Towards standardized EMC assurance case patterns for the certification of medical devices

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Abstract *Transitioning from traditional text-based arguments to graphical Goal Structuring Notation (GSN) based EMC assurance cases is efficient for reasoning why a medical device is safe, effective, and compliant with electromagnetic compatibility (EMC) standards. To demonstrate comprehensive reasoning, the compliance argument must be interlinked with risk and resilience arguments. However, interlinking these inherently complex risk-resilience-compliance arguments should also explicitly reveal their overlaps, which further adds to the overall complexity while building a unified safety argument within a unified EMC assurance case. To mitigate this argumentative complexity, there is a necessity to focus on utilizing GSN's modular approach to develop abstract sub-modules for these three arguments. The unified EMC assurance case thereby demonstrates adherence to EMC standards through effective risk management and EM-resilience design practices and highlights the overlapping EMC artifacts through modular extensions of GSN.*