

Medical Device
Maintenance Compliance
An Issue of Medical Safety

Policy Proposal

American Medical Devices and Diagnostics
Manufacturers' Association (AMDD)
Capital Equipment Committee

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Executive Summary

Since 1951, Japanese law requires all automobiles be subjected to periodic and thorough inspection and maintenance in order to ensure safety and protect Japan's citizens. Fail to comply with the "SHAKEN" system and your vehicle will no longer be allowed to operate.

Similar mandatory inspection and maintenance systems exist for elevators and building boilers with universal compliance.

While a similar law exists for medical devices, there are few consequences for non-compliance. The fact is that there are a number of critical medical devices that are not maintained or serviced regularly in Japan. This results in lower productivity (downtime of equipment), increased failure rates and safety related incidents involving patients and hospital staff.

The AMDD's position on this critical issue is as follows:

- 1) There is a need for greater awareness of this medical safety issue and actions need to be taken to resolve the lack of compliance with the Medical Law.
- 2) Hospitals should be encouraged to utilize their staff and systems to assure daily maintenance and inspection of devices, and request manufacturers to conduct inspection and maintenance that is beyond their ability.
- 3) Government incentives should be made available for compliant hospitals.

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1. Current Status of Medical Equipment Law and Maintenance Compliance

Since June 1994, the requirements for the proper and periodic maintenance of a specific list of medical devices (See Attachment 1) were added to the Japanese Pharmaceutical Affairs Law. In the revision of the Medical Law in April 2007, the requirements for planning and proper maintenance of medical devices were added. While some of these devices are maintained regularly, there are a number of products with inherent risks that are not maintained as prescribed by law. This causes a reduction in productivity as emergency repair becomes necessary when a problem occurs, but more importantly this results in higher failure rates for unmaintained equipment and compromises safety for patients and hospital staff.

According to a survey sent to 1000 Japanese hospitals conducted in 2009 and published in 2010 by JIRA (Japan Industries Association of Radiological Systems), 16.8% of contrast media injectors used in combination with MR, CT and X-Ray scanners (which inject directly into the human vascular system at pressure settings as high as 1200 PSI), are inspected and maintained as prescribed. This is even more disconcerting when one considers that there are more than 10,000 injectors across Japan with about 10 million exams performed annually.

A similar situation exists for a number of other products, including surgical x-ray and portable x-ray equipment, with only 20.4% and 16.2% reportedly under contract for maintenance.

Percentage of Products under Contracted Maintenance in Japan

Portable X-Ray	16.2%
Contrast Media Injectors	16.8%
Surgical X-Ray	20.4%
Mammography X-Ray	47.9%
Angiographic X-Ray	75.3%
CT Scanners	89.2%
MRI Scanners	91.5%

Source: JIRA Survey 2010

There are documented cases of safety related incidents involving those products that are not regularly maintained.

* All of the following are AMDD member company examples, with the exception of Example 3 from the "2009 Nihon Hoshasen Gishikai Journal."

Example 1 - Ceiling Arm for Contrast Media Injectors

These arms, which are subject to heavy use and stress, can loosen and fall from the ceiling if not properly maintained. These incidents sometimes lead to injury of patients and medical staff.

Example 2 – X-Ray Footswitch:

Following the insertion of a catheter during a diagnostic procedure, the Doctor attempted to start the x-ray equipment, but due to a malfunction of the footswitch the examination had to be terminated. This type of incident causes unnecessary risk to the patient as well as lowers productivity in the hospital.

Example 3 – MRI Scanner:

It is necessary to check and maintain the helium level in an MRI scanner. This point is also prescribed in the instructions for use. However, there are cases of MRI scanners that are not under maintenance contracts where the helium level falls and quenching occurs. (Source: 2009 Nihonhoshasengishikai Journal)

Example 4 – Respirator and Anesthetic Equipment:

When these devices are not maintained properly there is a risk of leakage of oxygen which in turn can cause a lack of oxygen for the patient.

Example 5 – Diagnostic Equipment:

If one or more of the cable connecting pins are broken, a screw has fallen inside the equipment, the air filter is clogged or calibration is not performed the data resulting from such equipment is subject to risk.

Example 6 – Surgical Power Tools, Endoscopes and Related Equipment

The poor regular maintenance of surgical power tools, endoscopy cameras and video integration systems can lead to systemic failure in operating rooms during surgery. This

can have serious patient safety implications with increased patient and caregiver risk where surgery could be halted or in severe cases procedures would be continued as open surgery. Issues like this have unintended consequences around an increase in negative clinical outcomes not to mention the incremental costs for healthcare delivery in Japan.

As medical equipment becomes more advanced, medical staff tends to overly rely on the equipment which can lead to the type of incidents described above.

2. Suggestions for the Hospitals

Today, medical equipment manufacturers are required to provide the details, in the operation manual, for hospitals to conduct daily inspection and maintenance. In addition, the timing and requirements for maintenance that can only be conducted by the manufacturer must be listed in the package insert that accompanies each product. These requirements are put in place to assure the safe operation of medical equipment. Hospitals should be encouraged to follow these instructions and implement standard operating procedures to assure daily inspection and maintenance. It should also be a top priority to make sure that new staff are fully trained on the operation of medical devices.

3. Need for Government Incentives for Maintenance Compliant Hospitals

In order to promote full maintenance compliance with the Medical Law, incentives should be considered.

Some examples of possible incentives:

- Japan Council for Quality Health Care can review and create more specific evaluation criteria for institutions required to maintain medical equipment and assure compliance through auditing procedures (Check the Annual Maintenance History of Tokutei-Hosyukanri -Iryoukiki).
- Provide reimbursement for procedures in hospitals that are maintenance compliant.

4. Suggestions for Medical Device Manufacturers

Manufacturers should be encouraged to actively provide information (in addition to that in the package inserts and operation manuals) on daily inspection and maintenance as well as the key requirements for manufacturers` maintenance. In addition, training could be

Medical Device Maintenance Compliance

offered to Medical Engineers and others in the hospitals to fully comply with these daily requirements.

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