AXREM Problem Statement

Safety updates on non-contract Medical Devices

Medical device regulations require the manufacturer to provide updates for medical devices in response to identified issues. These updates may be related to product safety or product performance and are reported to the local regulators (MHRA) as well as to affected customers.

Performing any update on a medical device requires certain conditions are met to ensure the update operates as expected and does not in itself result in an issue that could compromise the safety or performance of the device. The device owner/operator should confirm the following preconditions for the medical device are expected before an update is conducted:

- All previously required updates must have been installed. This includes any updates to parts that have been exchanged, such repair parts or exchanged components and assemblies.
- The product must be unmodified from the conformity assessed state (CE or UKCA marked). This includes the hardware, software, licences, and associated licence keys.
- The product must be operating within the manufactures documented specification.
- All required service and maintenance actions have been performed (e.g., periodic replacement of parts/consumables performed), including safety critical components (e.g., wire ropes and spring-loaded mechanisms).
- Only manufacturers approved spares have been used and that those parts are intended for the product they have been installed in.

Installing any update without ensuring the preconditions are met can lead to erroneous medical device operation and hazards both to the operators and patients.

However, where the medical device owner/operator does not have a contract with the device manufacture or their approved agent, it is impossible to verify all the prerequisite conditions are met. In this case the only possible solution would be to undertake an inspection of the medical device to ascertain the conditions are met, which would be chargeable, which may not be accepted by the owner/operator. A manufacturer applying an update without satisfying themselves the medical equipment is in a suitable condition for updating would leave them liable if anything detrimental occurred (e.g., patient or user injury, loss of function, downtime, etc.).

Some owner/operators may consider that their chosen independent service provider should be tasked with installing any required update. However, this creates issues for the device manufacturer because the update instructions and material may contain confidential or proprietary information that is not intended for circulation outside the company, and they cannot be sure those undertaking the update have the required certified training for the update (especially important for new software revisions). They also have no assurance that the above-mentioned preconditions have been met. Therefore, the device manufacturer could not satisfy themselves the

AXREM
Rotherwick House
3 Thomas More Street
London E1W 1YZ
Tel: +44 (0)20 7642 8087
Web: www.AXREM.org.uk
Director: S Edgington
Email: sally.edgington@axrem.org.uk

update could be undertaken safely and be unable to report to the regulatory authority the update had been carried out correctly.

It should be noted that AXREM members have reported that during inspections prior to returning medical devices to contract or where inspections have been carried out prior to performing an update the above-mentioned preconditions have not always been met. For example, fitted parts have not had the required updates applied, as they have been harvested from scrapped equipment, incorrect versions of parts for the device have been used, non-OEM parts have been fitted (such as x-ray tubes from third-party manufactures), safety components (e.g., wire ropes) have not been replaced at the required interval, software has been modified to bypass service keys, adjustments (specifications) are not aligned with the manufacturers requirements, incorrect lubricants and service consumables have been used, etc. This can impact the safety of the device and is therefore not in line with the MHRA published guidance on managing medical devices, which highlights that healthcare organisations are responsible for ensuring that their medical devices are maintained appropriately, as indicated in section 8 of their guidance document.

Modifications to Medical Devices

Manufacturers of Medical Devices, either for in-vivo (MD) or in-vitro (IVD) use, certify (CE or UKCA mark) them to fulfil a declared intended use and register them with the MHRA as such. With regard to modifications or use outside the manufactures declaration the MHRA guidance on managing medical devices states (3.4):

> *Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications. It may also count as manufacture of a new device under the UK MDR 2002. The original manufacturer's liability is limited and liability may be partly or wholly transferred to the organisation or person making the modifications, if the device is implicated in an adverse incident.*
>
> *It is essential that modifications outside of the manufacturer's intended use are only considered as part of a fully documented risk management process within the healthcare organisation's risk management policy and procedures.*
>
> *In specific cases, where it is deemed that using an alternative accessory to that specified by the device manufacturer would give improved benefits, then a risk assessment should be carried out to ensure that all components within a system are compatible and can be used safely, e.g. batteries, chargers, connectors.*
>
> *If a device fails in use following replacement of a part with one not corresponding to the device manufacturer's specifications and this leads to the death or serious injury of a patient/user, there is a greater likelihood of the organisation responsible for medical device repair/maintenance being held liable for the injuries caused.*

In circumstances when one manufacturer wants to use their product with the device of another manufacturer it is normal practice, so as to reduce risk, for compatibility testing to be undertaken by both manufactures, and a declaration issued if mutual compatibility is agreed (Article 12, of

AXREM
Rotherwick House
3 Thomas More Street
London E1W 1YZ
Tel: +44 (0)20 7642 8087
Web: www.AXREM.org.uk
Director: S Edgington
Email: sally.edgington@axrem.org.uk

Council Directive 93/42/EEC). This can be applicable if one device is intended to be mounted or incorporated on/within another device (possibly forming a Medical Electrical System according to IEC 60601-1), or where the proximity of one device may affect the other device, such as when one device incorporates wireless technology that may interfere with the other device. Therefore, the best practice is to always request a compatibility declaration document and ensure any modification is carried out only in accordance with the declaration, as deviations would require another mutual certification.

In addition to the issues raised in the MHRA guidance other concerns would be the modification may cause issues when the one party wants to service their item and the other party's device interferes with that operation, as they are not trained or competent to work on the other manufactures device. The modification may also result in additional wear, damage, or sporadic malfunctions. Therefore, the terms of warranty or service contact may be breached and result in the termination of any associated service contact.

ENDS

AXREM
Rotherwick House
3 Thomas More Street
London E1W 1YZ
Tel: +44 (0)20 7642 8087
Web: www.AXREM.org.uk
Director: S Edgington
Email: sally.edgington@axrem.org.uk