

NIST IR 8477-Based Set Theory Relationship Mapping (STRM)

Reference Document : Secure Controls Framework (SCF) version 2025.3

STRM Guidance: <https://securecontrolsframework.com/content/strm/scf-strm-general-iec-tr-60601-4-5.pdf>

Focal Document:

Focal Document URL: <https://webstore.iec.ch/publication/64703>

Published STRM URL: <https://securecontrolsframework.com/content/strm/scf-strm-general-iec-tr-60601-4-5.pdf>

IEC TR 60601-4-5

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship (optional)	Notes (optional)
1.0	Scope	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	no relationship	N/A	N/A	N/A	N/A	No requirements to map to.
2.0	Normative references	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	no relationship	N/A	N/A	N/A	N/A	No requirements to map to.
3.0	Terms and definitions	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Standardized Terminology	SEA-02.1	Mechanisms exist to standardize technology and process terminology to reduce confusion amongst groups and departments.	5	
4.0	Common Security Constraints	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	no relationship	N/A	N/A	N/A	N/A	No requirements to map to.
4.1	Overview	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Asset Scope Classification	AST-04.1	Mechanisms exist to determine cybersecurity and data protection control applicability by identifying, assigning and documenting the appropriate asset scope categorization for all Technology Assets, Applications and/or Services (TAAS) and personnel (internal and third-parties).	5	
4.1	Overview	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Select Controls	GOV-15.1	Mechanisms exist to compel data and/or process owners to select required cybersecurity and data protection controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.1	Overview	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Operationalizing Cybersecurity & Data Protection Practices	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize cybersecurity and data protection practices for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.1	Overview	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Risk Management Program	RSK-01	Mechanisms exist to facilitate the implementation of strategic, operational and tactical risk management controls.	5	
4.1	Overview	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Compliance Scope	CPL-01.2	Mechanisms exist to document and validate the scope of cybersecurity and data protection controls that are determined to meet statutory, regulatory and/or contractual compliance obligations.	5	
4.1	Overview	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required cybersecurity and data protection controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.2	Support of Essential Function	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Endpoint Device Management (EDM)	END-01	Mechanisms exist to facilitate the implementation of Endpoint Device Management (EDM) controls.	5	
4.2	Support of Essential Function	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Configuration Management Program	CFG-01	Mechanisms exist to facilitate the implementation of configuration management controls.	5	
4.2	Support of Essential Function	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	System Hardening Through Baseline Configurations	CFG-02	Mechanisms exist to develop, document and maintain secure baseline configurations for Technology Assets, Applications and/or Services (TAAS) that are consistent with industry-accepted system hardening standards.	5	
4.2	Support of Essential Function	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Identity & Access Management (IAM)	IAC-01	Mechanisms exist to facilitate the implementation of identification and access management controls.	5	
4.2	Support of Essential Function	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	5	
4.2	Support of Essential Function	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Minimum Viable Product (MVP) Security Requirements	TDA-02	Mechanisms exist to design, develop and produce Technology Assets, Applications and/or Services (TAAS) in such a way that risk-based technical and functional specifications ensure Minimum Viable Product (MVP) criteria establish an appropriate level of security and resiliency based on applicable risks and threats.	5	
4.3	Compensating Countermeasures	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	equal	Compensating Countermeasures	RSK-06.2	Mechanisms exist to identify and implement compensating countermeasures to reduce risk and exposure to threats.	10	
4.4	Least Privilege	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Least Privilege	IAC-21	Mechanisms exist to utilize the concept of least privilege, allowing only authorized access to processes necessary to accomplish assigned tasks in accordance with organizational business functions.	5	
4.5	Data Minimization	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Minimize Sensitive / Regulated Data	DCH-18.1	Mechanisms exist to minimize sensitive/regulated data that is collected, received, processed, stored and/or transmitted throughout the information lifecycle to only those elements necessary to support necessary business processes.	5	
4.5	Data Minimization	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Collection Minimization	END-13.3	Mechanisms exist to utilize sensors that are configured to minimize the collection of information about individuals.	5	
4.6	Overarching Constraints	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	no relationship	N/A	N/A	N/A	N/A	No requirements to map to.
4.6.1	Constraints Referenced by the Medical Device Specifications	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Select Controls	GOV-15.1	Mechanisms exist to compel data and/or process owners to select required cybersecurity and data protection controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.6.1	Constraints Referenced by the Medical Device Specifications	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Operationalizing Cybersecurity & Data Protection Practices	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize cybersecurity and data protection practices for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.6.1	Constraints Referenced by the Medical Device Specifications	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required cybersecurity and data protection controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.6.2	Hardware Security	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Minimum Viable Product (MVP) Security Requirements	TDA-02	Mechanisms exist to design, develop and produce Technology Assets, Applications and/or Services (TAAS) in such a way that risk-based technical and functional specifications ensure Minimum Viable Product (MVP) criteria establish an appropriate level of security and resiliency based on applicable risks and threats.	5	
4.6.2	Hardware Security	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Risk Assessment	RSK-04	Mechanisms exist to conduct recurring assessments of risk that includes the likelihood and magnitude of harm, from unauthorized access, use, disclosure, disruption, modification or destruction of the organization's systems and data.	5	
4.6.2	Hardware Security	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	5	
4.6.2	Hardware Security	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Threat Analysis	THR-10	Mechanisms exist to identify, assess, prioritize and document the potential impact(s) and likelihood(s) of applicable internal and external threats.	5	
4.6.3	Specific Security Features for Medical Devices	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	5	
4.6.3	Specific Security Features for Medical Devices	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Minimum Viable Product (MVP) Security Requirements	TDA-02	Mechanisms exist to design, develop and produce Technology Assets, Applications and/or Services (TAAS) in such a way that risk-based technical and functional specifications ensure Minimum Viable Product (MVP) criteria establish an appropriate level of security and resiliency based on applicable risks and threats.	5	
5.0	Security Levels for the Different Foundational Requirements	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	no relationship	N/A	N/A	N/A	N/A	No requirements to map to.
5.1	Application of Security Levels	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Configuration Management Program	CFG-01	Mechanisms exist to facilitate the implementation of configuration management controls.	5	
5.1	Application of Security Levels	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required cybersecurity and data protection controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
5.1	Application of Security Levels	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	System Hardening Through Baseline Configurations	CFG-02	Mechanisms exist to develop, document and maintain secure baseline configurations for Technology Assets, Applications and/or Services (TAAS) that are consistent with industry-accepted system hardening standards.	5	
5.1	Application of Security Levels	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Operationalizing Cybersecurity & Data Protection Practices	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize cybersecurity and data protection practices for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
5.2	Modified Specifications for Security Levels	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Compensating Countermeasures	RSK-06.2	Mechanisms exist to identify and implement compensating countermeasures to reduce risk and exposure to threats.	5	
5.2	Modified Specifications for Security Levels	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Approved Baseline Deviations	AST-02.4	Mechanisms exist to document and govern instances of approved deviations from established baseline configurations.	5	

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship (optional)	Notes (optional)
5.2 - CR 1.2 RE(1)	Unique Identification and Authentication	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Device Authorization Enforcement	IAC-04.2	Mechanisms exist to enforce unique device cryptographic communications keys to prevent one key from being used to access multiple devices.	5	
5.2 - CR 2.1	Authorization Enforcement	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	System Privileges Isolation	SEA-04.4	Mechanisms exist to isolate, or logically separate, any application, service and/or process running with system privileges.	5	
5.2 - CR 2.1	Authorization Enforcement	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Process Isolation	SEA-04	Mechanisms exist to implement a separate execution domain for each executing process.	5	
5.2 - CR 4.1	Health Data De-identification	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	De-Identification (Anonymization)	DCH-23	Mechanisms exist to anonymize data by removing Personal Data (PD) from datasets.	5	
5.2 - CR 5.1	Network Segmentation (macrosegmentation)	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	equal	Network Segmentation (macrosegmentation)	NET-06	Mechanisms exist to ensure network architecture utilizes network segmentation to isolate systems, applications and services that protections from other network resources.	10	
6.0	Technical Description	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	no relationship	N/A	N/A	N/A	N/A	No requirements to map to.
6(a)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(b)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(c)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(d)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(e)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(f)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(g)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(h)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(i)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(j)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(k)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(l)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(m)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(n)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(o)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(p)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(q)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(r)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(s)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship (optional)	Notes (optional)
6(t)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(u)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
6(v)	N/A	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	intersects with	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for systems that describe: (1) Secure configuration, installation and operation of the system; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	