Medical Device Reprocessing

MDRAO ETA Chapter 1st Meeting.

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Reprocessing Standards a Changing Landscape

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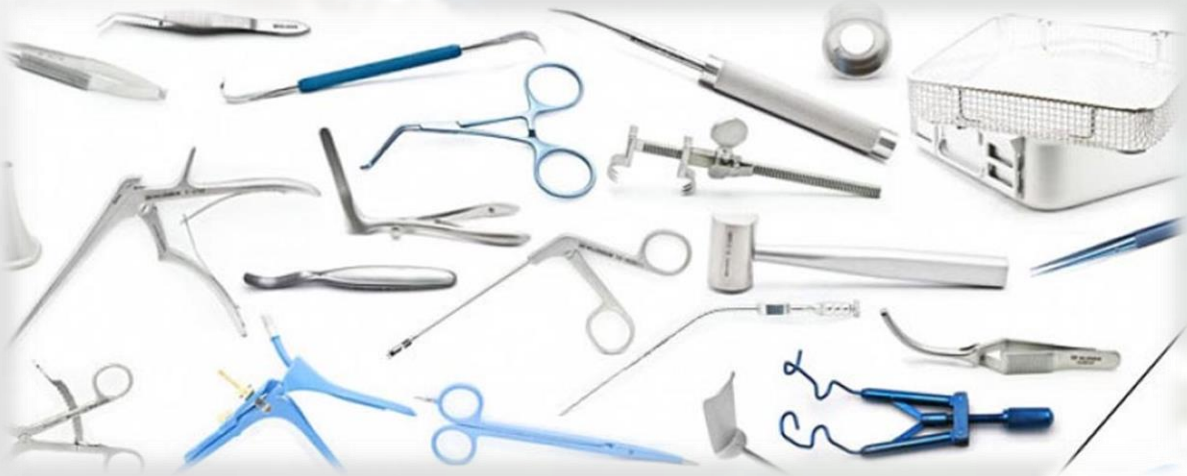
Medical Devices

- Medical devices are used in some way in nearly every medical procedure – devices that are expected to be both functionally and microbiologically safe.
- Safety depends upon a detailed process that begins with the manufacturer and ends with correctly reprocessed medical devices.
- Medical device reprocessing is supported and maintained by a system of national standards and government regulations that Includes medical device licensing, construction and performance standards, troubleshooting, and reporting.



Standards and Authoring Bodies

Performance Standards

- *Process definition and characterization, validation*
- *Design considerations*
- *Performance requirements*
- *Test Methods*
- *Quality Systems^*

Practice Guidelines

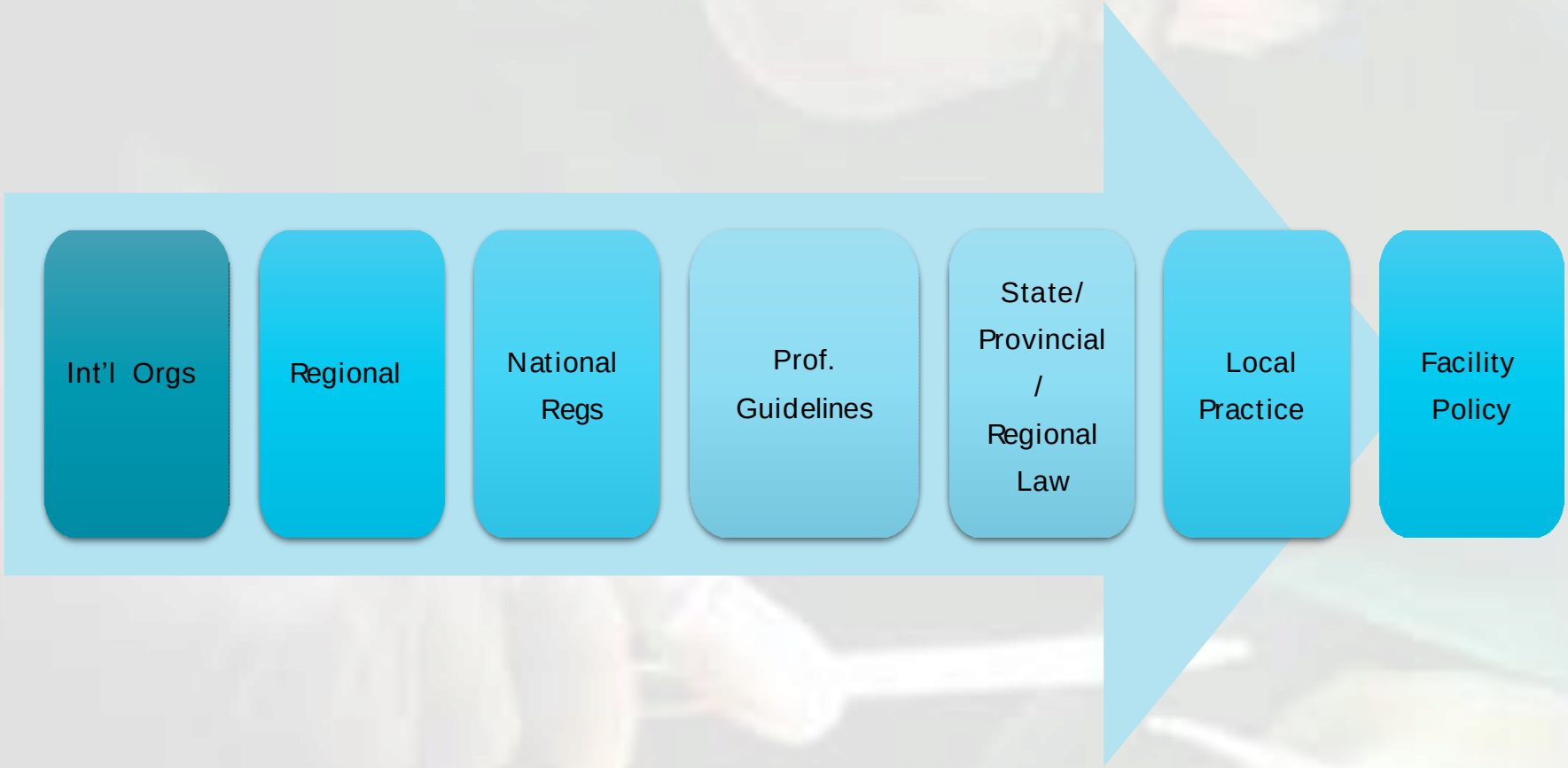
- *Professional Org*
- *Recommended Practices*
- *Multi-society endorsement*
- *Consensus standards*
- *National*
- *International*

Governmental Regulation

- *MOH*
- *FDA*
- *Regional MOH orDPH*
- *Advisory organizations*
- *Advisory committees*
- *Research groups*
- *Joint committees*

Evidence – clinical, economic, scientific

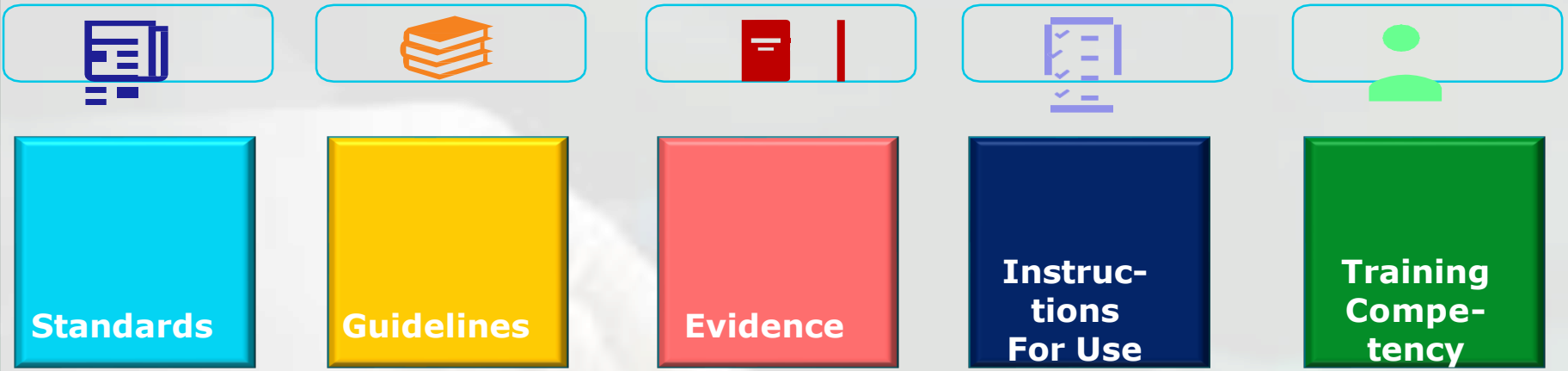
Standards and Guidelines Hierarchy



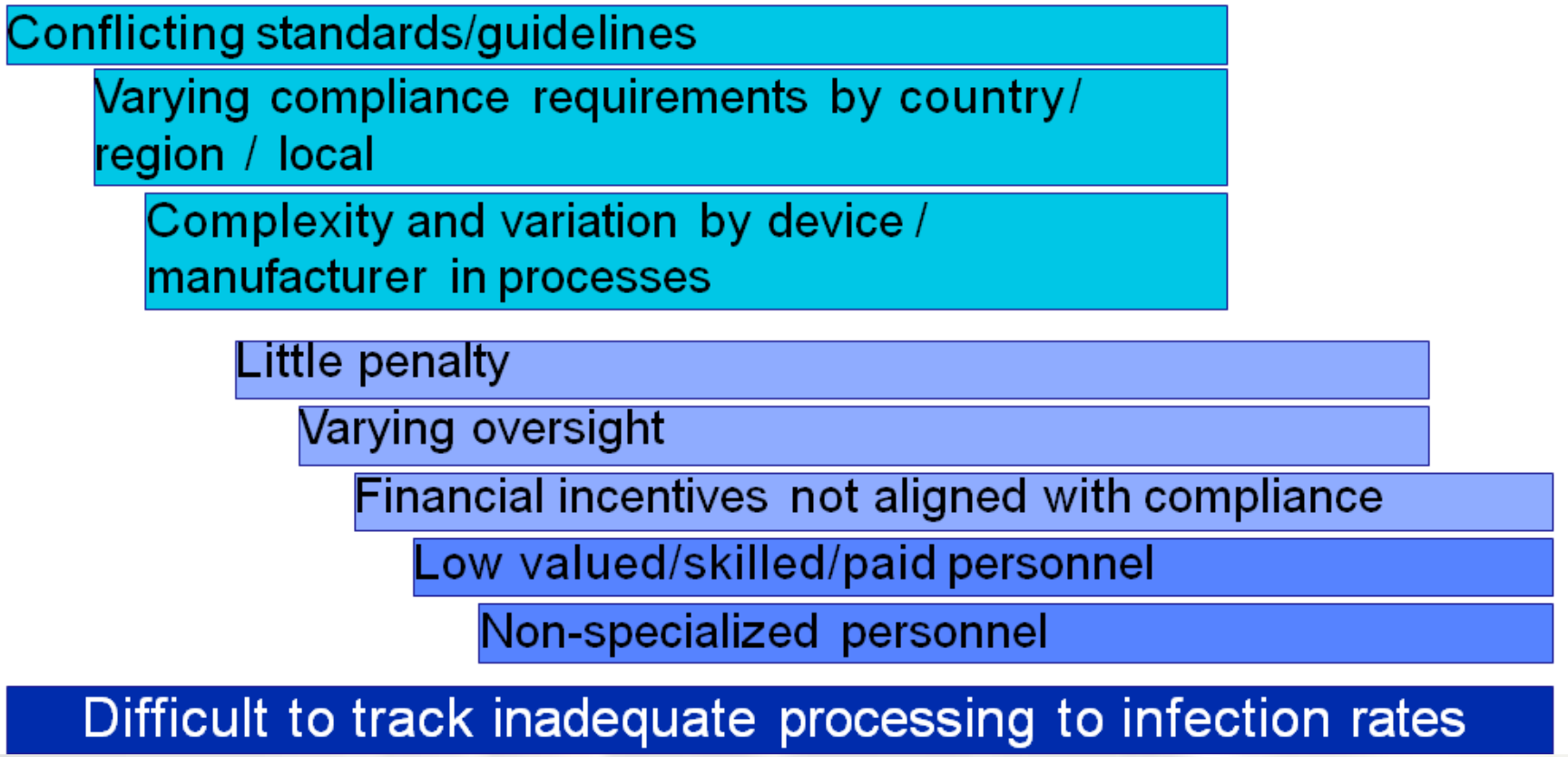
Disparity

- **ISO**
  - Does not differentiate between industrial sterilization and health care processing
- **Professional organizations**
  - Multiple guidelines often not aligned
- **Joint committees**
  - Not aligned with org guideline
- **Selected evidence**
  - Challenge for device reprocessing
- **Auditing or reporting body reference**
  - Selected
- **HC facility interpretation**
  - Minimum required
  - Most rigorous
  - Aligned with resources

Foundations



Device Reprocessing Key Challenges

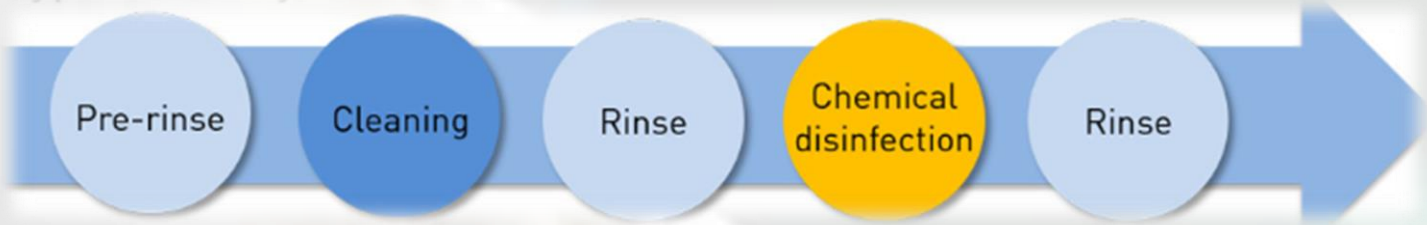


CSA Standards

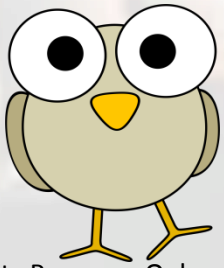
- With this in mind, CSA Group recently published a new national standard of Canada that replaces nine standards from the CSA Z314 Medical Device Reprocessing series: Z314.0, Z314.3, Z314.8, Z314.10.1, Z314.10.2, Z314.14, Z314.15, Z314.22, and Z314.23. This new standard serves as a valuable resource for all healthcare settings where reusable medical devices are utilized and require reprocessing – from private offices such as dentists, podiatry and surgery clinics to large hospitals and acute/long-term care facilities. It was developed to streamline content – a 375 page document versus the 633 pages of the standards separately - as well as remove redundancies, improve readability and flow, update technical content where needed, and to better align with the medical device reprocessing workflow.

Clause 4 - General Requirements

- Mandates cleaning before further reprocessing
- Further Reprocessing defined as Disinfection or Sterilization
- Remove Soil – Enzymatic / Detergent
- Rinse the Device
- Disinfect
- Disinfection may be hindered if Soil or other chemicals are still present on the device.



Q: What else affects soil:



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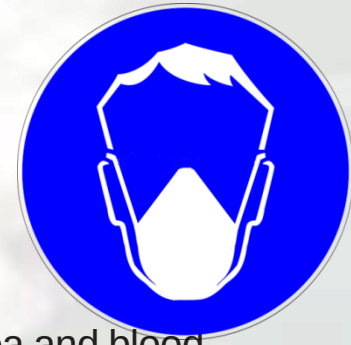
Clause 6 Personnel



- Better addresses personal protective equipment (PPE) for the decontamination area and blood and body fluid spills

PPE can be a source of contamination

Attire – Outside Attire not to be worn inside. Inside Attire not to be worn Outside. Exposes personnel to contamination and Exposes MDRD to outside contamination.

Gloves – Appropriate for the task, chemical resistant for disinfection, long enough, density and dexterity.

Surgical or Examination Gloves – Not a good idea. Not Appropriate PPE.

Recommended Disposable (inspect and discard) wash hands before donning new gloves – Reusable need to be disinfected at the end of each shift.

Sterilization Gloves – Elbow Length, Heat Proof, Laundered weekly

Gowns – Backless, Impervious, Water Resistant covering areas at risk.

Face Shield – In Decontamination Water Resistant, full face shield extending below the chin

Q: Is Donning and Doffing standardized across North America ?

Clause 8 Evaluation and Purchase

- Added new sections on validation and MIFUs, performance characteristics of container syste
  reprocess newly purchased reusable medical devices before use
- evidence of sterilization processes used (if the product is purchased as sterile
- written evidence of validation studies (e.g., a letter or summary
- types of tests completed, any standards that are complied with, specific conditions that are validated, and any conditions that are contraindicated) that support the intended use of the medical device or product as stated in the MIFUs.
- For devices that are difficult to reprocess or cannot be reprocessed effectively or safely (devices with
- sharp components, small lumens, etc.), single-use devices or components shall be used. This decision
- should be made in consultation with the MDRD, infection prevention and control, OHS, and risk
- management.
- **8.1.6**
- All newly purchased reusable medical devices shall be reprocessed before initial use unless they are
- packaged and sterilized by the manufacturer.
- **8.1.7**
- Medical devices used on animals or cadavers shall not be loaned or accepted for human use.
- At the request of the receiving site, the vendor or supplier of the device shall confirm that the loaned,
- reusable medical devices have not been used on animals or cadavers.
- Medical devices used on animals and cadavers shall not be reprocessed in the medical device
- reprocessing department used for humans.

Q: Reprocessing New Instruments – How – Does anyone have a standardized protocol?
Any Instrument Company which have protocols around New Instrument Reprocessing?

Q: Are Loaner companies tracking to the instrument serial #?

Clause 10 Work Areas and Design

- Criteria for location of reprocessing equipment
- Strong recommendation to use automated reprocessing equipment
- Requirements for protecting clean and sterile medical devices and supplies stored in treatment rooms or operating rooms

- Areas outside the MDRD that reprocess medical devices shall comply with the design, construction, and environmental requirements of the MDRD.
- Renovations and newly constructed areas shall adhere at all times to the MDRD work area design format of Clause 10.2 of this Standard and CSA Z8000.
- When designing a new MDRD or renovating an existing one, consideration shall be given for

reprocessing equipment that has pass-through capabilities.

- Whenever possible, automated reprocessing equipment rather than manual methods shall be used for medical device reprocessing. The service space for the equipment shall also be considered.

Medical devices shall be protected from contamination by

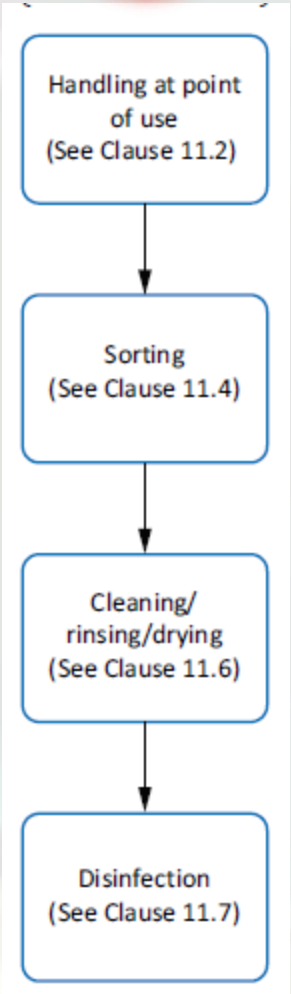
- a) rotating stock via first-in, first-out (FIFO);
- b) keeping them clean, dry, and protected; and
- c) keeping them well-separated from soiled item via barriers and/or distance.
- Medical devices shall be stored separately from hazardous material.
- Liquids shall not be stored above medical devices except where the sterile medical device contains small
- amounts of liquid (e.g., procedure kit with solution).

For clean and sterile medical devices and supplies stored in treatment rooms, procedure rooms, or

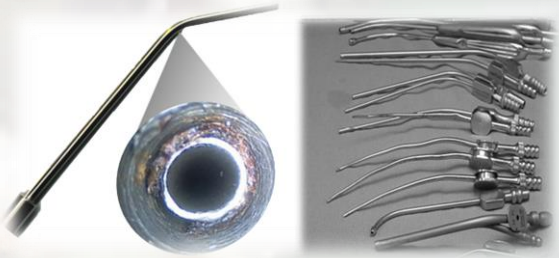
- operating rooms, inventory shall be kept to a minimum and the devices protected from damage or
- contamination. Protection shall include
- a) enclosed storage (e.g., cabinets, drawers) that meets the requirements of Clause 17.5.3; and
- b) hand hygiene before handling.

Clause 11 Decontamination of Reusable Medical Devices

- Revised figure 11.1 on decontamination steps
- Performance testing to ensure cleanliness is now required for each day that an automated cleaning system is used
- Need to remove visible soil from the medical device before ultrasonic cleaning is performed –Requirement to test sonication performance of an ultrasonic cleaner at least weekly, or preferably each day it is used
- Drying requirements now include medical devices meant to be further disinfected or chemically sterilized. Now covers testing for the MEC of a reusable HLD
- Requirement to test the washer disinfector daily for cleaning and weekly for temperature.
- **Q:** Ultrasonic – Table top ultrasonic can we fill and press start? Anything we need to do prior? What materials impede the cavitation force?



New Clauses



- **NEW Clause 12 Flexible Endoscopes**
- Requirement to visually inspect endoscopes for cleanliness and damage following cleaning and rinsing.
- **NEW Clause 13 Ultrasound Transducer Probes**
- Must take precautions not to mix two different chemicals in the same reprocessing space
- **NEW Clause 14 Preparation of Medical Devices for Reprocessing**
- Must verify cleanliness and functionality of all medical devices by visual inspection
- Lighting and magnification requirements

- Must disassemble devices to their simplest component parts before inspecting for cleanliness
- – Need to follow the chemical sterilizer MIFUs regarding the lumen lengths and inside diameters, and number of lumens per device

Q: 10 Kg (22lbs for wrapped sets – What about Basins?

Q: Do containers have lumen restrictions?

Thank You

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