

**NIST IR 8477-based Set Theory Relationship Mapping (STRM)**  
**Reference document:** Secure Controls Framework (SCF) version 2026.1  
<https://securecontrolsframework.com/set-theory-relationship-mapping-strm/>

**Focal Document:** IEC TR 60601-4-5  
**Focal Document URL:** <https://webstore.iec.ch/publication/64703>  
**Published STRM URL:** <https://content.securecontrolsframework.com/strm/scf-strm-general-iec-tr-60601-4-5-2021.pdf>

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Security Controls Framework (SCF) Control Description	Strength of Relationship	Notes
1.0	Scope	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
2.0	Normative references	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
3.0	Terms and definitions	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
4.1	Overview	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Asset Scope Classification	AST-04.1	Mechanisms exist to determine security, compliance and resilience 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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Select Controls	GOV-15.1	Mechanisms exist to compel data and/or process owners to select required security, compliance and resilience controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.1	Overview	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Operationalizing Security, Compliance & Resilience Capabilities	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize security, compliance and resilience practices for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.1	Overview	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Compliance Scope	CPL-01.2	Mechanisms exist to document and validate the scope of security, compliance and resilience controls that are determined to meet statutory, regulatory and/or contractual compliance obligations.	5	
4.1	Overview	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required security, compliance and resilience controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.2	Support of Essential Function	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Secure 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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
4.6.1	Constraints Referenced by the Medical Device Specifications	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Select Controls	GOV-15.1	Mechanisms exist to compel data and/or process owners to select required security, compliance and resilience controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.6.1	Constraints Referenced by the Medical Device Specifications	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Operationalizing Security, Compliance & Resilience Capabilities	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize security, compliance and resilience practices for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.6.1	Constraints Referenced by the Medical Device Specifications	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required security, compliance and resilience controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
4.6.2	Hardware Security	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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 Technology Assets, Applications, and/or Services (TAAS).	5	
4.6.2	Hardware Security	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
5.1	Application of Security Levels	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Implement Controls	GOV-15.2	Mechanisms exist to compel data and/or process owners to implement required security, compliance and resilience controls for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
5.1	Application of Security Levels	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Secure 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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Operationalizing Security, Compliance & Resilience Capabilities	GOV-15	Mechanisms exist to compel data and/or process owners to operationalize security, compliance and resilience practices for each Technology Asset, Application and/or Service (TAAS) under their control.	5	
5.2	Modified Specifications for Security Levels	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Device Authorization Enforcement	IAC-04.2	Mechanisms exist to enforce cryptographic communications keys to prevent one key from being used to access multiple devices.	5	
5.2 - CR 2.1	Authorization Enforcement	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	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)	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Equal	Network Segmentation (macrosegmentation)	NET-06	Mechanisms exist to ensure network architecture utilizes network segmentation to isolate Technology Assets, Applications and/or Services (TAAS) to protect from other resources.	10	
6.0	Technical Description	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
6(a)	N/A	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for Technology Assets, Applications and/or Services (TAAS) that describe: (1) Secure configuration, installation and operation of the TAAS; (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	For specific requirement details, buy a licensed copy of the Focal Document at: <a href="https://webstore.iec.ch/publication/64703">https://webstore.iec.ch/publication/64703</a>	Functional	Intersects With	Documentation Requirements	TDA-04	Mechanisms exist to obtain, protect and distribute administrator documentation for Technology Assets, Applications and/or Services (TAAS) that describe: (1) Secure configuration, installation and operation of the TAAS; (2) Effective use and maintenance of security features/functions; and (3) Known vulnerabilities regarding configuration and use of administrative (e.g., privileged) functions.	5	

