Organization of sterilization of MD in healthcare organizations.

Development of medical service

V. Akimkin, MD, Professor, Corresponding Member of the RAMS Russian Academy of Medical Science, Assistant of Director of National institute of Desinfectology of Russian Federation, head of Cafedra of Desinfectology of First Moscow Medical Sechenov Institute

P. Demidov, RN, M.P.H., CSSD Manager City hospital #4 Moscow, Russia
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.
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.
**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
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.

<table>
<thead>
<tr>
<th>Function</th>
<th>EU, Great Britain</th>
<th>Russian Federation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory compliance to the standards</td>
<td>ISO 13485, ISO 9001</td>
<td>Sanitary regulations and standards, GOST (recommended)</td>
</tr>
<tr>
<td>Sterilization - as production</td>
<td>Certified as production</td>
<td>2006-2012 - is not certified and licensed. Government Resolution № 291 as of April 16, 2012</td>
</tr>
<tr>
<td>Service fee</td>
<td>Included in the cost of treatment</td>
<td>Free of charge, Compulsory medical insurance is free</td>
</tr>
<tr>
<td>Validation</td>
<td>mandatory</td>
<td>non-mandatory</td>
</tr>
<tr>
<td>Packing</td>
<td>Carried out in « Cleanrooms » that correspond to the requirements of ISO 14644 , Class 8.</td>
<td>Instruments packing is carried out in class “B” areas according to Sanitary regulations and standards 2.1.3.2630-10</td>
</tr>
<tr>
<td>Existence in Hospital</td>
<td>Not necessary if not profitable</td>
<td>Available in every Hospital</td>
</tr>
<tr>
<td>Staff</td>
<td>Non-medical staff, special training is required</td>
<td>Medical staff, special training is required.</td>
</tr>
</tbody>
</table>
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
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)?
«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).
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.
EN15223-1-2012 Symbols to be used with medical device labels, labeling and information to be supplied.
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
Sterilization of medical devices is "free of charge" service!
“No matter what we're talking about, we're talking about Money”

John Davison Rockefeller
According to experts, it takes 9 to 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!

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)

Literature
Sterilization – it’s professional area in which 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.
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!