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## Background

Medical information systems often incorporate commercial off-the-shelf software ("COTS"), e.g., operating systems, browsers, databases. COTS vendors often issue software patches, also called hotfixes, updates and service packs, to fix a variety of security, privacy, or stability problems. Typically, COTS vendors' procedures for testing or updating do not address the safety and effectiveness requirements mandated for medical information systems. This means that healthcare providers must follow different procedures when patching COTS incorporated in medical information systems.<sup>1</sup> In 2004, a coalition of medical industry stakeholders participated in a committee under the auspices NEMA<sup>2</sup>, COCIR<sup>3</sup>, and JIRA<sup>4</sup> to develop a guidance document for patching COTS used in medical information systems. The guidance document is available to the general public at the URL shown below.

[http://www.nema.org/prod/med/security/upload/Patching\\_OffTheShelfSoftware\\_Used\\_in\\_MedIS\\_October\\_2004.pdf](http://www.nema.org/prod/med/security/upload/Patching_OffTheShelfSoftware_Used_in_MedIS_October_2004.pdf)

## Scope

The scope of this policy statement includes the following products and their derivatives: Fusion RIS, Fusion PACS, eFilm Workstation, eMed.net Web Server, eMed Compression Server, eMed DICOM Bridge, eMed Workstations, Matrix Server, and eMed Image CD.

## Policy Statement

Merge Healthcare is committed to providing products and services that meet or exceed customer expectations. As part of this commitment, Merge Healthcare is hereby stating a policy on the deployment of COTS patches in conjunction with its products.

- Customers are strongly discouraged from applying COTS patches until Merge Healthcare has validated the patches with product application software.
- Merge Healthcare will validate COTS patches in a timely manner. Results of the validation will be shared with the Technical Support team so that customers may call the toll-free support line for the latest information on COTS patches. This information may also be posted on the Merge Healthcare public website. In general, the cycle for validating COTS patches and posting updates will be quarterly. Special circumstances may require urgent bulletins in between the quarterly postings.
- Merge Healthcare validates its products using Symantec Anti-Virus software. Customers shall assume full responsibility for maintaining the proper updates to this anti-virus software after initial installation of the Merge Healthcare products at their site. The customer shall also assume full responsibility for any damage or malfunction that occurs as the result from using any other type of anti-virus software.
- Merge Healthcare will take full responsibility to deploy COTS patches that are required as part of the installation or upgrade of Merge Healthcare product application software. Other than these situations, customers shall assume full responsibility for deploying COTS patches at their site.

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<sup>1</sup> "Patching Off-the-Shelf Software Used in Medical Information Systems", Joint NEMA/COCIR/JIRA Security and Privacy Committee, October 2004

<sup>2</sup> NEMA is the National Electrical Manufacturers Associations.

<sup>3</sup> COCIR is European Coordination Committee of the Radiological and Electromedical Industry.

<sup>4</sup> JIRA is the Japan Industries Association of Radiological Systems.

