Set Theory Relationship Mapping (STRM)

Reference Document : Secure Controls Framework (SCF) version 2024.1
Focal Document: IEC TR 60601-4-5
STRM URL: https://content.securecontrolsframework.com/strm/scf-2024-1-iec-tr-60601-4-5.pdf

Set Theory Relationship Mapping (STRM) is well-suited for mapping between sets of elements that exist in two distinct concepts that are mostly the same as each other (e.g., cybersecurity & data privacy requirements). STRM also allows the strength of the mapping to be captured.

STRM relies on a justification for the relationship claim. There are three (3) options for the rationale, which is a high-level context within which the two concepts are related:

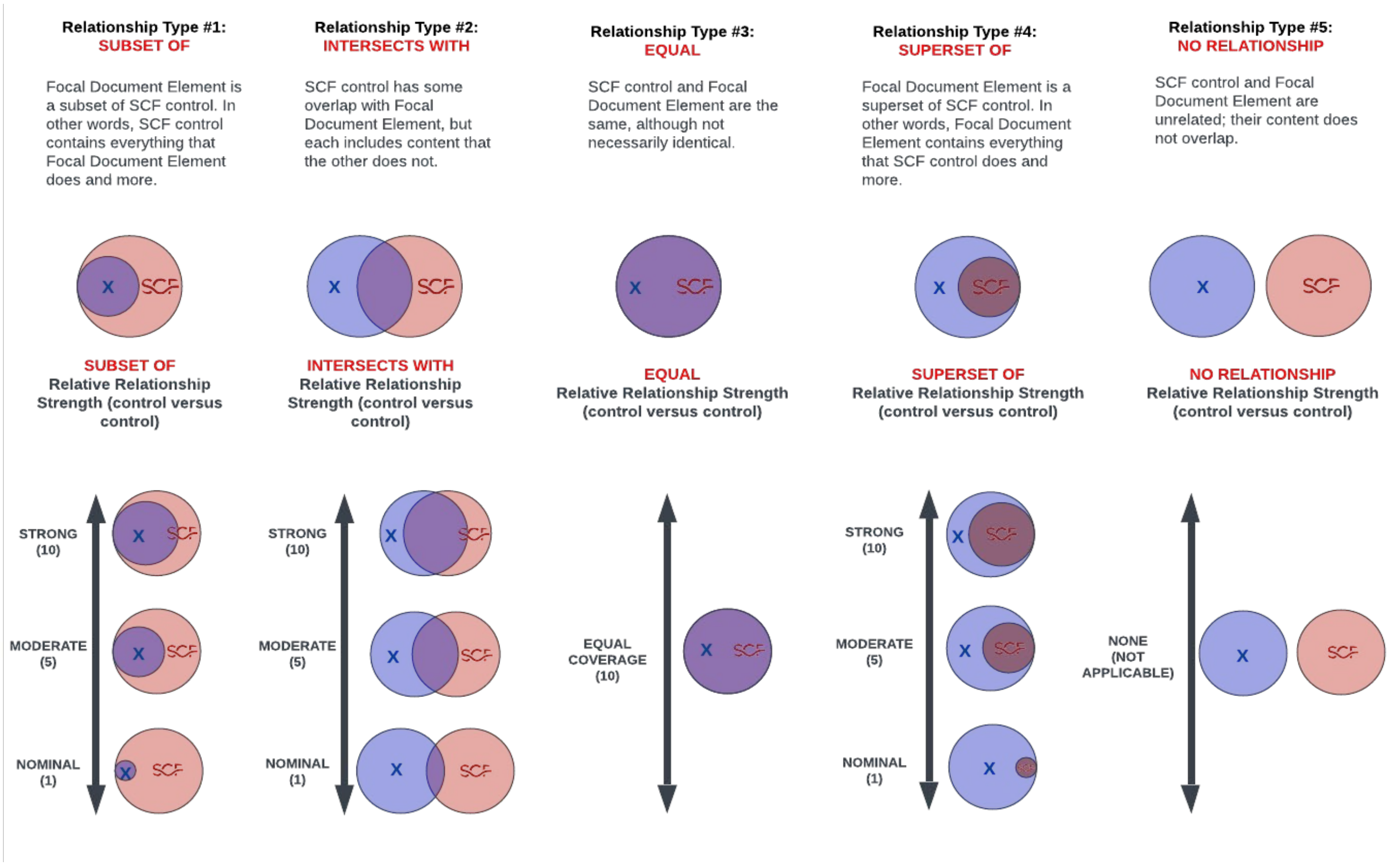
1. **Syntactic**: How similar is the wording that expresses the two concepts? This is a word-for-word analysis of the relationship, not an interpretation of the language.
2. **Semantic**: How similar are the meanings of the two concepts? This involves some interpretation of each concept's language.
3. **Functional**: How similar are the results of executing the two concepts? This involves understanding what will happen if the two concepts are implemented, performed, or otherwise executed.

Based on NIST IR 8477, STRM supports five (5) five relationship types to describe the logical similarity between two distinct concepts:

1. **Subset Of**
2. **Intersects With**
3. **Equal**
4. **Superset Of**
5. **No Relationship**

SCF **Reference Document**

Law, Regulation or Framework **Focal Document**



Relationship Type #1: SUBSET OF

Focal Document Element is a subset of SCF control. In other words, SCF control contains everything that Focal Document Element does and more.

Relationship Type #2: INTERSECTS WITH

SCF control has some overlap with Focal Document Element, but each includes content that the other does not.

Relationship Type #3: EQUAL

SCF control and Focal Document Element are the same, although not necessarily identical.

Relationship Type #4: SUPERSET OF

Focal Document Element is a superset of SCF control. In other words, Focal Document Element contains everything that SCF control does and more.

Relationship Type #5: NO RELATIONSHIP

SCF control and Focal Document Element are unrelated; their content does not overlap.

X
SCF
SUBSET OF
Relative Relationship Strength (control versus control)
INTERSECTS WITH
Relative Relationship Strength (control versus control)
EQUAL
Relative Relationship Strength (control versus control)
SUPERSET OF
Relative Relationship Strength (control versus control)
NO RELATIONSHIP
Relative Relationship Strength (control versus control)
STRONG (10)
MODERATE (5)
NOMINAL (1)
EQUAL COVERAGE (10)
NONE (NOT APPLICABLE)

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 & data privacy control applicability by identifying, assigning and documenting the appropriate asset scope categorization for all systems, applications, services and personnel (internal and third-parties).	5	
			Functional	intersects with	Select Controls	GOV-15.1	Mechanisms exist to compel data and/or process owners to select required cybersecurity & data privacy controls for each system, application and/or service under their control.	5	
			Functional	intersects with	Operationalizing Cybersecurity & Data Protection Practices	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize cybersecurity & data privacy practices for each system, application and/or service under their control.	5	
			Functional	intersects with	Risk Management Program	RSK-01	Mechanisms exist to facilitate the implementation of strategic, operational and tactical risk management controls.	5	
			Functional	intersects with	Compliance Scope	CPL-01.2	Mechanisms exist to document and validate the scope of cybersecurity & data privacy controls that are determined to meet statutory, regulatory and/or contractual compliance obligations.	5	
			Functional	intersects with	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required cybersecurity & data privacy controls for each system, application and/or service 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 Security	END-01	Mechanisms exist to facilitate the implementation of endpoint security controls.	5	
			Functional	intersects with	Configuration Management Program	CFG-01	Mechanisms exist to facilitate the implementation of configuration management controls.	5	
			Functional	intersects with	System Hardening Through Baseline Configurations	CFG-02	Mechanisms exist to develop, document and maintain secure baseline configurations for technology platforms that are consistent with industry-accepted system hardening standards.	5	
			Functional	intersects with	Identity & Access Management (IAM)	IAC-01	Mechanisms exist to facilitate the implementation of identification and access management controls.	5	
			Functional	intersects with	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to update products, including systems, software and services, to improve functionality and correct security deficiencies.	5	
			Functional	intersects with	Minimum Viable Product (MVP) Security Requirements	TDA-02	Mechanisms exist to ensure risk-based technical and functional specifications are established to define a Minimum Viable Product (MVP).	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 Personal Data (PD)	DCH-18.1	Mechanisms exist to limit Personal Data (PD) being processed in the information lifecycle to elements identified in the Data Protection Impact Assessment (DPIA).	5	
			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 & data privacy controls for each system, application and/or service under their control.	5	
			Functional	intersects with	Operationalizing Cybersecurity & Data Protection Practices	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize cybersecurity & data privacy practices for each system, application and/or service under their control.	5	
			Functional	intersects with	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required cybersecurity & data privacy controls for each system, application and/or service 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 ensure risk-based technical and functional specifications are established to define a Minimum Viable Product (MVP).	5	
			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	
			Functional	intersects with	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to update products, including systems, software and services, to improve functionality and correct security deficiencies.	5	
			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 update products, including systems, software and services, to improve functionality and correct security deficiencies.	5	
			Functional	intersects with	Minimum Viable Product (MVP) Security Requirements	TDA-02	Mechanisms exist to ensure risk-based technical and functional specifications are established to define a Minimum Viable Product (MVP).	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	
			Functional	intersects with	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required cybersecurity & data privacy controls for each system, application and/or service under their control.	5	
			Functional	intersects with	System Hardening Through Baseline Configurations	CFG-02	Mechanisms exist to develop, document and maintain secure baseline configurations for technology platforms that are consistent with industry-accepted system hardening standards.	5	
			Functional	intersects with	Operationalizing Cybersecurity & Data Protection Practices	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize cybersecurity & data privacy practices for each system, application and/or service 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	
			Functional	intersects with	Approved Baseline Deviations	AST-02.4	Mechanisms exist to document and govern instances of approved deviations from established baseline configurations.	5	
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	
			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	Buy a copy of IEC TR 60601-4-5:2021 for control content: https://webstore.iec.ch/publication/64703	Functional	equal	Network Segmentation	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: ▪ Secure configuration, installation and operation of the system; ▪ Effective use and maintenance of security features/functions; and ▪ 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: ▪ Secure configuration, installation and operation of the system; ▪ Effective use and maintenance of security features/functions; and ▪ 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: ▪ Secure configuration, installation and operation of the system; ▪ Effective use and maintenance of security features/functions; and ▪ Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	

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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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	
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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • 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: • Secure configuration, installation and operation of the system; • Effective use and maintenance of security features/functions; and • Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	