

Japan's maintenance of devices is lacking

Cars and elevators are checked more regularly than many medical devices in Japan. Michael Bobrove, a member of the American Medical Devices and Diagnostic Manufacturers' Association's (AMDD) capital equipment committee, provides a disturbing insight into device maintenance in Japan

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. Failure to comply with the "shaken" system means your vehicle will no longer be allowed to operate on the road.

Similar mandatory inspection and maintenance systems exist for elevators as well as for other devices with inherent risks.

In sharp contrast to this "safety-first" mind-set, today's reality in thousands of Japan's hospitals is that a number of critical medical devices in those facilities are not regularly inspected nor maintained as prescribed by law. Such equipment is left to operate with the implied hope that there will not be any critical adverse events. Unfortunately, this situation can result in undesirable consequences and there are numerous documented incidents directly linked to the failure to maintain medical devices.

According to a survey of 1,000 Japanese hospitals conducted in 2009 by Japan Industries Association of Radiological Systems (JIRA), less than 15% of contrast media injectors used in combination with MRI, CT and X-ray scanners (which inject directly into the human vascular system at pressure settings as high as 1,200 PSI) are inspected and maintained as prescribed (see Table 1). 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.

Similar situation exists for a number of other products, including surgical X-ray and portable X-ray equipment, with only 19% reportedly under contract for maintenance.

In many cases, these maintenance percentages lag far behind the US and many European countries.

The government has taken major steps to improve the situation, classifying eight medical devices in a category that provides insurance funds for their maintenance (see Table 2).

In addition, hospitals are now required to assign a Device Risk Manager to monitor and ensure proper equipment maintenance. Since April 2007, manufacturers of

medical devices approved in Japan are required to provide specific instructions for their safe use and maintenance. These legislative efforts, along with cooperation from hospitals and clinicians, have resulted in higher maintenance compliance for some medical devices like CT and MRI scanners, with about 90% reportedly under maintenance contracts.

There is a growing recognition of the need to maintain medical devices to ensure safety, but a lack of designated funding to realize these aspirations--along with the fact that there are few consequences for non-compliance--appear to be the major hurdles for many medical institutions in Japan.

Recently, the Japanese medical community and government have begun to openly and jointly address this serious problem. This is an extremely positive development, and progress in this important area will further ensure the safety of critical medical equipment for patients across Japan.

Table 1: Percentage of products under contracted maintenance in Japan

Contrast media injectors	12.7%
Surgical X-ray	18.5%
Portable X-ray	19.1%
Mammography X-ray	46.6%
Angiographic X-ray	77.6%
CT scanners	88.7%
MRI scanners	90.8%

Source: JIRA survey 2009

Table 2: List of medical devices which receive government insurance funding for maintenance

Pump oxygenator
Ventricular assistance device
Respirator
Haemodiafiltration system
Defibrillator
Closed incubator
High-Energy radiation generator for medical use (Linac)
Irradiation apparatus for medical use (Gamma knife)

Source: Japanese Ministry of Health, Labor and Welfare; Iseishihatsu No. 0330001, March 30 2007