

EQUIPMENT DESIGN AND SAFETY FACTORS IN THE MAINTENANCE OF RADIOLOGICAL EQUIPMENT

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Medical X ray imaging and radiation therapy equipment emit energy targeting patient's anatomy.

These energies are not visible, audible or directly sensible but are ionizing.

Due to the lack of ability to sense what is emitted, we rely on appropriate equipment maintenance, quality control and calibration to ensure the equipment functions safely.

Without appropriate maintenance, equipment performance cannot be assured and may result in patient or user harm.

Medical Device market

The medical device market is well controlled in all industrialized countries around the world on the basis of regulations established during the last decades, mainly involving national and/or regional authorities and in some cases, global international structures.

- The fact that diagnostic imaging has become increasingly available to patients the exposure to ionizing radiation has almost doubled in the past 20 years.
- The Joint Commission has recently announced new and revised diagnostic standards for accredited hospitals, critical access hospitals and ambulatory healthcare organizations that provide **diagnostic imaging services**.
- To minimize radiation exposure of patient and staff, one should focus on radiation safety, overall staff competency and equipment maintenance

However when put into service the performance of medical equipment is strongly dependent on the conditions of use, user training, quality control and appropriate maintenance, which are under the responsibility of the health care institutions where the equipment is installed.

At the EU the Medical Device Directives provide clear requirements on these issues stating that medical equipment should be maintained and used under conditions which guarantee that their performance is as intended by the manufacturers during their entire life cycle.

Unfortunately, this is frequently neglected leading to considerable cost, reliability and safety problems.

Medical personnel rely upon medical imaging and radiation therapy equipment to function when needed.

Inappropriate maintenance, may result in reduced system performance, increased downtime, reduced quality, and other negative consequences, leading in potential missed diagnosis or treatment.

Many factors influence the way and the extent to which maintenance is provided today such as: manufacturers' policy, hospital decision making, technical means and human resources, know-how, availability of spare parts and documentation, etc.

However there is no adequate information regarding the real maintenance costs associated with medical equipment

The dependence of the quality of the equipment output on radiation parameters makes X ray imaging and Radiation therapy equipment more complicated and its maintenance must be oriented not only to electronic or mechanical aspects but additionally, and more importantly, to radiation issues.

Equipment design is a major parameter that facilitates or hinders maintenance tasks in general.

Especially in the case of medical equipment using ionizing radiation this factor is very critical from both safety and performance points of view.

Moreover when such equipment is used harsh environments simple, robust and easy maintenance is of prime importance given environmental, infrastructure, human expertise and distance parameters.

Human factor engineering and user interface are also very important in x-ray imaging and radiation therapy equipment because they are directly related to safety issues.

