NIST CYBERSECURITY PROCESS
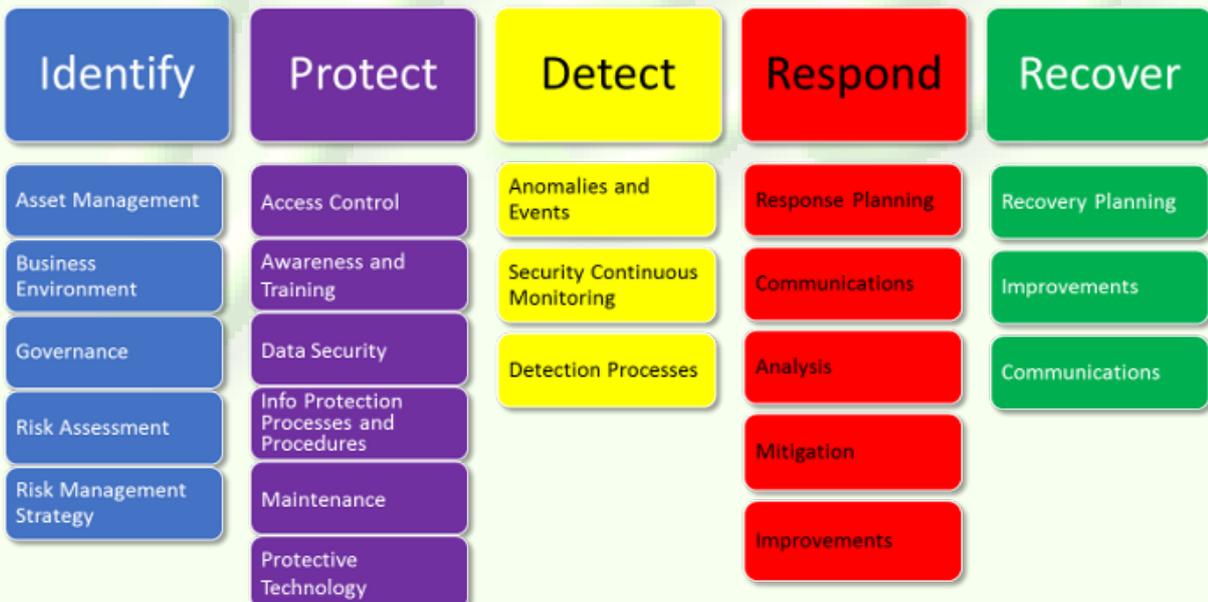
CYBERSCURITY REPORT

1. Design Documentation

1.1. Determination of Tier 1 or Tier 2 Devices (for FDA only)

1.2. System Diagram

1.3. A summary describing the design features that permit validated software updates and patches as needed throughout the life cycle of the medical device to continue to ensure its safety and effectiveness

2. Risk Management Documentation

2.1. A system level threat model

2.2. A specific list of all cybersecurity risks

2.3. A specific list and justification for all cybersecurity controls

2.4. A description of the testing that was done to ensure the adequacy of cybersecurity risk controls

2.5. A traceability matrix that links your actual cybersecurity controls to the cybersecurity risks that were considered in your security risk and hazard analysis

3. Labelling information

3.1. Warning and precautions

3.2. Backup and Restore Features

3.3. Network ports and interfaces

3.4. Procedures to download version-identifiable software or firmware

3.5. Description of forensic evidence