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Medical devices
Swissmedic Hospital Inspections
2021 / 2022

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Monitoring medical devices in hospitals

Swissmedic is the central Swiss federal surveillance authority for therapeutic products. Its activities derive from Switzerland's therapeutic products legislation. In the field of medical devices, Swissmedic monitors maintenance, reprocessing and vigilance in around 300 Swiss hospitals, with the aim of ensuring that the hospitals fulfil their responsibility and that the medical devices used satisfy the legal requirements. Swissmedic's surveillance mandate also includes third-party providers of medical device maintenance and reprocessing services for hospitals.

This statutory enforcement remit is regulated in the Medical Devices Ordinance (MedDO, SR 812.213) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO, SR 812.219).

Definition of medical devices

Medical devices are all those products used for medical purposes in humans, but which are not medicinal products. They include instruments, apparatus, in vitro diagnostic medical devices and software. With over 10,000 categories, medical devices cover a very wide variety of products, including surgical instruments, X-ray equipment, surgical robots, breast and dental implants, artificial joints, blood pressure monitors, operating tables, patient beds, flexible endoscopes for bronchoscopies and colonoscopies, medical software and applications, certain cleaning agents and disinfectants, as well as in vitro diagnostic medical devices such as HIV tests, COVID tests, hormone tests and sexually transmitted disease tests.

Swissmedic monitors the following activities in hospitals in accordance with its legally defined mandate.

Interaction of maintenance, reprocessing and vigilance in hospitals

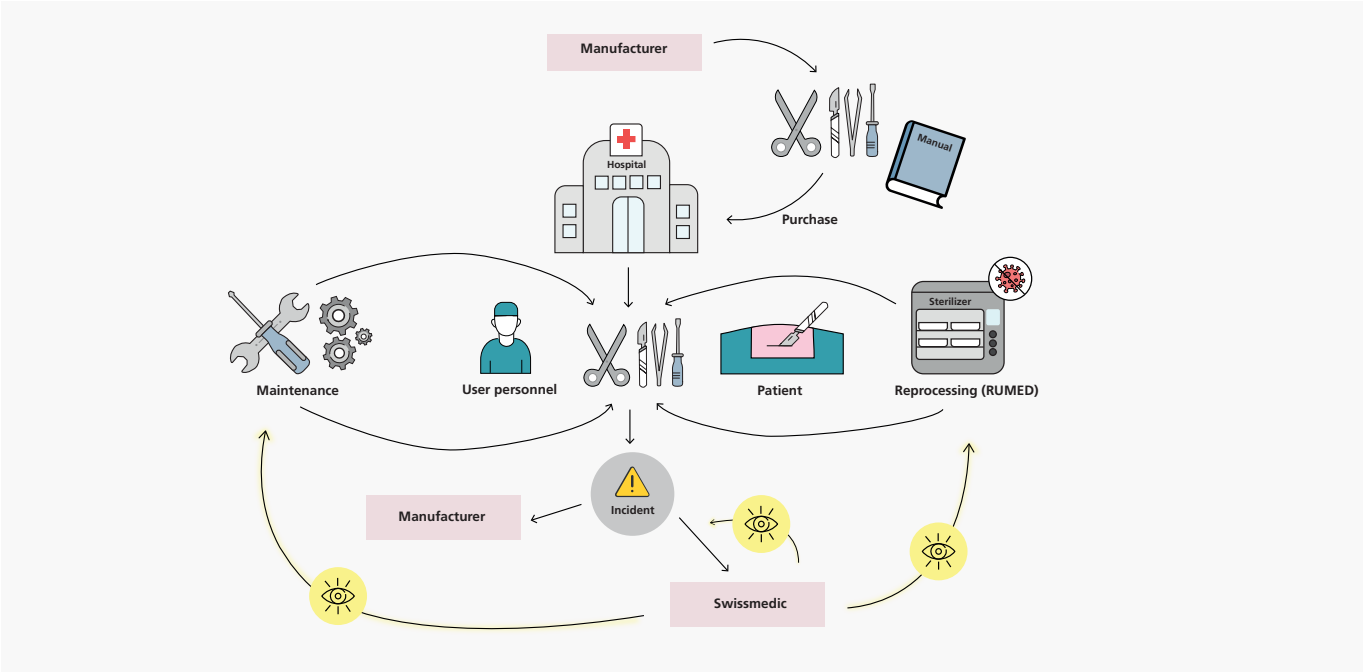

Figure 1. Schematic representation of the interaction of maintenance, reprocessing and vigilance during the life cycle of a medical device in a hospital (example: surgical instruments)

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Terms

Reprocessing

This includes processes such as cleaning, disinfection, packaging, sterilisation and storage of medical devices if these are used again on patients after an initial use. Such devices include surgical instruments and endoscopes, i.e. various medical devices for investigating body cavities. Medical devices in hospitals are usually reprocessed in central Reprocessing Units for Medical Devices (RUMEDs / Central Sterile Services departments) and in Endoscopy departments, while other hospitals have outsourced the reprocessing procedures to certified service providers. Since reprocessing represents a critical activity for patient safety (potential risk of infections caused by contaminated instruments), it may only be carried out by qualified staff.

Maintenance

This essentially involves measures such as preventive maintenance, repair, and inspection designed to preserve or restore the functional condition of a medical device. The correct execution of maintenance by qualified staff is vital for ensuring that medical devices, e.g. CT scanners or surgical robots, can be safely used and operated on patients. In hospitals, the maintenance of medical devices is usually managed by the Medical Technology department, Technical Services or the Diagnostics Laboratory. Some hospitals have outsourced maintenance operations to certified service providers.

Vigilance

Vigilance is a surveillance system that includes the discovery, assessment and understanding of adverse effects, incidents, events or other problems connected with medical devices. The aim of vigilance is to prevent the occurrence or repetition of adverse events and effects and thereby improve device and patient safety. As part of vigilance, professionals and hospitals that use medical devices are obliged to report serious incidents connected with them both to Swissmedic and the suppliers.

By law, the reprocessing, maintenance and vigilance of medical devices in hospitals must be carried out as part of an appropriate quality management system (QMS).

In accordance with its legal mandate, Swissmedic carries out announced and unannounced inspections of the reprocessing, maintenance and vigilance of medical devices in hospitals and clinics in all regions of Switzerland. The inspected hospitals differ considerably in terms of their size and the medical services they offer, ranging from small private clinics, medium-sized cantonal hospitals and regional hospitals, through to large central hospitals and university hospitals. Although the actual inspection normally lasts a day, the entire process, including preparation and follow-up through to completion, can take up to 18 months. This is the time needed by the hospitals to be able to implement all the necessary corrective actions in an appropriate manner.

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Key figures for 2021 / 2022

Selection of hospitals

The hospitals to be inspected were determined by a scientific selection process that also took into account internal and external signals (incl. whistleblower reports), as well as criteria such as the region of Switzerland, the size of the hospital and the date of the last inspection. This multi-stage selection process ensures that the inspections cover a representative selection of the whole Swiss hospital landscape.

Number of inspected hospitals and areas

In the years 2021 and 2022, Swissmedic conducted inspections in 35 hospitals. Reprocessing in the RUMEDs and Endoscopy departments was checked in 86 and 60 percent, respectively, of the inspections. Vigilance was inspected in 94 percent and maintenance in 54 percent of the inspections.

Number of inspected hospitals and areas in 2021 and 2022

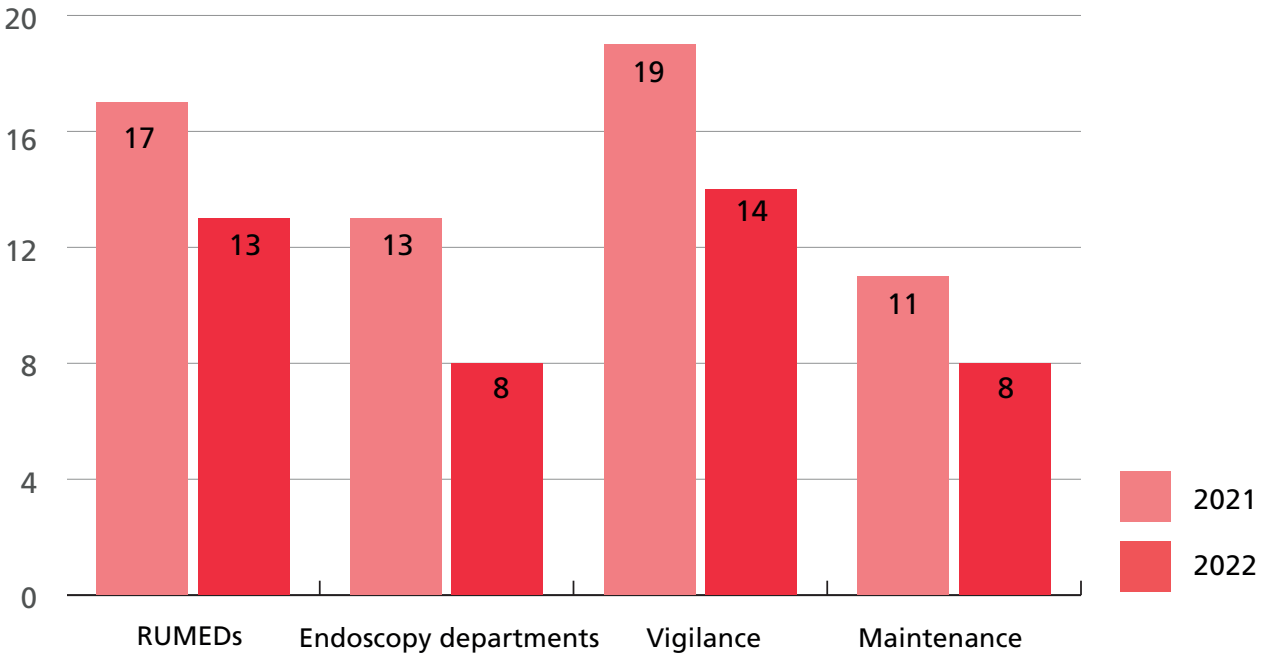

Figure 2. Number of hospital inspections in 2021 and 2022 in the various areas (RUMED reprocessing, Endoscopy reprocessing, vigilance, maintenance)

Number of deviations observed

As regards reprocessing, an average of 12.8 and 7.8 observations per hospital were noted in the RUMEDs and Endoscopy departments, respectively. In both areas, the average number of critical deviations was 1.4 per hospital. For maintenance, an average of 5.8 observations and 0.9 critical deviations were reported. During the inspection of vigilance, the average number of noted observations and critical deviations was 5.1 and 1.2, respectively, per hospital.

	Average number of observations per inspection	Average number of critical deviations per inspection
RUMED	12.8	1.4
Endoscopy	7.8	1.4
Maintenance	5.8	0.9
Vigilance	5.1	1.2

Regions

Most of the inspected hospitals were in the Lake Geneva region, at 29 percent, followed by Espace Mittelland, at around 24 percent. 18 percent of the inspections were conducted in Central and Eastern Switzerland. The proportion of hospital inspections carried out in North-western Switzerland and the Greater Zurich Area was 15 percent in both cases.

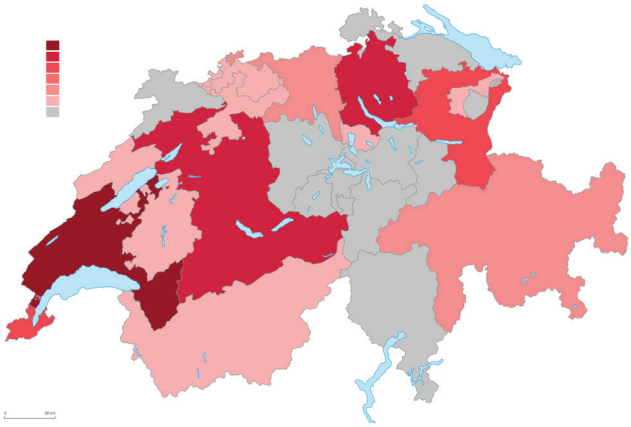

Figure 3. Distribution of hospital inspections by canton in 2021 and 2022. Gradient from 0 (grey) to 6 (dark red) inspections

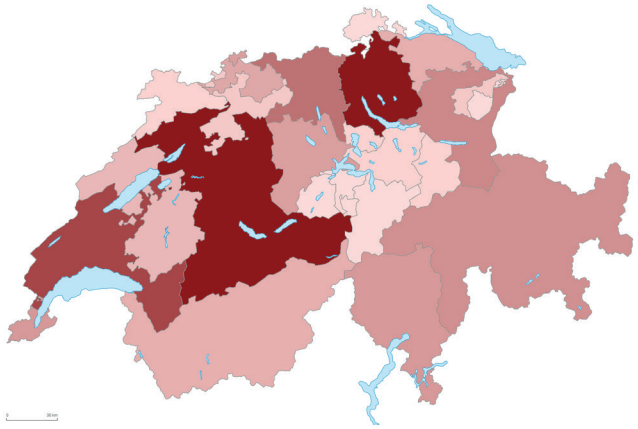

Figure 4. Distribution of Swiss hospitals by canton.Gradient from 0 percent (grey) to 13.5 percent (dark red) of all Swiss hospitals

Key deficiencies in the inspected areas

Reprocessing in RUMEDs (Central Sterile Services departments)

The area most frequently affected by deficiencies was resources, particularly staff resources (63 percent) and the RUMED premises and equipment (60 percent). Critical deficiencies in the area of staff resources included inadequate professional qualifications and the lack of further training for the RUMED personnel. In the area of premises, critical deviations most commonly involved the hygiene requirements, e.g. inadequate physical separation between dirty and clean zones. As regards equipment, e.g. cleaning/disinfection equipment and sealing devices, missing or incomplete performance qualifications, in particular, were criticised.

In 93 percent of the inspections, deficiencies were observed in the individual reprocessing procedures. Those most affected were, in particular, the cleaning and disinfection process (53 percent), function testing (50 percent), the packaging process (63 percent) and the storage of sterile instruments (57 percent).

Frequent shortcomings were also found in the quality management systems of the RUMEDs, which were affected by deviations in 67 percent of the inspections. Missing or deficient operating procedures and interface agreements, and the absence of risk management, were particularly striking here.

Inspections of RUMEDs: areas with the most deficiencies
Number (%) of inspections with deficiencies in relevant area

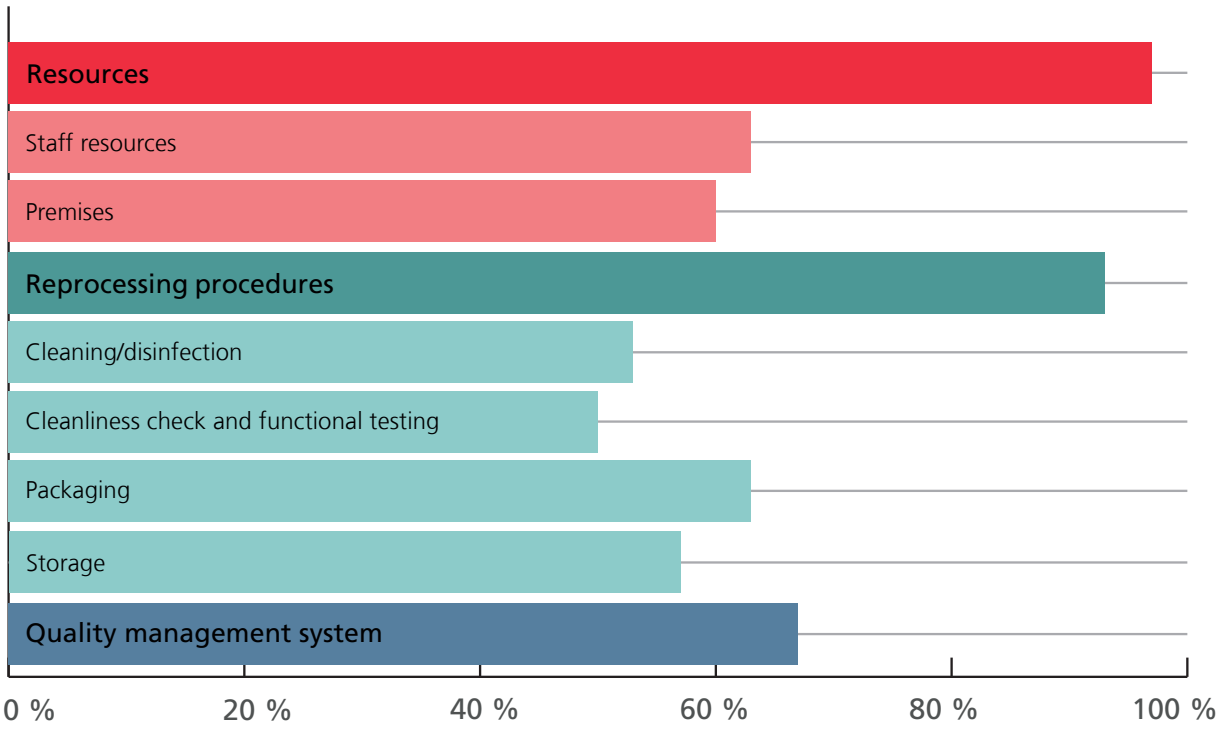

Figure 5. RUMED areas most frequently affected by deficiencies during the inspections. Deficiencies in resources, the various reprocessing procedures and quality management were observed in 97, 93 and 67 percent of the inspections, respectively.

Reprocessing of flexible endoscopes in Endoscopy departments

Here, too, the area of resources was most frequently affected by deficiencies, particularly staff resources (62 percent) and the endoscope reprocessing premises (43 percent). Critical deficiencies in the area of staff resources included inadequate professional qualifications and the lack of further training for the endoscopy reprocessing personnel. In the area of premises, critical deviations most commonly involved the hygiene requirements, e.g. inadequate physical separation between dirty and clean zones and storage zones. A further critical deficiency was the lack of adequate room ventilation or extraction devices for protecting staff from toxic chemical vapours (the chemicals used for reprocessing the endoscopes, e.g. peracetic acid or glutaraldehyde, are highly corrosive). In this context, the lack of safe storage of the chemical containers, in terms of protecting people and the environment (e.g. storage in secured chemical cabinets), was also frequently observed.

In 43 percent of the inspections, deficiencies were observed in the endoscope storage process. These usually involved the specification of excessively long storage times and the use of storage cabinets that do not comply with the current hygiene requirements. In a third of the inspected hospitals, the compressed air used for drying the endoscopes did not satisfy the specified purity requirements.

Inspections of reprocessing of flexible endoscopes: areas with the most deficiencies
Number (%) of inspections with deficiencies in relevant area

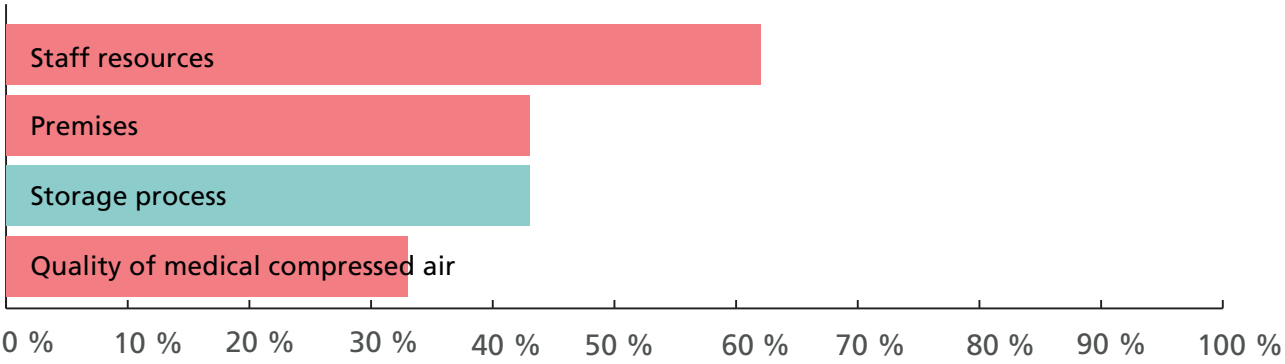

Figure 6. Areas in the reprocessing of flexible endoscopes most frequently affected by deficiencies during the inspections. Deficiencies were noticed in the area of staff resources in 62 percent of the inspections, compared to 43 percent in premises and the storage process and 33 percent in the quality of the compressed air for drying the endoscopes.

Maintenance of medical devices

Smaller hospitals, in particular, outsource all their management and maintenance operations to external service providers (maintenance by third parties). Nevertheless, the legally stipulated responsibility remains with the hospitals themselves. The maintenance by third parties was the aspect most frequently criticised, namely in 84 percent of the inspections. Criticism here focused especially on poorly regulated interfaces (e.g. responsibilities, maintenance processes) between the hospitals and the third-party companies (53 percent). In 42 percent of cases, the hospitals did not have an updated equipment inventory or overview of the status of planned maintenance operations by the third-party companies. Another observation was that over a third of the hospitals did not systematically record the costs or key performance figures for the maintenance operations provided by third-party companies.

In 58 percent of the inspected hospitals, the various maintenance processes and associated interfaces, e.g. the procurement, release, preventive maintenance, repair and decommissioning of the medical devices, were poorly regulated and documented, and did not satisfy the requirements of an appropriate QMS. The systematic measurement, periodic reporting and continuous improvement of the quality of the internally provided maintenance operations using defined quality indicators were found to be lacking in 42 percent of the inspections.

Inspections of maintenance: areas with the most deficiencies
Number (%) of inspections with deficiencies in relevant area

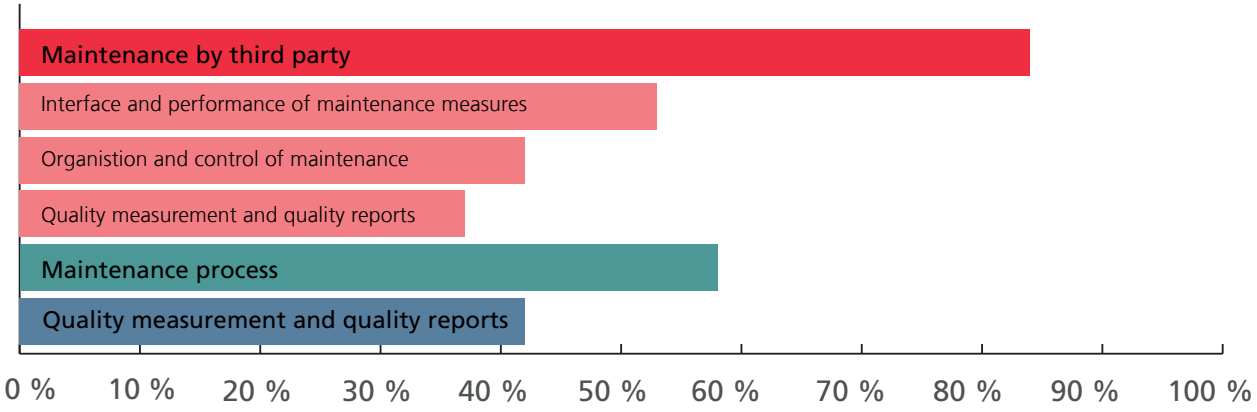

Figure 7. Areas in the maintenance of medical devices most frequently affected by deficiencies during the inspections. Deficiencies in the areas of maintenance by third-party companies, internal maintenance processes and quality measurement and reporting were observed in 84, 58 and 42 percent of inspections, respectively.

Vigilance of medical devices

The most commonly observed deficiency (76 percent) concerned the training in vigilance (reporting of serious incidents): The medical and paramedical staff and the medical technicians had either not been trained at all, or were only poorly trained or not trained regularly. In many cases, vigilance training was completely lacking for affiliated doctors and paramedics. The content of the vigilance training courses was also inadequate in most cases.

In 72 percent of the inspected hospitals, a vigilance strategy that satisfied the requirements pertaining to the reporting processes, responsibilities and interfaces as part of an appropriate quality management system either did not exist or was deficient. In around half of the inspected hospitals, the vigilance processes were poorly regulated and documented, and failed to satisfy the requirements of an appropriate QMS.

Inspections of vigilance: areas with the most deficiencies
Number (%) of inspections with deficiencies in relevant area

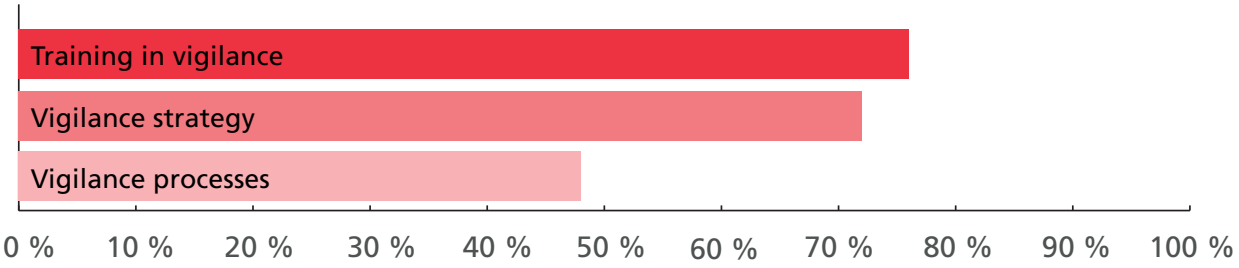

Figure 8. The aspects of vigilance most frequently criticised during the inspections were the vigilance training (76 percent), the quality of the vigilance strategy (72 percent) and the vigilance reporting processes (48 percent).

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Conclusions and outlook

Safety of medical devices:
Need for action in hospitals

The observed deficiencies can be described as follows:

- One problem that was often observed in all inspected areas was the lack of a controlled, effective quality management system with appropriate quality-assuring measures.
- In the reprocessing of medical devices in the RUMEDs and Endoscopy departments, critical deficiencies were most frequently noted in respect of the qualifications and further training of the reprocessing staff, as well as deficiencies concerning the hygiene requirements relating to room layouts..
- In maintenance, the processes for interfacing with external maintenance service providers were most often affected by deviations.
- In vigilance, the hospital staff were frequently inadequately trained, or not trained at all, and were unaware of their legal obligation to report serious incidents connected with medical devices.

The findings obtained from the hospital inspections in 2021 and 2022 show that there is considerable need for improvement and investment in Swiss hospitals in the areas of technical quality management, basic and further training of the reprocessing personnel and the infrastructure of the reprocessing departments.

Since the deviations noted for medical devices during the hospital inspections have a direct or indirect effect on device safety, and thus on the safety of patients, hospitals absolutely need to implement improvement measures and ensure their compliance with the legal requirements relating to the maintenance, reprocessing and vigilance of medical devices.

Strategic objectives of Swissmedic: Implications for the hospitals

Step up supervisory and surveillance activities

The strategic objectives of Swissmedic for the strategy period 2023–2026, which were approved by the Federal Council on 9 December 2022, also address the existing deficits in the hospital landscape in the area of medical devices:

Swissmedic ensures compliance with the legal requirements in the therapeutic products sector. By stepping up its supervisory and surveillance activities, Swissmedic aims to ascertain the conformity and safety of medical devices. In the area of medical devices, Swissmedic is increasing the number of annually inspected hospitals to 10% of all hospitals (currently: 5%). If violations occur, Swissmedic takes measures to restore a state of legal compliance, thus making a major contribution to patient safety.

Targeted collaboration with medical professionals

As a further strategic objective, and as a relevant part of the Swiss healthcare system, Swissmedic promotes good collaboration with the system partners. The aim of this collaboration is to help improve the healthcare system in Switzerland. In the area of hospitals, Swissmedic has already been actively working for some years in a targeted manner with professional associations in order to improve the safety and quality of medical devices.

In 2022 for example Swissmedic, in collaboration with the Swiss Society for Sterile Supply (SGSV) and the Swiss Society for Hospital Hygiene (SGSH), published a new edition of the „Swiss good practice for the reprocessing of medical devices“, which includes binding specifications for the reprocessing units in hospitals based on the state of the art in science and technology.

Swissmedic is also currently working with various professional associations on the preparation of a new „Swiss good practice for the reprocessing of thermolabile endoscopes“. At the start of 2023, and under the auspices of Swissmedic, another working group started drafting a „Swiss good practice for the maintenance of medical devices“, with input from the professional association of Swiss Hospital Engineers (IHS), the Association of Reprocessing in Healthcare (IG WiG) and various hospitals in the German- and French-speaking regions of Switzerland.

In the short term, additional guidelines are scheduled to be drafted in cooperation with professional associations, societies and hospitals, particularly in the area of vigilance (in vitro diagnostic and other medical devices).

Moreover, in the area of hospitals, Swissmedic regularly takes part in professional conferences and other further training events, thereby promoting the productive sharing of views and dialogue with the relevant professionals.

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