monitoring the safety of medicines in circulation**

**Issuing permits for the importation into the territory of the Russian Federation and export from the territory of the Russian Federation potent substances, which are not precursors of narcotic drugs and psychotropic substances**

**Issuance of certificates for the right of importation (exportation) of narcotic drugs, psychotropic substances and their precursors**

**The issuance of approvals for the issuance of licenses for export and (or) import of organs and (or) human tissues, blood and its components**

**Issue opinions on the possibility of importing to the territory of the Russian Federation and export from the territory of the Russian Federation hematopoietic stem cells and bone marrow for the purpose of conducting unrelated transplantation**

**The monitoring of range and prices for vital and essential drugs**



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# Control and Supervision in the Sphere of Medical Device circulation

**The functions of Roszdravnadzor under the state control and supervision in the sphere of medical device circulation**

**Licensing of production and maintenance (except if the specified activity is carried out for own needs of a legal entity or individual entrepreneur) medical equipment**

**State registration of medical devices**

**Control over observance of the subjects of medical products circulation rules in the sphere of circulation of medical devices**

**Issuing permits for the importation into the territory of the Russian Federation with the purpose of state registration of medical devices**

**Safety monitoring of medical devices**

**The register notices of commencement of business activity in the sphere of circulation of medical devices**



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## Other functions of the Federal Service on Surveillance in Healthcare

Accreditation of foreign professionals

### **Performs:**

Control over the medicines circulation, intended for treatment of cancer

### **State control over:**

Documented reliability data, provided by medical organizations





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# New functions of Roszdravnadzor from January 1, 2014

## Roszdravnadzor is considering cases about administrative offences

**Art. 6.28**

**Violation of rules in the field of treatment of medical devices**

**Art. 6.29**

**The lack of information on conflict of interest**

**Art. 6.30**

**The neglect of duty of informing citizens about how to obtain free medical care under the program of state guarantees**

**Art.14.4.2  
part 1**

**Violation of the rules of the wholesale trade in medicines  
and order of retail trade in medicines**

**Art. 19.4  
part 5**

**Failure to comply with the legal requirements of Roszdravnadzor and  
obstruction of official duties by the officials of Roszdravnadzor**

**Art. 19.5  
part 21**

**Failure to comply within the prescribed period the provisions  
of the decision of Roszdravnadzor**

**Art.19.7.8**

**Failure to submit or late submission in Roszdravnadzor the required  
information or submission of false information**



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# Regulatory Activity

## Control activities of the Central office and territorial bodies of Roszdravnadzor in 2013

performed - **7808** control activities, of which:  
*planned* – **6408** control activities  
*unscheduled* – **11400** control activities

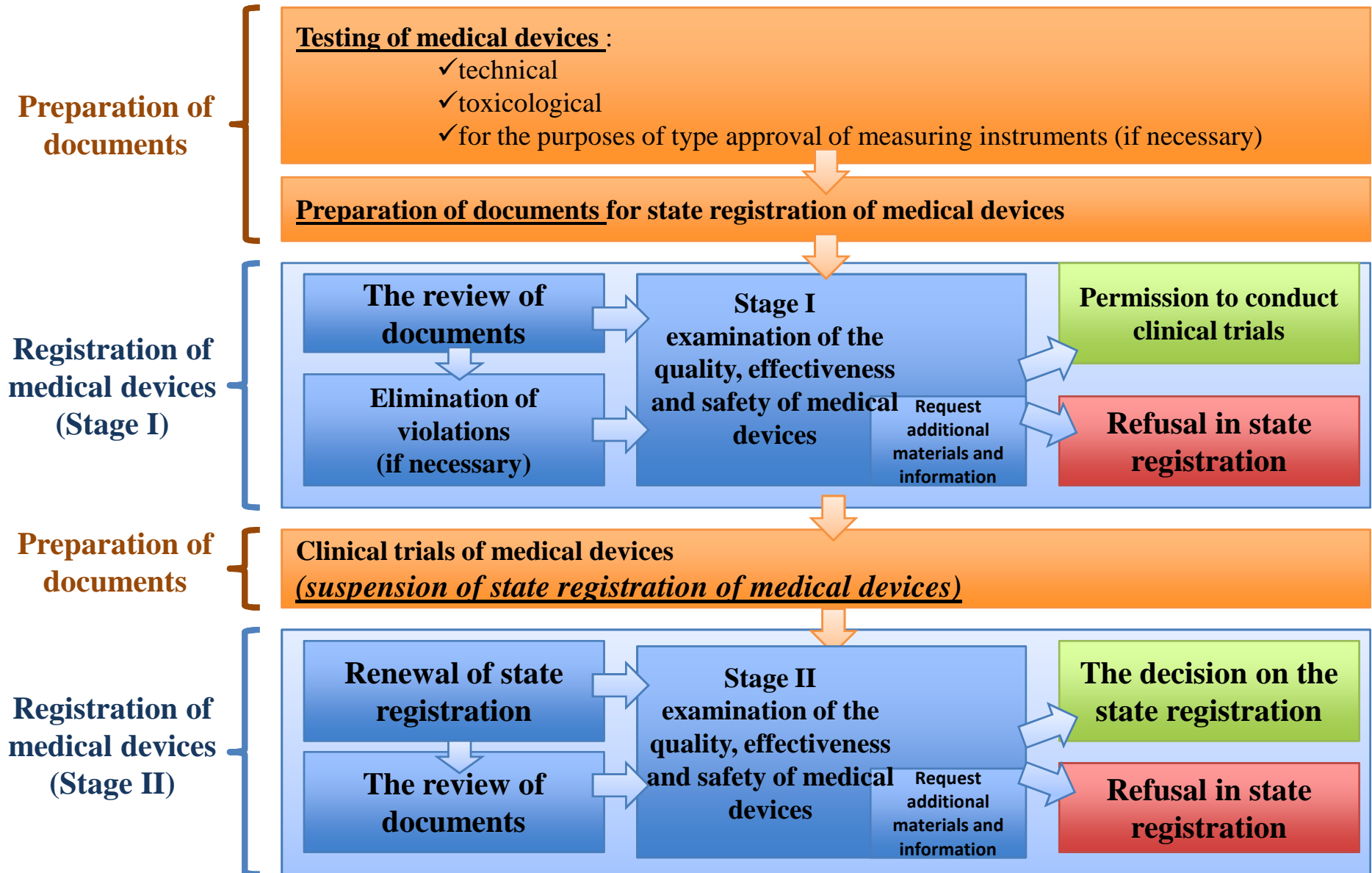
## Results of Roszdravnadzor control activities in 2013

- ✓ the detection rate in 2013 was **40%**;
- ✓ the share of organizations - offenders increased by **12% (from 35 to 40%)**;
- ✓ identified violations **16120**;
- ✓ **however, 1861 test** - is violation of the mandatory requirements;
- ✓ **in 349 (1,95%)** - the breach caused harm to the life and health of citizens.
- ✓ the protocols of administrative violations – **1753**, i.e. **9,8%**;
- ✓ the assigned administrative fines in the amount of **45 376 thousand rubles**, which is 1.7 times more compared to 2012
- ✓ judicial authorities suspended **48** licenses;
- ✓ the decision of the court cancelled **5** licenses;
- ✓ the proportion of fines paid to the budget in comparison with 2012, decreased **from 80 to 68%**;
- ✓ the average fine was **3.6** thousand rubles (in 2012 to 3.4 thousand rubles)



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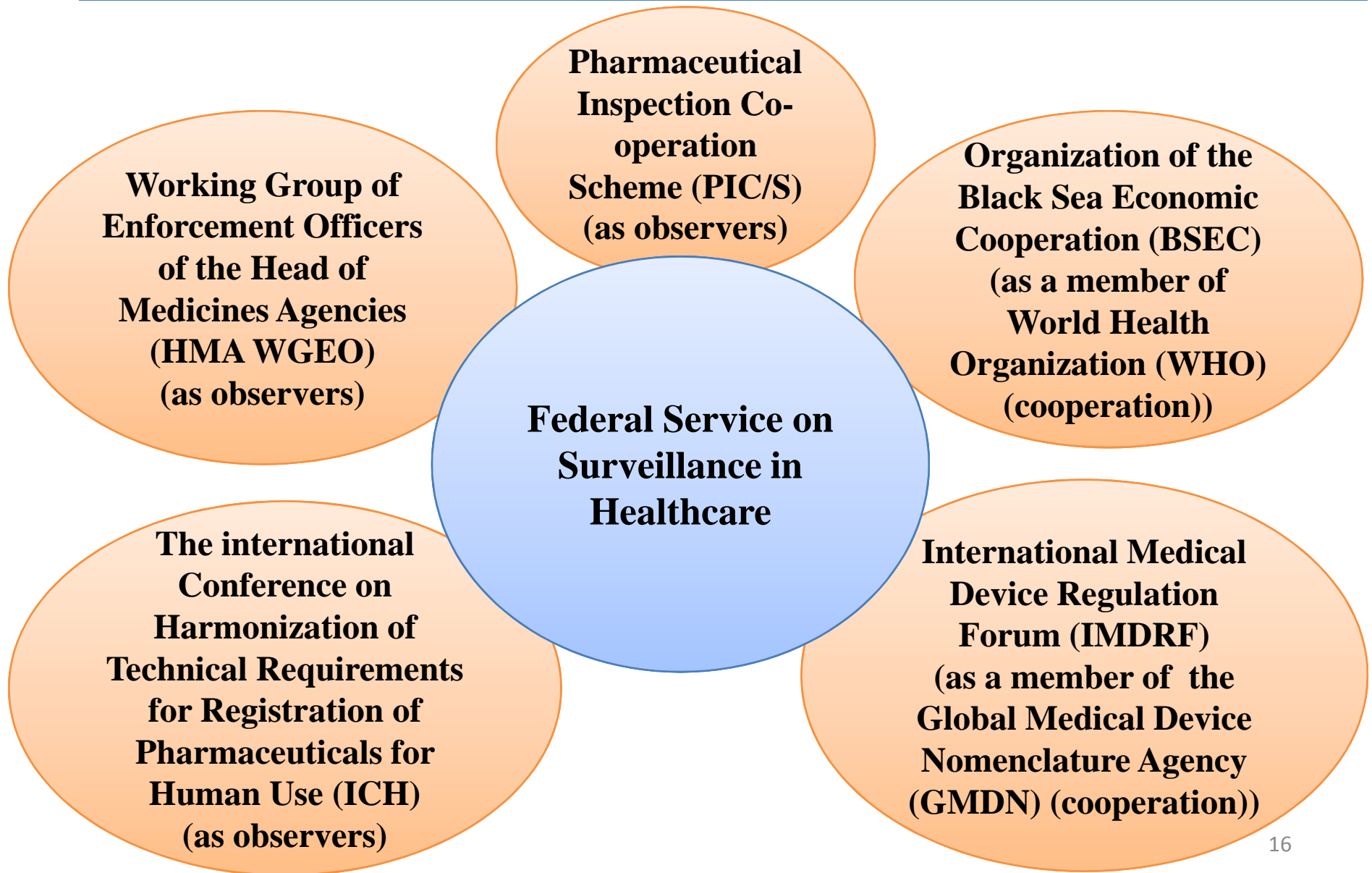
# The Scheme of State Registration of Medical Devices in the Russian Federation





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## International Organizations Cooperating with Roszdravnadzor







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## International Activities of Roszdravnadzor with Regulatory Agencies in Other Countries

- **The Ministry of health of the Republic of Belarus**
- **National center for expertise of drugs, medical devices and medical equipment of the Ministry of health and social development of the Republic of Kazakhstan**
- **China Food and Drug Administration (CFDA)**
- **The National Institutes for Food and Drug Control, China (NIFDC)**
- **Central Drugs Standard Control Organization, Republic of India (CDSCO)**
- **Medicines and Medical Devices Agency of Serbia**
- **European Directorate for Quality of Medicines & HealthCare of the Council of Europe (EDQM)**
- **European Medicines Agency (EMA)**
- **State Service for the Drug Quality Control, Ukraine**
- **The state expert center of the Ministry of health of Ukraine**
- **Food and Drug Administration (US FDA)**
- **U.S. Pharmacopoeia Convention (USP)**
- **Pharmaceuticals and Medical Devices Agency, Japan (PMDA)**



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# Federal Service on Surveillance in Healthcare

**Thank you!**

**[www.roszdravnadzor.ru](http://www.roszdravnadzor.ru)**

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