Organization of sterilization of MD in healthcare organizations. Development of medical service

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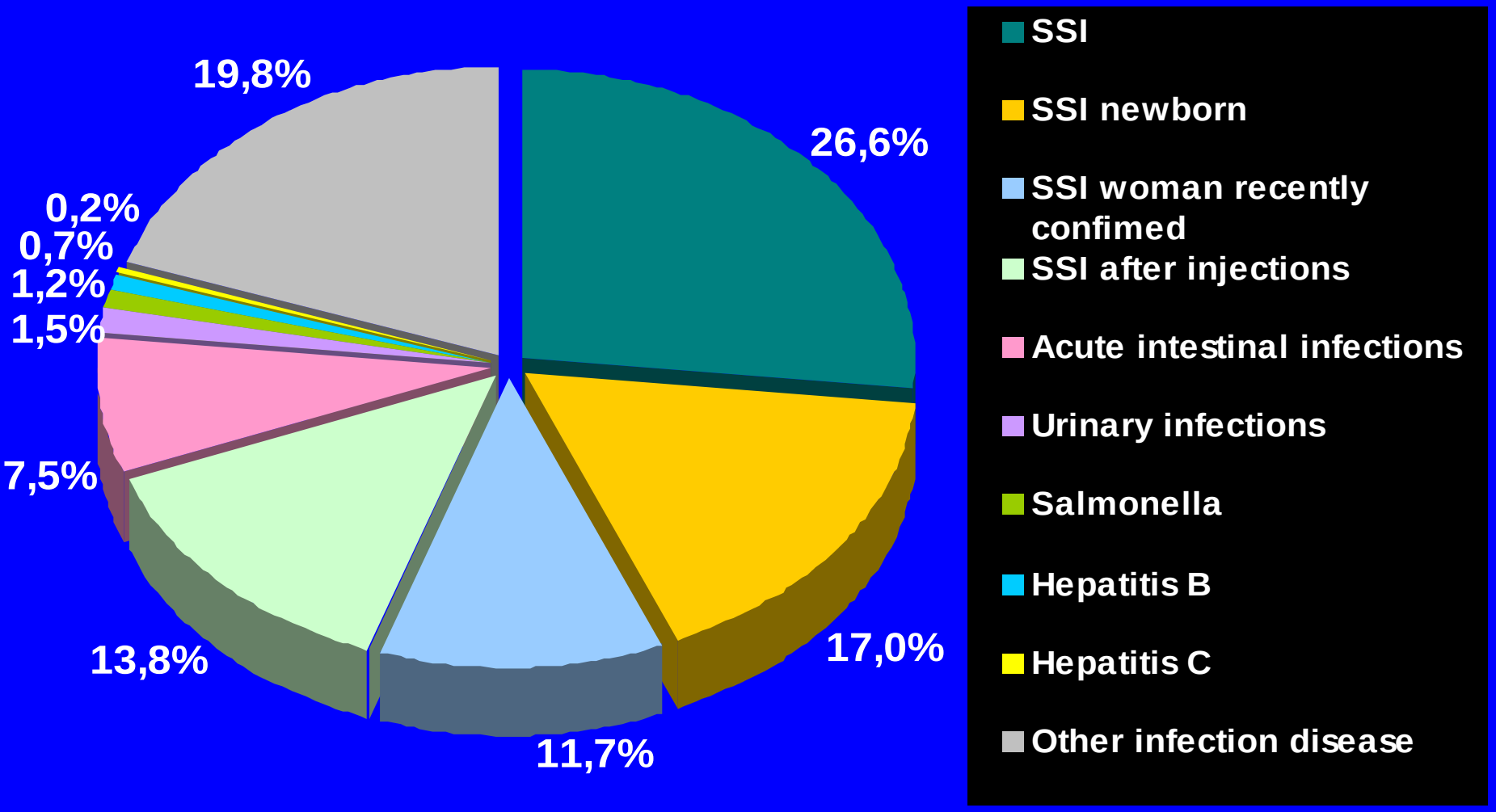
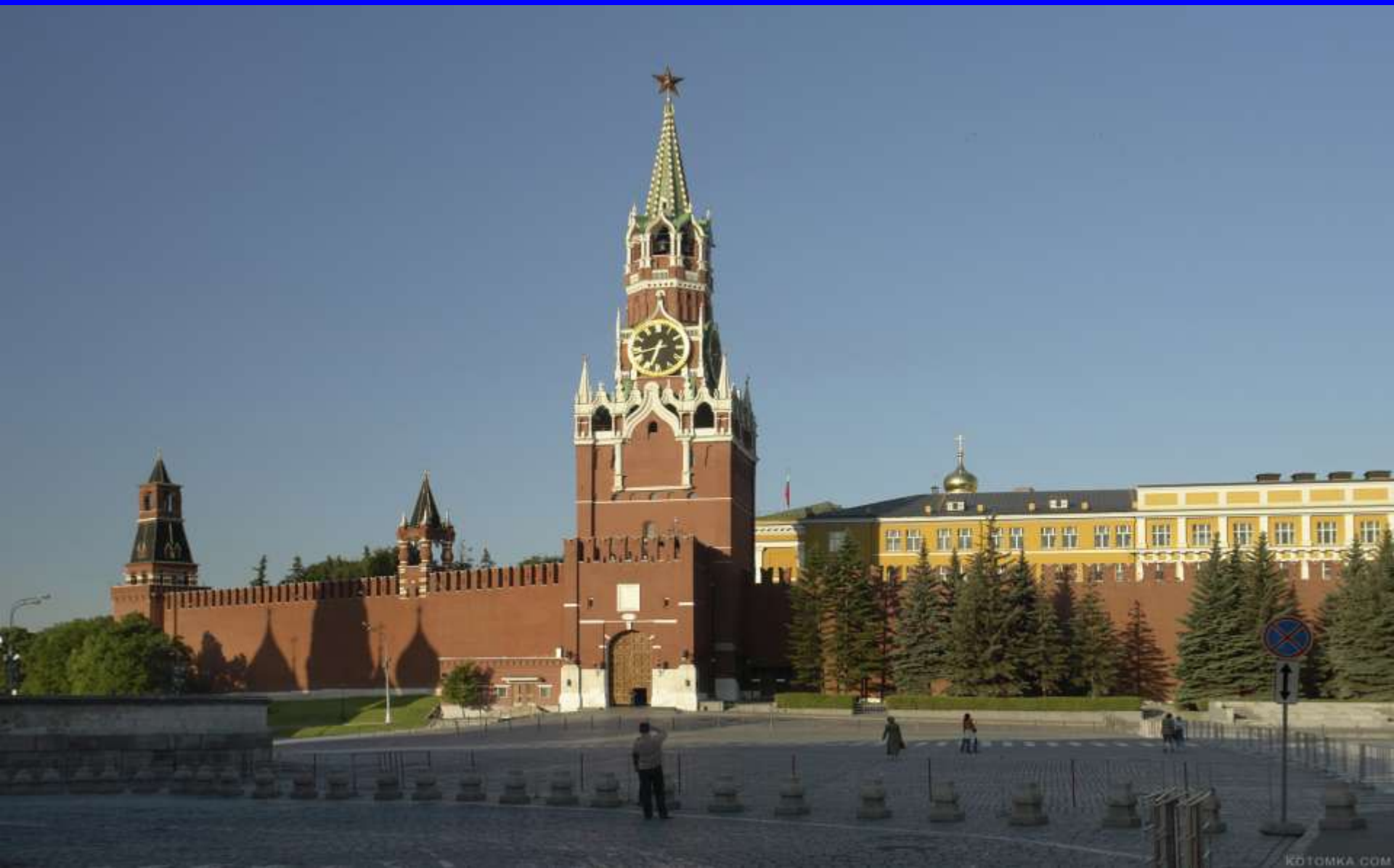
Structure of HAI in Russian Federation



69% of all infections tie with MD circulation (surgical instruments, etc)

Perfection of law system about questions of reprocessing of medical devices in Russian Federation.



GOST ISO 17664-2013 (Russian National Standard)

«The information that should be provided by the manufacturer for resterilization of medical devices»

This standard specifies the requirements to the information that should be provided by the manufacturer of medical device to ensure safe sterilization.

RESPONSIBILITY FOR SELECTION AND VALIDATION OF THE SPECIFIC REPROCESSING METHOD for specific medical device should be borne by the manufacturer.

The organization, responsible for the reprocessing of medical device should act according to the instructions provided by the manufacturer, especially when choosing the equipment and/or chemicals.

Federal Law on Medical devices circulation (Project):

Medical device - is an instrument, apparatus, implement, equipment, material and other article used for medical purposes alone or in combination together with any accessories, spare parts, consumables or software for its proper functioning intended by the manufacturer to be used in the:

-Prophylaxis, diagnosis, treatment and alleviation of diseases,
-monitoring of patient's condition;
-Medical investigations, reconstruction, replacement or modification of the anatomy or of a physiological process;
-Control of conception; ….

Medical device safety – full absence of unacceptable risk of harm to the life or health of people, property of private or legal persons, state or municipal property, the environment, the life or health of animals and plants, or when the potential risk of a medical device

Federal Law on Medical devices circulation (Project):

Article 24. The main requirements to the development, production and manufacture of medical devices.

The manufacturer should document, implement and maintain a quality management system according to GOST ISO 13485, including the production conditions, the methods of monitoring and evaluation of product quality that would ensure the compliance of every medical device to its characteristics according to technical documentation and requirements, specified in Article 9 of the present Federal Law.

Russian Federation Government Decree No 291 of April 16, 2012 “On licensing of Medical service»

MEDICAL SERVICE INCLUDES THE FOLLOWING LIST OF SERVICES

Services associated with:

Disinfectology

Epidemiology

ISO 9001 and ISO 13485 - Main standards of CSSD in GB

Differences between the sterilization organization in Russia and abroad.

Function	EU, Great Britain	Russian Federation
Mandatory compliance to the standards	ISO 13485, ISO 9001	Sanitary regulations and standards, GOST (recommended)
Sterilization - as production	Certified as production	2006-2012 - is not certified and licensed. Government Resolution № 291 as of April 16, 2012
Service fee	Included in the cost of treatment	Free of charge, Compulsory medical insurance is free
Validation	mandatory	non-mandatory
Packing	Carried out in « Cleanrooms » that correspond to the requirements of ISO 14644 , Class 8.	Instruments packing is carried out in class “B” areas according to Sanitary regulations and standards 2.1.3.2630-10
Existence in Hospital	Not necessary if not profitable	Available in every Hospital
Staff	Non-medical staff, special training is required	Medical staff, special training is required.

The main difficulties with the organization of CSSD in Russia:

- ✓ Lack of space in planning of hospital building
- ✓ Unsuitable area for equipment (threading, ventilation, zoning, communication, decoration)
- ✓ Staff (training and safety)
- ✓ Interaction with other services and consumers (utilities, customers)
- ✓ Transportation (closed containers)
- ✓ Instrument loss (usage of the sophisticated systems to track and trace the instrument from patient, through decontamination process and to the next patient)
- ✓ The quality control system (usage of physical, chemical and bacteriological tests, VALIDATION!)

What should be sterilized?

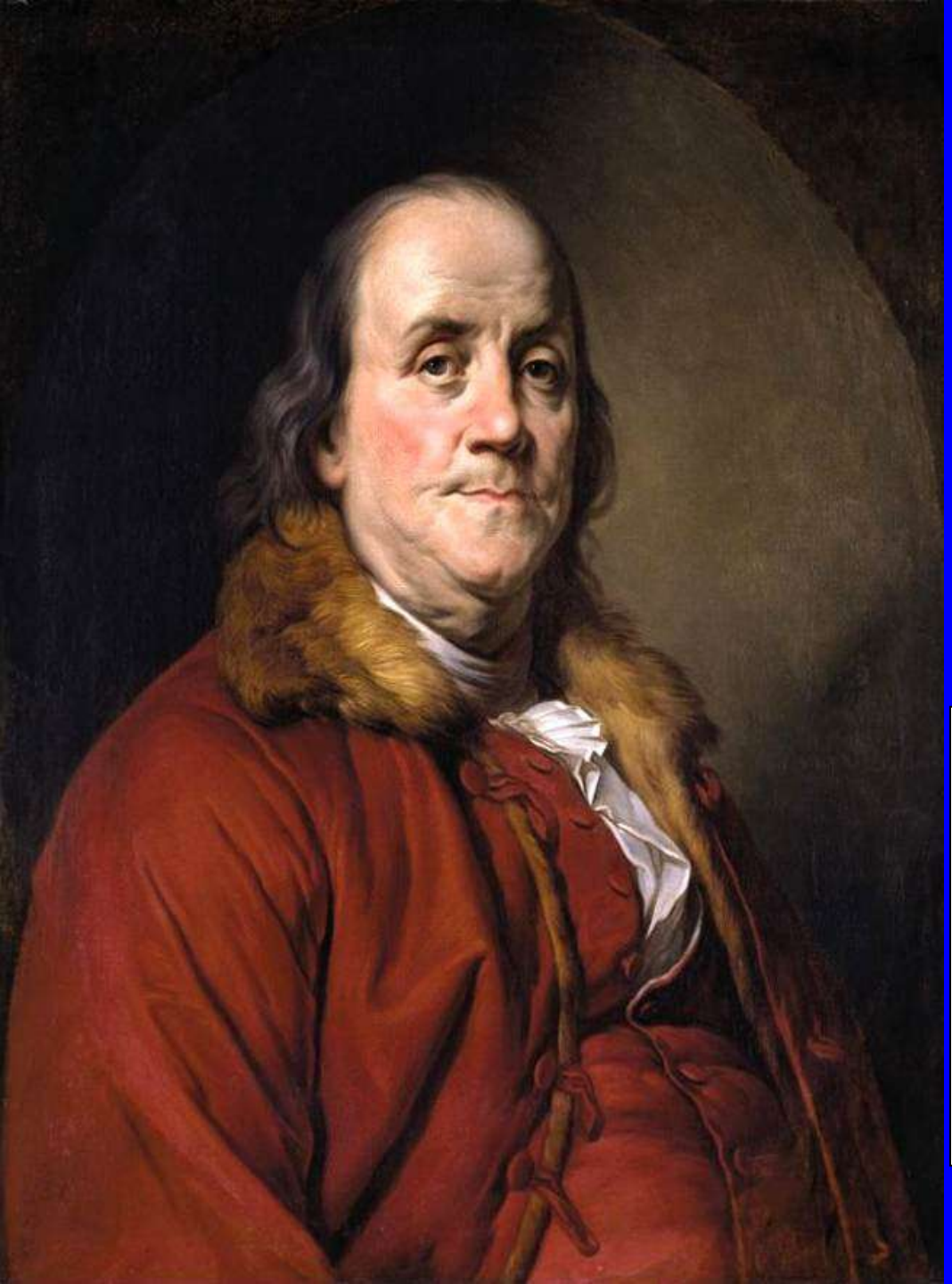
- ✓ It's necessary to get rid of all non-specialized textiles like reusable clothing (surgical drapes, gowns, dressing material, etc) that do not correspond to the requirements of GOST R EN 13795-2008 "Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment", emitting large amount of textile dust that creates a threat of causing the aseptic inflammation of the surgical wound, that quickly leads to the secondary infections.
- ✓ Bandages. There's no sense in sterilization of bandages, as the aseptic dressing is placed on the wound.
- ✓ Glass rods used for determination of a blood type, reusable glass pipettes, etc
- ✓ Resterilization of single use or expired medical devices (that is generally not permissible), etc

Federal Law on Medical devices circulation (Project):

Article 29: Realization of medical devices.

The circulation of medical devices that do not meet the quality, safety and efficacy requirements and forged medical devices is prohibited within the territory of the Russian Federation.

Cotton balls, cotton rolls, wipes of different sizes, swabs, textile linen (that do not meet the requirements of standard GOST EN 13795-2008)?



Work of CSSD- 24 hours in a day!

«Time is money»

Benjamin Franklin
American scientist and politician (*The Way to Wealth*, 1758 г.)

CSSD Staff

- ✓ **Head of the department – the specialist with higher medical education and Good organizational skills (Manager of nursing, bachelor, master, doctor).**
- ✓ **Medium-level medical staff (18 years old, specialized secondary education, professional certificate, permit to work on receptacles under pressure).**
- ✓ **Junior-level medical staff**

Sterilization Technician?

NO curses

NO a lot of teaching specialists

NO education programs

Training

Training of specialists in medical postgraduate training schools.

1.Nursing care in CSSD (All-Russian scientific-methodical educational center, 1998)

2. Specialized training – 210 hours, Advanced training – 144 hours

2.Disinfection and sterilization (Thematic advanced training – 72 hours).

3.Conferences, organized by governmental agencies or commercial companies (all hours are calculated during the next training course - funded system).

Государственное бюджетное образовательное учреждение
среднего профессионального образования
«МЕДИЦИНСКОЕ УЧИЛИЩЕ № 8
Департамента здравоохранения города Москвы»
(ГБОУ СПО «МУ № 8 ДЗМ»)
отделение повышения квалификации

Согласовано на заседании
методического совета
Протокол № 3
от 21.03 2013 г.

Утверждаю
Директор «МУ№8ДЗМ»
Л.К.Никитина
«28» марта 2013 г.

Унифицированный экзаменационный материал для образовательных учреждений системы дополнительного профессионального среднего медицинского и фармацевтического образования

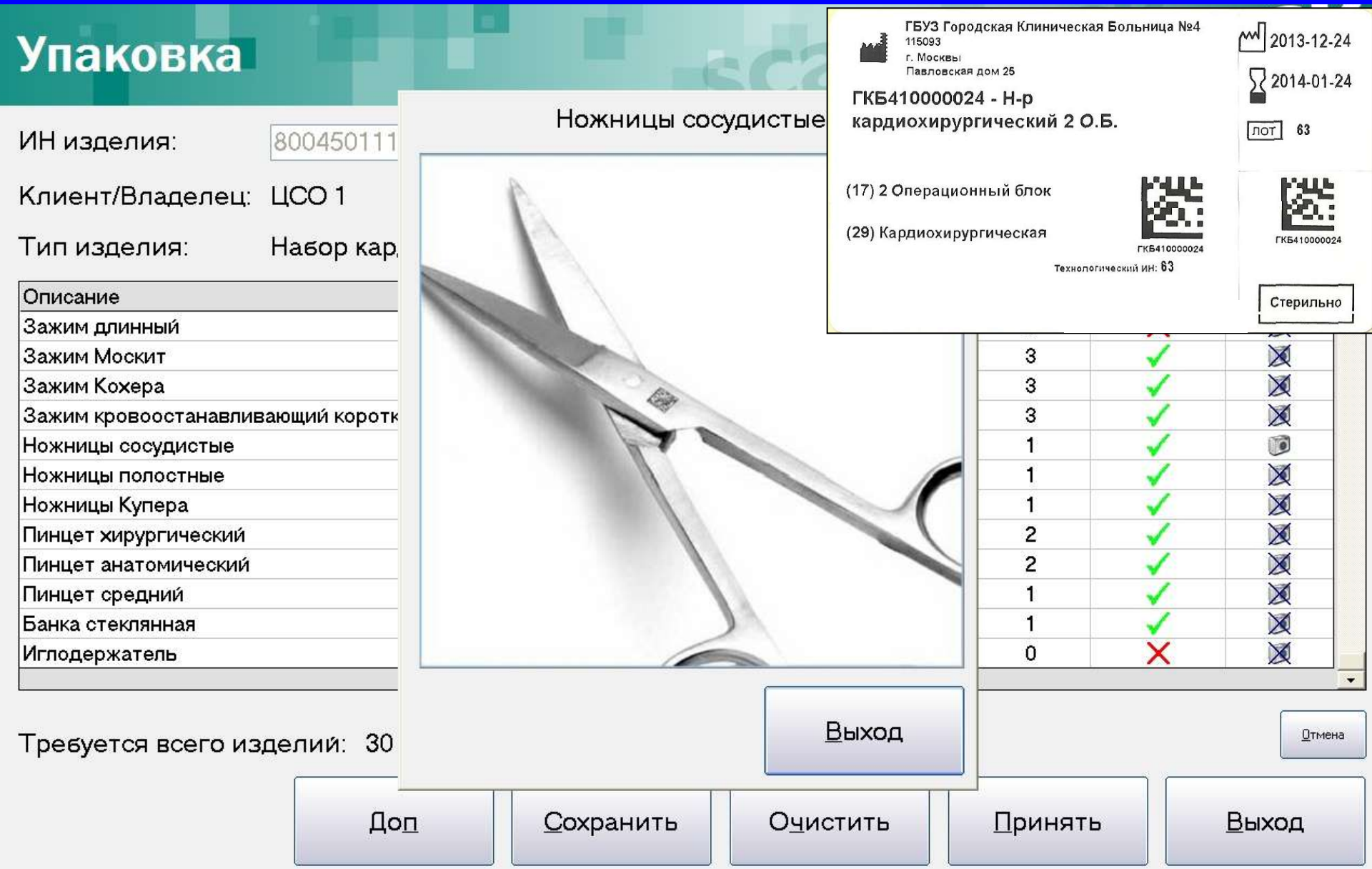
Специальность: «Сестринское дело»

Тематика цикла: «Сестринское дело в ЦСО ЛПУ»

2013г.

Moscow Medical College №8 has developed the unified examination material majoring in Nursing, subject-matter "Nursing in CSSD» in 2013.

Accounting of sterilized material volumes with the reference of instrument to patient.




AIR
CYLINDERS
CHANGED

Label on MD

CSSD (address)

Data of sterilization

Expoury date

IN of item

Lot(load)

Removable bar code

Name of special set

Department

Technological number

Main bar code

EN15223-1-2012 Symbols to be used with medical device labels, labeling and information to be supplied.

Transportation of sterile medical devices.

1.The delivery of sterile products from CSSD is carried out in **closed containers or bags made of strong fabric.** Products for operating theatres, delivery rooms, dressing rooms and other services with high aesthetic requirements should be released from transportation packing only at the entry of such rooms.

2. The delivery of sterile products **is carried out by trained staff, responsible for the delivery.**

3. **Never leave the sterile products** without designated staff supervision during the delivery.

4. Accidentally opened, wetted, dropped or damaged sterilizing boxes must not be used and require re-sterilization.

5. Processed sterile products **should be stored in dedicated cabinets,** on shelves, racks or tables designed to be easily cleaned and disinfected.

Methodological recommendations N 11-16/03-03 as of January 31, 1994.

Transportation

Medical devices storage and transportation regulations compliance monitoring.

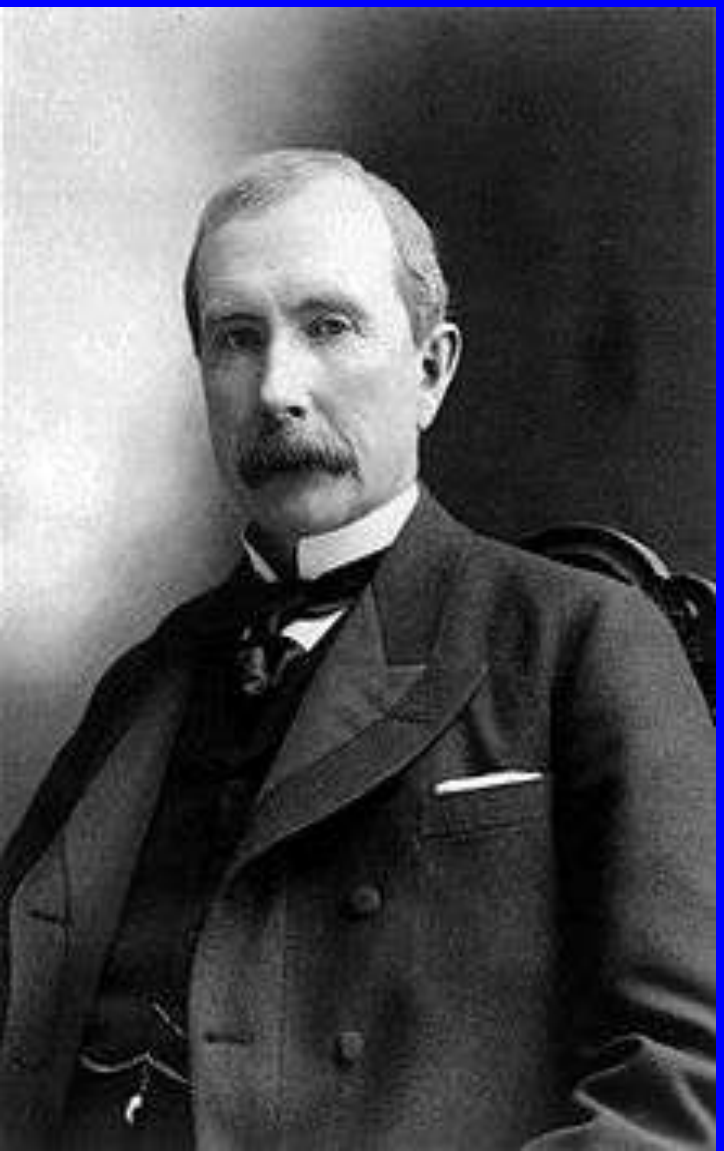
Healthcare service (Medical service) – **is a service or package of services focused on the diagnosis, treatment, and prevention of diseases at certain cost.**

*** Industry-specific standard 91500.01.0005-2001**

Moscow Government Health Committee Order No. 686 as of December 30, 1998 "Moscow City Adult Inpatient Medical Aid Standards"

Sterilization of medical devices is “free of charge” service!

“No matter what we're talking about, we're talking about Money”



John Davison Rockefeller

Service fee

According to experts, it takes 9 2 sterile medical devices per day for every patient receiving healthcare service, regardless of the type of healthcare service. *

It’s necessary to include the medical devices sterilization as one of the healthcare services in all Medical and Economic Standards!

E.V. Yurkova "Some aspects of sterilization in hospitals of Moscow". Abstracts of the Third Research and Practical Conference on Hospital-acquired infection in different inpatient facilities, prevention and treatment of complications. March 24-25, 2005.

Literature

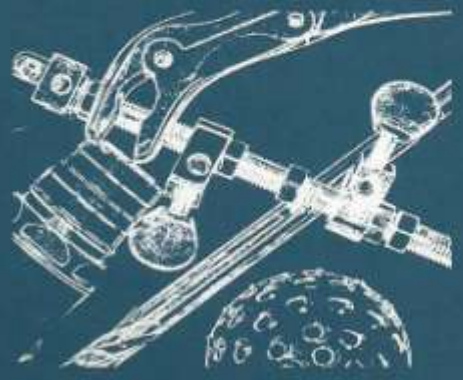
К.И. Корнев

СТЕРИЛИЗАЦИЯ ИЗДЕЛИЙ МЕДИЦИНСКОГО НАЗНАЧЕНИЯ В ЛЕЧЕБНО-ПРОФИЛАКТИЧЕСКИХ УЧРЕЖДЕНИЯХ

И.И.Корнев
С.М.Савенко

Современные методы предстерилизационной очистки изделий медицинского назначения

- Внутрибольничные инфекции
- Методы дезинфекции
- Контроль качества
- Организационные мероприятия



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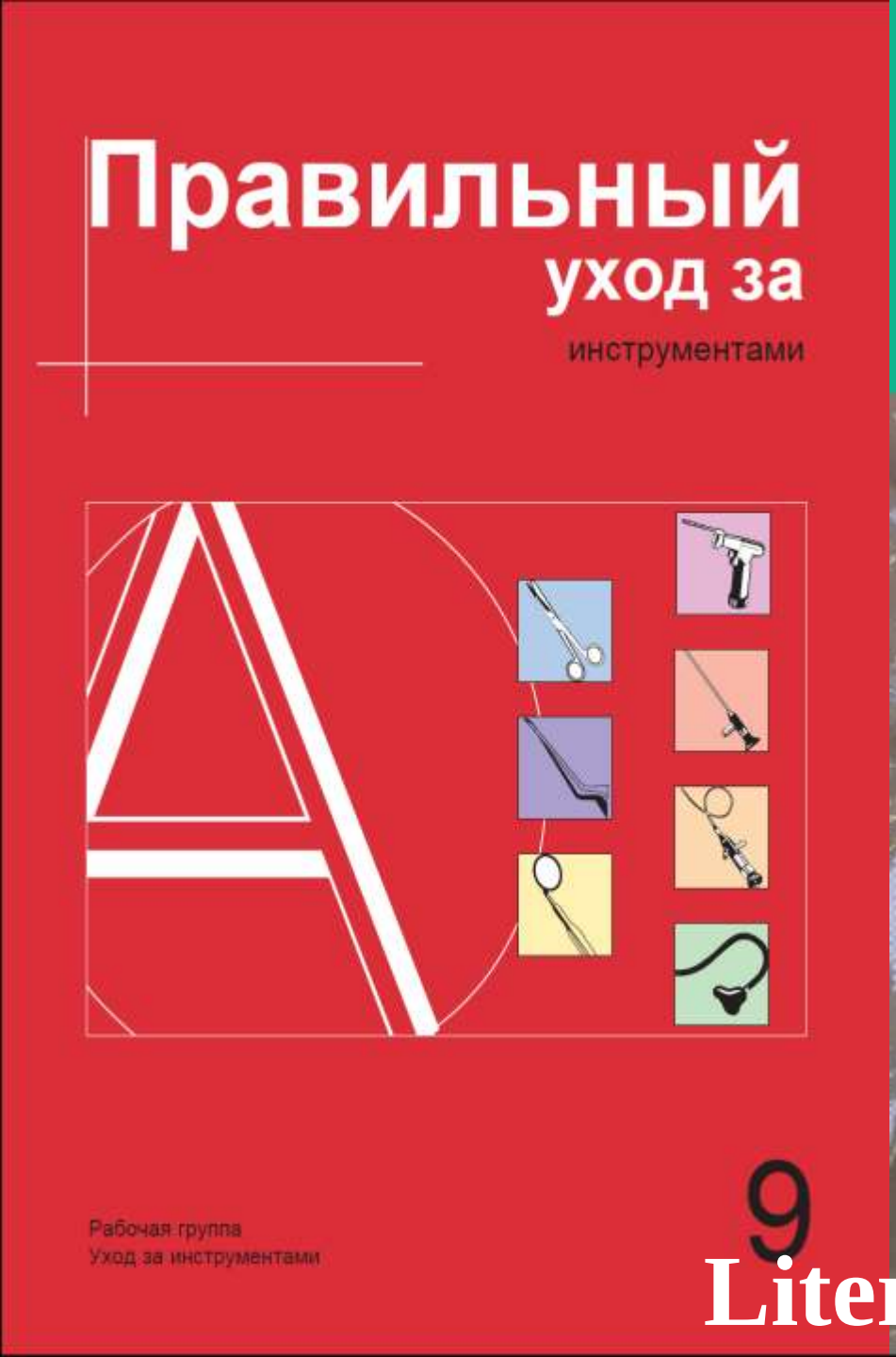
Правильный
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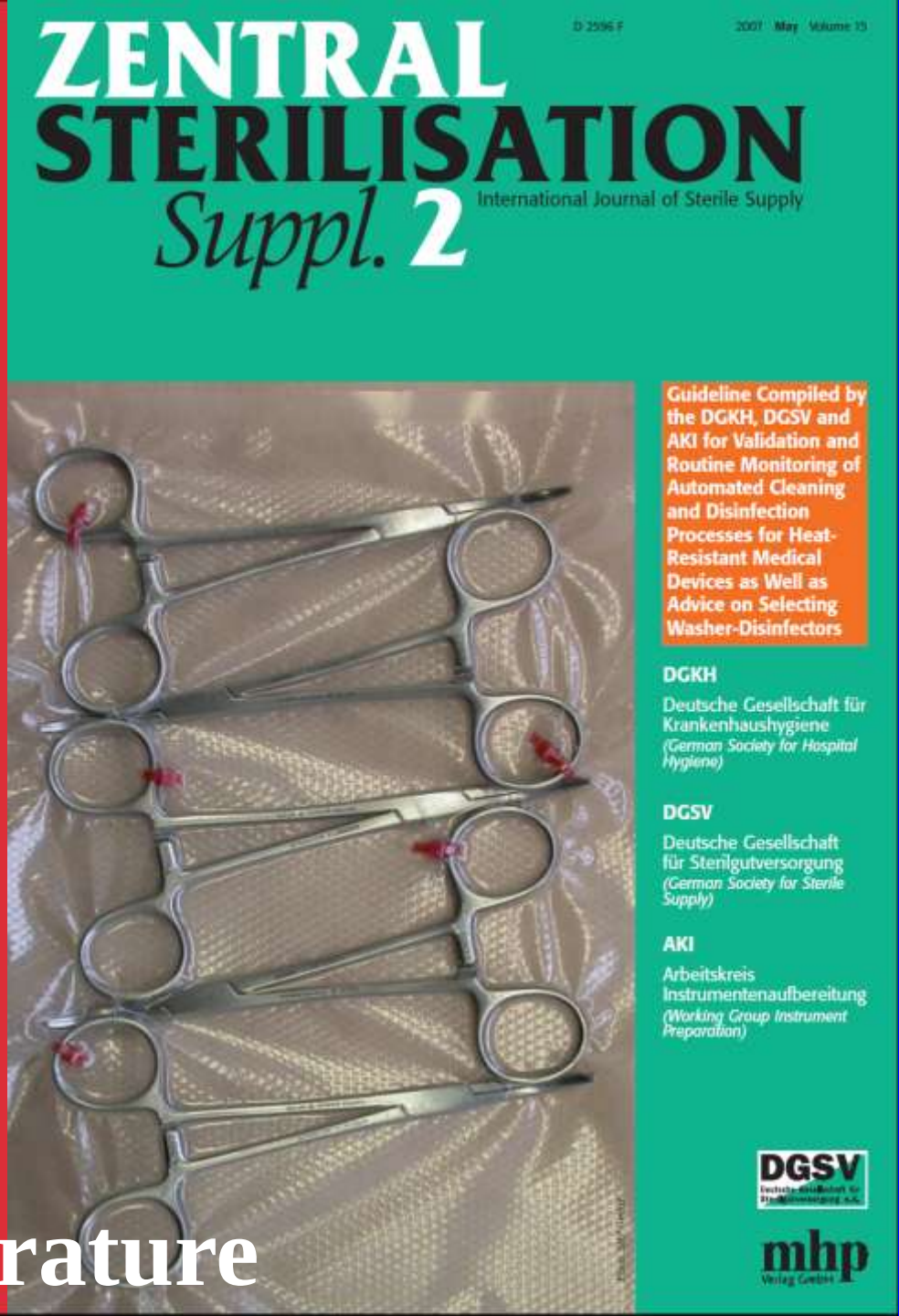
Рабочая группа
Уход за инструментами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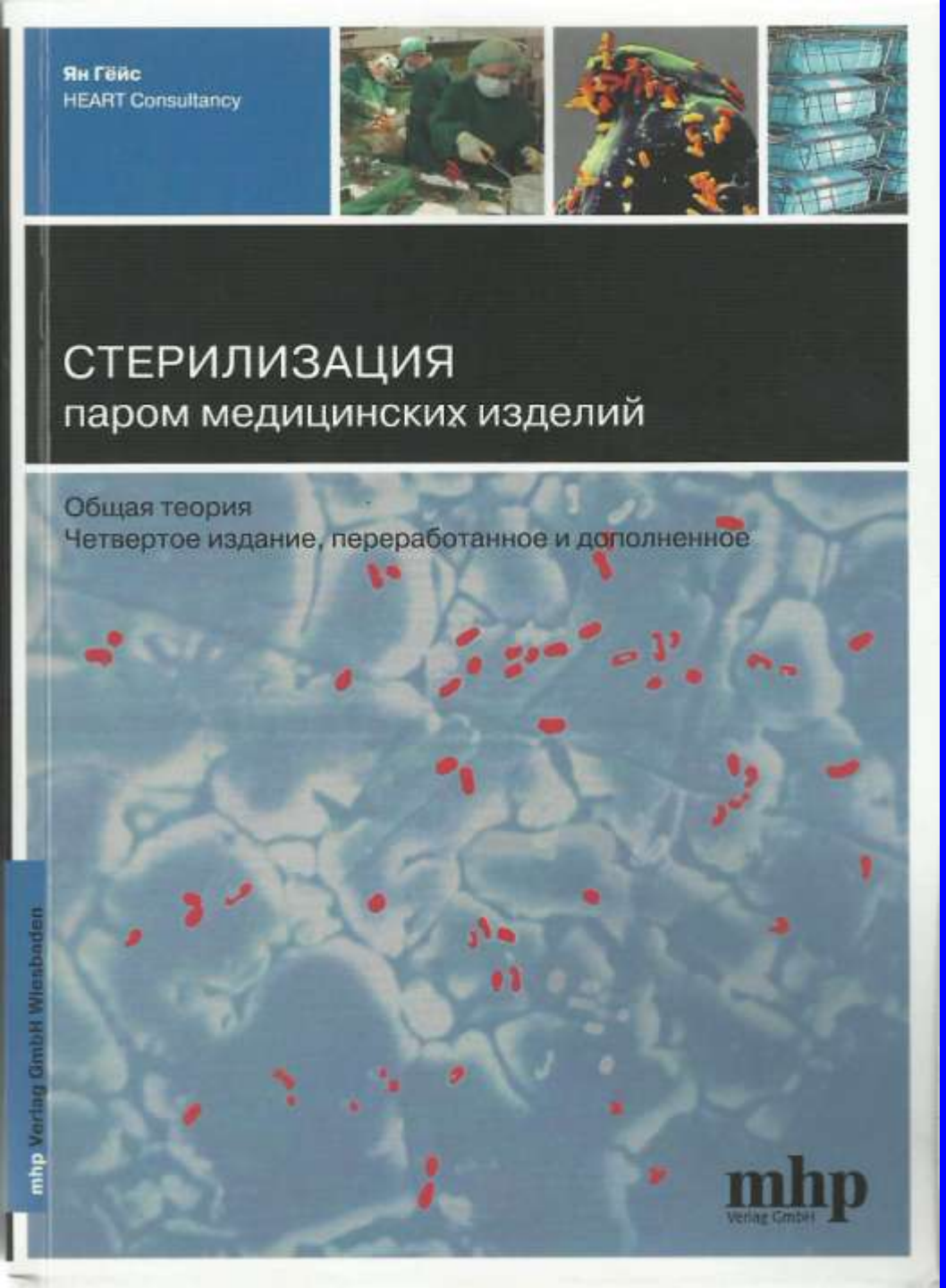
2007 May Volume 15
ZENTRAL STERILISATION
Suppl. 2
International Journal of Sterile Supply
Guideline Compiled by the DGKH, DGSV and AKI for Validation and Routine Monitoring of Automated Cleaning and Disinfection Processes for Heat-Resistant Medical Devices as Well as Advice on Selecting Washer-Disinfectors
DGKH
Deutsche Gesellschaft für Krankenhaushygiene
(German Society for Hospital Hygiene)
DGSV
Deutsche Gesellschaft für Sterilgutversorgung
(German Society for Sterile Supply)
AKI
Arbeitskreis Instrumentenaufbereitung
(Working Group Instrument Preparation)
DGSV
mhp Verlag GmbH



Sterilization –it's professional area in witch are meeting a lot of interesting science and technologies: **microbiology,**

healthcare

electrical engineering

and reprocessing technology

And, like in other aspects of the life, **information technologies** are coming in this profession too.

Jan Huys «Steam sterilization of medical devices» DGM Pharma apparate rus, 2013

Federal Law on Medical devices circulation (Project):

Article 24. The main requirements to the development, production and manufacturing of medical devices.

2. **Manufacturing of medical devices should be carried out by organizations authorized by self-regulatory organization to carry out the specific type of activity on specific medical devices.**

Non commercial partnership "Russian National Association of specialists of sterilization of medical devices".

Conclusion

- ✓ **Up to date federal law equals the hospital sterilization to the sterile production level.**
- ✓ **Healthcare organizations should ensure uniform safety for single and multiple use medical devices that would increase the requirements to quality of work, technologies and monitoring arrangements in sterilization departments in healthcare organizations.**
- ✓ **Medical organizations with CSSD, should obtain the following approval documents: license permitting to carry out the activity marked as “Disinfectology", certificates GOST R ISO 13485-2004 and ISO 9001.**
- ✓ **Due to high cost of the project, maintenance, equipment and work organization in modern CSSD, it’s necessary to look ahead and allow the possibility of setting up the department for several medical establishments.**

Conclusion

- ✓ **Modern CSSD should provide a full range of services for the reprocessing of medical devices, collect and store information on the reprocessing throughout their shelf life.**
- ✓ **Sterilization of medical devices is chargeable service; its payment should be included in the cost of treatment.**
- ✓ **Education of CSSD specialists must to developing on new education programs with allow of ISO standards.**
- ✓ **It is very necessary to create National association of specialists in sterilization of MD.**

Thank you for your attention!