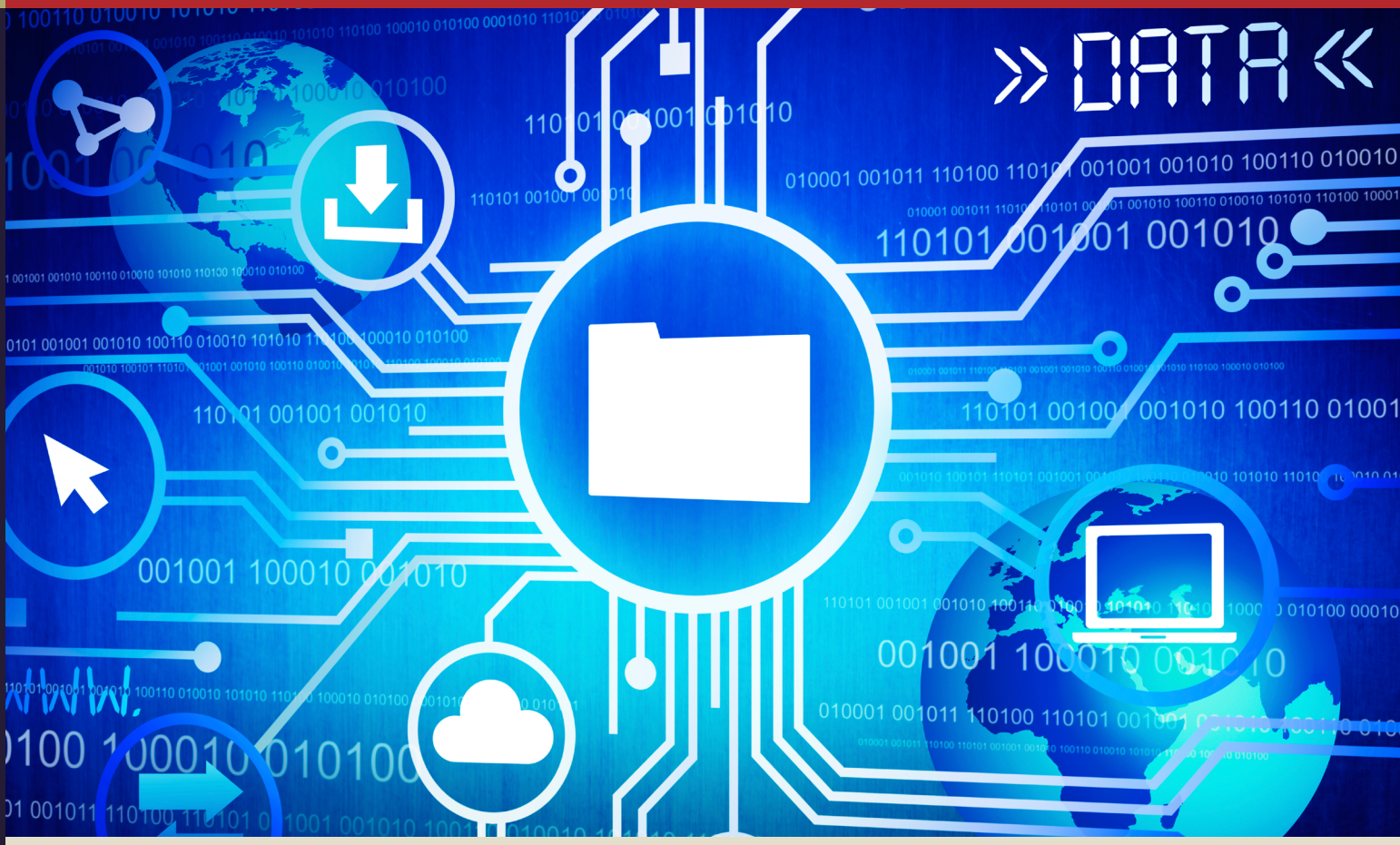
HITRUST
Health Information Trust Alliance



CSF Assessment Methodology

Version 8.0

June 2016

Contents

Contents

Introduction

The Health Information Trust Alliance (HITRUST) exists to ensure that information security becomes a core pillar of, rather than an obstacle to, the broad adoption of health information systems and exchanges. Security is critical to the broad adoption, utilization and confidence in health information systems, medical technologies and electronic exchanges of health information. This, in turn, is critical to realizing the related promise of quality improvement and cost containment in America's healthcare system.

HITRUST collaborated with healthcare, business, technology and information security leaders to establish the first ever framework, HITRUST CSF (CSF), to be used by any and all organizations that create, access, store or exchange sensitive information in healthcare. HITRUST is also driving adoption and widespread confidence in the CSF and sound risk mitigation practices through the HITRUST community that provides awareness, education, advocacy, support, knowledge sharing and additional leadership and outreach activities.

The HITRUST CSF addresses the challenges facing the industry by leveraging and enhancing existing standards and regulations to provide organizations of any size with prescriptive implementation requirements. By engaging HITRUST and implementing the CSF, certified organizations will have a common security baseline and mechanism for communicating validated security controls to different constituents, including regulators, auditors, business partners and customers. Through the CSF, HITRUST aims to ensure the healthcare industry is a leader in protecting the privacy and security of sensitive information.

This document communicates the process to prepare for and perform an assessment of an organization's existing control infrastructure against the HITRUST CSF, provide increased assurance, and meet the following objectives:

- Identify critical information systems storing, processing or transmitting sensitive information
- Identify, classify and manage vulnerabilities based on their relative risk to the company
- Provide the organization an awareness of its state of compliance with the CSF
- Establish and prioritize solutions that address root-cause issues to mitigate system vulnerabilities.

Assessment Process Flow

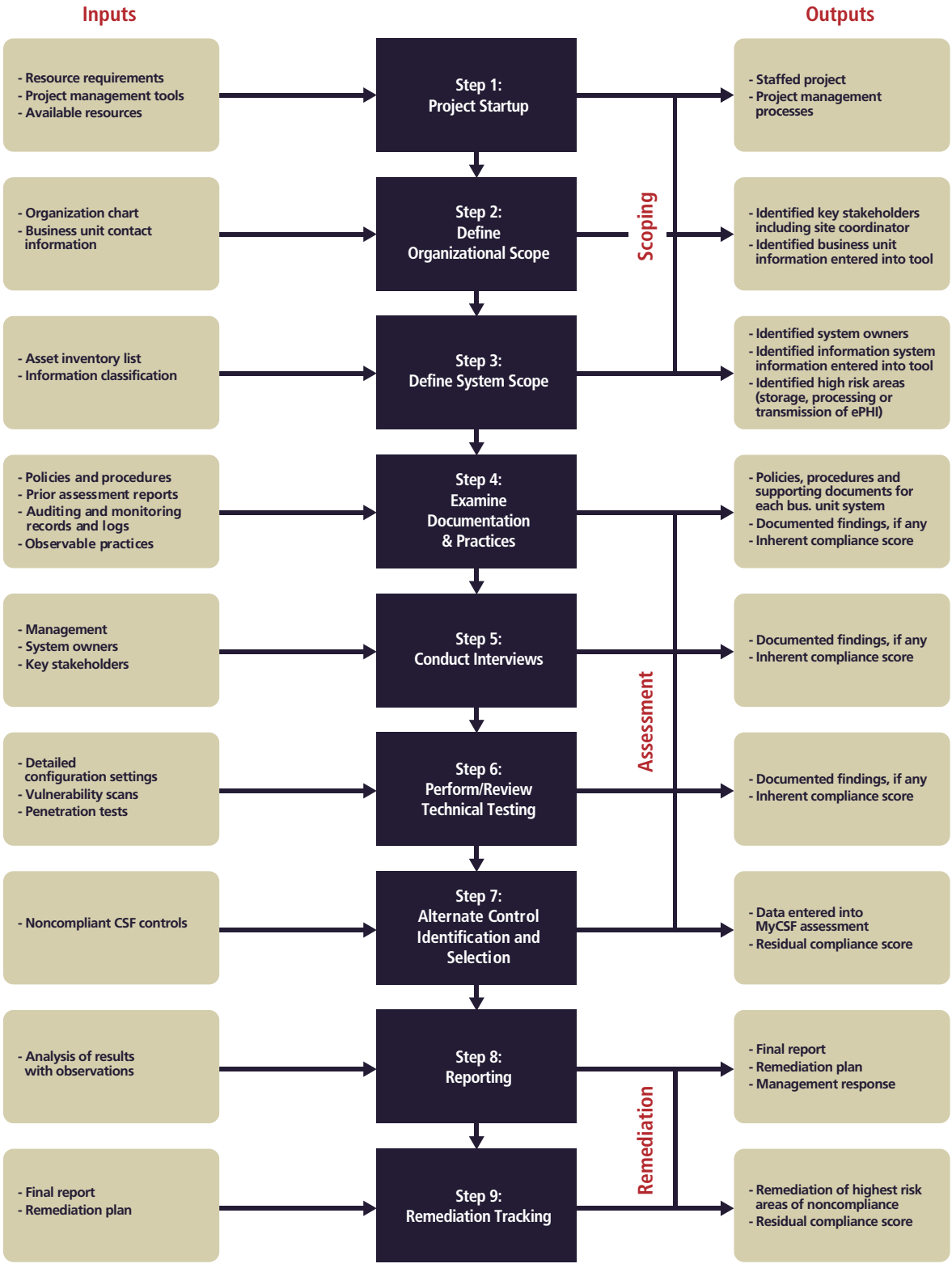
At a high level, the process will follow the steps below:

1. Identify the project coordinator and the supporting review team personnel at the organization being assessed and project management techniques to be used
2. Define the scope of the assessment in terms of business units and identify appropriate stakeholders from each business unit, including a coordinator
3. Define the scope of the assessment for each business unit in terms of systems, including those with higher risk profiles (e.g., store, process or transmit ePHI)

4. Gather and examine the necessary information (e.g., policies, procedures, records, logs, vulnerability assessment reports, risk assessment reports) and examine configuration settings, physical surroundings, processes and other observable information protection practices
5. Conduct interviews with the business unit stakeholders, where applicable
6. Perform system tests to validate the implementation of controls, as applicable
7. Select and document any Alternate Controls for any noncompliant controls and/or opportunities to enhance existing controls
8. Develop the assessment report with all noncompliant controls and document any recommended remediation tasks in a formal corrective action plan (CAP)
9. Finalize report and begin tracking any remediation activities

A visualization of the process flow can be found on the following page. Subsequent sections of this document describe this process in greater detail.

HITRUST CSF Assessment Activities



Project Startup (Step 1)

The purpose of the start-up process is to provide a framework for establishing the organizational and logistical requirements to accurately determine the scope and the structure of the assessment.

Identify Project Coordinator

The project coordinator is critical to the success of the assessment for communicating expectations to other organizational personnel, gathering documentation, coordinating interviews, and providing insight throughout the assessment. This person should have sufficient authority within the organization to gain access to other executives, influence participation in the assessment, and generally represent the commitment of senior management to the assessment. The organization should identify the project coordinator approximately 6 weeks before the fieldwork commences.

Define Project Management Organization Structure and Standards

The project coordinator should work with the organizational stakeholders to define and agree upon the management structure for the assessment and any standards, procedures or tools needed to support the project management process. The assessment project management tools will typically include the following documents and sections:

- Project Plan
  - Tasks
  - Resources assigned to each task
  - Planned start date
  - Actual start date
  - Planned completion date
  - Actual completion date
  - Dependencies
- Interview Tracking
  - Interviewee
  - Topic
  - Date
  - General comments
- Documentation Request Tracking
  - Document topic/name
  - Brief description
  - Date requested
  - Date received

- Stakeholder/Contact Tracking
  - Name
  - Title
  - Business unit
  - Role within assessment
  - Contact phone(s)
  - Email address
- Meeting Minutes
  - Topic
  - Date
  - Attendees
  - High-level notes
  - Action items
- Weekly Project Status
  - Current status/accomplishments
  - Percent complete
  - Upcoming meetings, events and tasks
  - Open items/issues/risks

Any issues or risks that arise during the course of the project can either be maintained within the weekly project status document or in a separate issue/risk tracking log. In either case, the project coordinator should always track and monitor risks as they relate to the project. At a minimum, the following items should be tracked:

- Description of issue/risk
- Action required to resolve the issue/risk
- Priority of the issue/risk
- Date the issue/risk is identified
- Date the issue/risk is resolved
- Individual(s) responsible for resolution

Depending on the complexity and scope of the assessment, additional project management tools and templates may need to be developed.

Assessment Kickoff

Before beginning the scoping and assessment process, the assessor should conduct an official kickoff meeting. The meeting should occur 3-4 weeks prior to the assessment fieldwork and should include the assessor, project coordinator, and any identified key organizational stakeholders. The meeting, at a minimum, should cover the following:

- Assessor contact information
- Overview of the assessment process and timeline
- High-level scope (covered facilities, systems)
- Expectations of the organization

Assessment Scoping

Purpose

The assessment scoping process is the method for determining the scope of the assessment regarding organizational business units and related systems. This ensures that the necessary data is collected in an effective and efficient manner. The process is designed to be flexible and adaptive so that it can be tailored to fit the unique environment of an organization based on size and complexity. A key initial step is to establish a clear scope, which should include the following:

- Start-up processes required to prepare the assessor and the organization
- Key contacts within the organization and each business unit
- Tailored assessment tasks based on the environment of the organization and business units
- Estimated timeframes to complete each task
- Systems and system owners within each business unit, with a focus on those that store, process or transmit covered information

By clearly defining and identifying upfront the scope of the CSF assessment at the organization, the assessor will focus and streamline analysis and information gathering tasks resulting in a timely completion of the assessment with a detailed report.

Define Organizational Scope (Step 2)

This section focuses on the key task of identifying the business units and key contacts within the organization and documenting the organizational factors that define the level of control for the CSF assessment. Once complete, the assessor can work with the identified coordinator and contacts within each business unit to determine the system scope and ensure a comprehensive review is performed.

Identifying the Business Units

A critical step in the assessment scoping process is to break up the organization into auditable business units to ensure the successful management of the assessment. An auditable business unit is defined as units or departments within the organization that can operate distinctly from one another. However, depending on the size and complexity of the organization, they may also represent geographical regions or associations with other (external) groups. Both distinctions are acceptable for the purposes of the CSF assessment and CSF Validation/Certification.

The project coordinator should work with the assessor and management to define the organization in terms of auditable business units. Once complete, the key contacts within each business unit should be identified along with a business unit coordinator to assist with the performance of the assessment tasks. The key contacts within each business unit include the department head(s), directors, managers, system owners, information security personnel, risk/compliance personnel, human resource personnel, and general users. This list is not exhaustive and may need to be expanded depending on the organization.

Organizational Factors

The CSF defines a number of organizational factors that increase the inherent risk to the organization, necessitating a potentially higher level of control. The organizational factors are defined based on the number of individual records that they hold and/or process, regardless of the class (or vertical) in which the organization resides. The rationale is based primarily on common use of the average cost of a breach per individual record compromised to estimate the costs of a specific breach. Further, the total number of individual records that could potentially be compromised then provides an estimate of the organization's maximum exposure in the event of such a catastrophic breach. However, since, in HITRUST's experience, not all healthcare organizations can provide a precise estimate of the total number of individual records they hold, an alternative risk factor is provided based on the number of individual records processed annually. While not the best indicator for the organization's maximum exposure due to a catastrophic breach of all records held, the two are reasonably correlated.

A definition of each class (vertical) is provided below followed by the primary (P) and alternate (A) organizational risk factors.

Payer: Payers are covered entities identified as "Health Plans" under HIPAA, and are defined as an individual or group plan that provides, or pays the cost of, medical care.[1] Health Insurance Exchanges (HIXs) are also considered payers for this purpose.[2]

- Record Count: Total (P)
- Record Count: Annual (A)
- Number of Covered Lives (A)

1. *§2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)*
2. *http://obamacarefacts.com/obamacare-health-insurance-exchange/*

Hospital / Inpatient Facility: Hospitals and other inpatient facilities are identified as "Providers" under HIPAA, and are generally defined as a place for receiving medical or surgical care, usually as an inpatient (resident).

- Record Count: Total (P)
- Record Count: Annual (A)
- Number of Admissions: Annual (A)
- Number of Beds (A)

Pharmacy / Pharmacy Benefit Management (PBM): Pharmacies are identified as "Providers" under HIPAA, and are generally defined as a place where medicines are prepared, compounded, dispensed or sold.

- Record Count: Total (P)
- Record Count: Annual (A)
- Number of Prescriptions: Annual (A)

Physician Practice: Physician practices are identified as "Providers" under HIPAA, and are defined as medical practices comprised of two or more physicians organized to provide patient care services (regardless of its legal form or ownership).[3]

- Record Count: Total (P)
- Record Count: Annual (A)
- Number of Patient Encounters: Annual (A)
- Number of Physicians (A)

Health Information Exchange (HIE): HIE is a term used to describe both the sharing of health information electronically among two or more entities and also a health information exchange organization that provides services that enable the sharing electronically of health information.[4]

- Record Count: Total (P)
- Record Count: Annual (A)
- Transactions: Annual (A)

3. *https://questions.cms.gov/faq.php?id=5005&faqId=2327*
4. *http://www.hrsa.gov/healthit/toolbox/RuralHealthITtoolbox/Collaboration/whatishie.html*

Service Provider (Information Technology, IT): Service providers (IT) are generally entities that provides IT services, such as Cloud services and hosted IT infrastructure.

- Record Count: Total (P)
- Record Count: Annual (A)
- Total Data Volume (A)

Service Provider (Non- IT): Non-IT service providers are generally defined as business associates that provide non-IT services, such as transcription services and clearinghouses.

- Record Count: Total (P)
- Record Count: Annual (A)
- Volume of Data Exchanged: Annual (A)

A record is defined as each instance where data items (fields) are stored with a unique identifier. Such records include but are NOT limited to the designated record set as defined under HIPAA § 164.501 (or record as it is defined for the designated record set) or a legal health record as it may be defined under state law.

The identifier may be simple (a single value) or complex (combination of values). Examples of simple identifiers are Social Security Number or Medical Record Number. Examples of a complex identifier would be the combination of First Name, Last Name, and Date of Birth, or essentially any combination of the eighteen (18) identifiers stipulated in the HIPAA Privacy Rule at § 164.514(b) (2)(i) that would allow a record to be attributed to an individual. Records do NOT include data items (fields) that are part of a data set that has been de-identified in accordance with HIPAA § 164.514(b) (1). It also does not include data that has been de-identified in accordance with the HITRUST De-Identification Framework as long as the data resides in its approved environment.

In an environment where information is stored in multiple locations, each location constitutes a record. For example, a provider has a lab and imaging department that each have their own information systems (LIS and RIS respectively), which feed data into an EMR system. Each instance of the information as it resides in the LIS, RIS and EMR would constitute a record under this definition.

In addition to volumes of information, geographical locations can drive complexity so it is also considered an organizational risk factor as follows:

- Geographic scope
  - State
  - Multistate
  - Offshore (Outside U.S.)

Regulatory Factors

The CSF also defines a number of regulatory factors based on the compliance requirements applicable to an organization:

- Subject to PCI compliance
- Subject to FISMA Compliance
- Subject to FTC Red Flags Rules compliance
- Subject to HITECH breach notification requirements
- Subject to the State of Massachusetts Data Protection Act
- Subject to the State of Nevada Security of Personal Information Requirements
- Subject to the State of Texas Medical Records Privacy Act
- Subject to Joint Commission Accreditation
- Subject to CMS Minimum Security Requirements (High)

Document Organizational and Regulatory Factors

The organizational, regulatory, and system factors (see *Document System Factors*) are used to determine the level of implementation requirements for a selection of controls within the CSF.

Once the organization has identified the auditable business units within scope, the above information should be gathered for the organization as a whole and for each business unit and documented in MyCSF. Once complete, the relevant level(s) of control will be provided with the associated assessment requirements statements to determine compliance with the CSF.

Define System Scope (Step 3)

This section focuses on scoping the information systems that will be the primary focus of the CSF assessment. Once complete, the assessor will be able to identify areas of higher risk and ensure a comprehensive review. The following are the steps that should be taken in order to identify the information systems within scope of the CSF assessment.

Information Systems Identification

A critical step in the assessment scoping process is to define the systems to be assessed for each business unit. The assessor should refer to an uptodate system inventory listing and work with the business unit coordinator and key security contacts at each business unit to conduct a business unit walkthrough to identify systems for the CSF assessment. It is important to note that supporting systems and applications that store or process covered information are all within the scope of an assessment and must be assessed, including application software components, databases, operating systems, interfaces, tools and servers. For example, the elements of an imaging

system will include the imaging application, the underlying operating system, interfaces with the application, the underlying database, and the physical servers. The key security contacts should help focus and streamline analysis and information gathering tasks by clearly identifying systems and the related system elements upfront in the assessment process.

The controls of the CSF are designed to apply to all information systems irrelevant of classification or function; however, for the purposes of CSF Validation/Certification, only those systems that store, process or transmit PHI or support the storing, processing or transmission of PHI (e.g., host infrastructure) should be included. The system scope of the assessment should cover the following:

- Patient care systems, applications and devices that store and process ePHI (e.g., pharmacy, infection control, cancer registry, MRI, CTI, Ultrasound), whether they are standalone systems or connected to the network
- Business systems and applications that store, process, or transmit ePHI to support billing, customer service and general administrative operations, (e.g., supply chain, state submissions, credentialing)
- Infrastructure components, such as routers and firewalls, that are connected to or facilitate the transmission of ePHI to/from the types of systems described above

System Grouping

When assessing systems, it is appropriate to aggregate information into one observation if it meets all of the following conditions:

- It is under the same direct management control
- It has the same function or mission objective
- It has essentially the same operating characteristics and security needs (confidentiality and criticality)
- It resides in the same general operating environment

The purpose of this aggregation is to logically group systems so that the assessment is performed and information reported in a comprehensive yet manageable manner. It is not necessary to complete the assessment for every element. For example, if an application runs on several different servers, and all of the servers run the same operating system, are located in the same computer room and managed by the same group, the analysis should be performed and findings documented for a representative sample of the servers. Likewise, a business unit with ten routers that are all from the same vendor, identically configured, managed by the same group and physically protected in the same way would only perform analysis and answer requirements statements for a sample of the routers and apply the results to all of the routers.

Medical Devices: Although there is a clear distinction between medical devices and systems, medical devices can be included within the scope of a CSF assessment.

A medical device is equipment that is used for medical purposes in patients or in diagnosis, therapy or surgery. It is machinery designed to aid medical therapies and is usually designed with rigorous safety standards. Examples of medical devices include medical ventilators, heart lung machines, dialysis machines, EKGs, ultrasound, MRI, CAT scans, and x--ray machines. For the purposes of the CSF assessment, an assessment should be completed for types of medical devices that have "on--board" computers (i.e., embedded systems) that typically store, process, or transmit ePHI. Devices may have embedded systems that are used to manage the equipment and for gathering, storing and analyzing results. Many of the computers on these devices have dial--up connections, so that vendors can support the equipment remotely. Some of the computers are also connected to the local area network in a business unit to transmit and share information with other applications or for administrative purposes. It is not necessary to gather and report on each individual device, rather, it is important to group and gather information on types of devices. For example, a business unit with Siemens EKG machines, GTE EKG machines, GTE MRI (of the same model and version respectively) will complete three assessments, one for each type of EKG machine and one for the MRI machine. In instances where a device is sufficiently different in model or version with different inherent functionality or security controls, a separate system assessment must be conducted on each device.

The following are some questions that can be used to help identify devices that should be included in the assessment:

- Is sensitive information entered into the device stored and available at a later date (e.g., patient's name)?
- Is a CPU attached directly to the device?
- Can you store and later save images to removable media (e.g., storing xray images on a thumb drive for a physician)?
- Is there a modem or phone line connected to the device (check the back of the device for a connected telephone line)?
- Is there a network cable connected to the device (check the back of the device for a connected network line)?
- Is there a wireless antenna in/on the device?

Systems that are Centrally Located and Managed: The approach for assessing systems that are located and managed at a centralized data center is based on a business unit's responsibility over that system. A business unit should focus the assessment on those aspects of the system operations that are directly under its control. For example, there are circumstances when a business unit only has responsibility over establishing accounts and access rights within an application but all other aspects of the system operation are managed by the data center (e.g., operating system, backups, physical security). In this case, the business unit will only address questions in the CSF assessment related to application access controls. The data center will address CSF assessment questions related to the other operational areas. Both can be documented in a single assessment for the system.

Vendor Applications: Similar to the systems at a data center, the approach for vendor-managed systems is based on the business unit's control of the system. The different scenarios for vendor-managed systems at a business unit and the related risk assessment scope are summarized in the table below:

#	Scenario	Assessment Scope
1	The system is located off-site from a business unit and managed by the vendor except for access control to the application	Questions related to application access
2	The system is located on-site at the business unit but completely managed by the vendor (e.g., dial-up access for administration) except for access control to the application	Questions related to physical security and application access
3	The system is located on-site and is managed by the IS personnel at the business unit with some support from the vendor	All questions

Document System Factors

The CSF defines a number of System Factors that can increase the inherent risk to the system, necessitating a higher level of control. Each system must be assessed to determine the associated level of control based on the following factors:

- Stores, processes, or transmits sensitive information
- Accessible from the Internet
- Accessible by a third party
- Exchanges data with a third party/business partner
- Publicly accessible
- Use of mobile devices
- Connects with or exchanges data with an HIE
- Number of interfaces to other systems
- Number of users
- Number of transactions per day

The assessor should work with the identified business unit coordinator(s) and other key stakeholders to identify all relevant information systems and document the necessary information in MyCSF. In addition to the abovementioned factors, other information to document includes system owner, platform (e.g., Windows, UNIX), date installed, IP address and ID. This information should be gathered and documented one to two weeks before the fieldwork occurs.

System Boundaries

Network architecture and design is a major factor in determining scope. Every system in an unsegmented or "flat" network will be in scope regardless of whether they store, process or transmit sensitive information. The recommended approach for scope reduction is to segment the network through the use of firewalls or alternate technologies that render one portion of the network unreachable to non-authorized users through the use of access control lists. When using an effective network segmentation approach, only the segment(s) storing, processing or transmitting PHI will be in scope.

Provide Document Request Listing

The document request list is a list of potentially relevant materials, including policies, procedures and standards used to support an organization's processes. The document request list should be distributed to business units in advance of the assessment. This will allow individuals the time to gather the requested documentation and to contribute to a more efficient process while conducting the assessment. For additional information, refer to the illustrative procedures in MyCSF.

Schedule Stakeholder Interviews

After completing the initial scoping process, relevant stakeholders should be identified to assist in completing the assessment process. Interviews will provide the assessor with necessary information regarding any organizational and system controls in place and whether additional documentation, interviews or testing is required. During the interviews, assessors should document existing processes (i.e., processes as actually implemented by the organization) and inquire about artifacts that could be used to test the process to determine if it is fully implemented and functioning as described.

It is important to schedule meetings in advance with the appropriate resources to ensure accurate information is collected and to maintain the timeliness of the assessment. Refer to the illustrative procedures in MyCSF for additional information. Also, when a system is included in the assessment scope, it may be necessary to review the application layer, database layer, operating system layer and the network layer. Interviews should typically be scheduled for 1--2 hours, depending on how much material will be covered.

Assessment Approach

Objective

The assessment approach is the method for assessing the organization's controls via data gathering techniques, including document reviews, interviews and system tests.

- **Examine:** Policies, standards, guidelines, procedures, records and other observable information protection practices to evaluate support of the control specification
- **Interview:** Management, system owners and select organization personnel with relevant job responsibilities to help verify the procedures and controls are followed
- **Test:** System configurations and functions to validate the requirements of the organization's policies and the CSF controls are implemented and functioning appropriately

These tests are to be performed by a self-assessing entity or CSF Assessor in determining what controls are implemented within the organization and for each system. Once the necessary information is gathered, the assessor will document any findings and provide the results of the assessment to HITRUST. (Additional information may be found in the HITRUST CSF Assurance Program Requirements document.)

Similar to the process for assessing scope, the approach should be designed to be flexible and adaptive so a comprehensive assessment can take place within the organization and identified business units with minimal impact on operations.

Implementation Requirement Levels

The CSF follows a risk-based approach by practically applying security resources commensurate with level of risk and applicable regulations or standards. HITRUST addresses risk by defining levels of implementation requirements, which increase in restrictiveness for each security control. Up to three (3) levels of requirements are defined based on relevant organizational and/or system risk factors. Level 1 provides the baseline control requirements as determined by the industry. Each additional level encompasses the level(s) before it and includes additional requirements commensurate with the increase in risk.

MyCSF

MyCSF was designed to assist CSF assessors and healthcare organizations in streamlining the assessment approach and identifying applicable CSF controls and implementation requirements. This fully integrated, optimized, and user-friendly tool marries the content and methodologies of the HITRUST CSF and CSF Assurance program with the technology and capabilities of a Governance Risk and Compliance (GRC) tool. The tool provides CSF assessors and healthcare organizations of all types and sizes with a secure, web-based solution for accessing the CSF, performing assessments, managing remediation activities, and reporting and tracking compliance.

By utilizing the capabilities of a GRC Platform, MyCSF provides CSF assessors and organizations with a sophisticated and user-friendly tool in which to scope and execute an assessment. The tool increases the efficiency with which CSF assessors and organizations can assess against the CSF by utilizing advanced workflows, custom criteria, automated data collection and notifications, and enhanced navigation and search tools. The tool also provides a user-friendly interface with the availability of dashboards and reports and acts as a central repository for managing documents, corrective action plans, test plans, and system scoping.

MyCSF components include:

- **MyCSF Risk Assessment:** This risk-based approach uses organizational, regulatory and system profile information to create a comprehensive and customized set of requirements statements from a standard set of controls. Assessments can be submitted directly to HITRUST for review, scoring and reporting.
  - **CSF Security Assessment:** Measures an organization against a streamlined set of requirements from the controls required for CSF Certification, which are identified and selected based upon risk.
  - **CSF Security & Privacy Assessment:** Measures an organization against a streamlined set of requirements from the controls required for CSF Certification, which are identified and selected based upon risk, plus all privacy controls
  - **CSF Comprehensive Security Assessment:** Measures an organization against a streamlined set of requirements from all 135 controls of the CSF.
  - **CSF Comprehensive Security & Privacy Assessment:** Measures an organization against a streamlined set of requirements from all 135 controls of the CSF plus all privacy controls
- **MyCSF Corrective Action Plan Management:** An add-on module to the MyCSF suite that organizations can use to determine, track and manage areas of non-compliance that were identified via an assessment utilizing the MyCSF tool.
- **Policy Management:** Allows for a single comprehensive resource for policy creation, publication and overall management.
- **MyCSF Incident Management:** Provides organizations with centralized monitoring and recording of incidents as well as automated investigation processes.
- **MyCSF Exception Management:** A comprehensive tool that acts as a central repository for exceptions and provides workflows to manage each exception from request to approval or rejection.

Examine Documentation and Practices (Step 4)

The assessor can evaluate compliance for all controls by examining information retained by the organization. For a listing of example documents that can be examined during the assessment, please refer to the Examine section of the control assessment guidance in the HITRUST CSF and/or the Illustrative Procedures in MyCSF. At a high--level, examine the documents to validate compliance with the associated requirements within the CSF. At a more granular level, examine documents to identify specific practices for more detailed tests and evaluation.

In addition to gathering and reviewing documentation, examination must include checking, inspecting, reviewing, observing, studying or analyzing one or more information security practices to facilitate an understanding, achieve clarification, or obtain evidence, which can be used to support the determination of control effectiveness. Examples include observation of processes and procedures, physical and environmental security (camera placement, locked doors, entry controls, emergency power cut-off switches, etc.), and other observable information security practices.

Conduct Interviews (Step 5)

The previously scheduled meetings with the various stakeholders are conducted to gain an overall understanding of how the organizational and system controls of the CSF are followed. Review the "interview section" of the control assessment guidance in the HITRUST CSF and/or the Illustrative Procedures in MyCSF to identify these stakeholders and what questions should be considered when validating controls.

Before conducting the interviews, the interviewer should take the following steps to understand what questions should be asked during the interview:

- Obtain and review any documentation relevant to the subject area. For instance, if you will be asking about a server's security policies, ensure that you have reviewed the overall policy regarding system security
- Based on the interviewee's role and responsibilities, identify and ask all related questions
- Conduct the interviews and document the results in the form of meeting minutes or other suitable tool, e.g., a security test plan

Perform/Review Technical Testing (Step 6)

Technical testing helps reveal security flaws or weaknesses in information systems and includes but is not limited to configuration setting validation, vulnerability assessment, and penetration testing.

Validation of configuration settings for select system controls provides evidence regarding the implemented security policies and procedures. Configuration settings for high risk applications may include the following:

- Audit settings
- Patch levels
- Password settings
- Account lockout
- Anti-virus data file (DAT) levels
- User listings

Validation of configuration settings helps an assessor determine if policy requirements have been met, especially with controls related to configuration, change and exception management.

Vulnerability assessments help identify, quantify, and prioritize weaknesses in an information system that may be exploitable by one or more threats. Assessors may conduct vulnerability assessments on information systems or review the results of recent vulnerability assessments to help evaluate CSF controls related to, for example, patching and exception management processes. Penetration tests can be used to help an assessor validate vulnerabilities identified during a vulnerability assessment as well as help identify additional vulnerabilities within the organization's environment.

Complete the following high-level steps when performing technical testing:

- Obtain the necessary tools, approvals and permissions to perform the system tests
- Conduct the tests and document the results in the form of formal notes or directly into a security test plan or work plan

Assessors should review any internal or external (third party) vulnerability or penetration test documentation that is within the scope of the assessment, especially if the assessor does not conduct its own.

Sampling

For both CSF Validated and CSF Certified assessments, the CSF Assessor may choose to use a sampling approach when selecting system components to determine the existence of controls. The sample must meet both of the following criteria:

- The sample should be representative of every component of the in-scope systems, applications, databases, networking devices and connected support systems included in the sample population (group)
- The sample should be large enough to allow the CSF Assessor to draw conclusions about the application of controls across the full sample population

Although not intended to be an authoritative source on sampling, what follows is general guidance that assessors should consider when sampling. Where a CSF Assessor organization has its own internal guidance on sample sizes, they may follow that guidance in lieu of what is described here; however, HITRUST would expect it to be similar to the methods described in this document.

As discussed earlier, items such as systems or auditable business units that are subject to the same controls can be grouped and tested as one sample population, which can be more efficient than testing all items in the population. This is often the case where IT general controls are being tested and common IT processes like change management or password administration support multiple systems.

Sample Size

Once the population to be tested has been identified, the first step is to calculate an appropriate sample size. The table below is based upon the assumption that the controls are operating effectively and the assessor does not expect any exceptions.

Nature of Control and Frequency of Performance	Minimum Number of Items to Test
Manual control, performed daily or many times a day, population > 250	25
Manual control, performed weekly	5
Manual control, performed monthly	2
Manual control, performed quarterly	2
IT General Controls (ITGCs)	Same as guidance for manual controls above
Application Control	Can perform a test of one (i.e., test the application control once) where ITGCs are tested and determined to be effective; else test the application control 25 times
50-250 items in population	10%
< 50 and not weekly, monthly or quarterly	Use judgment, but consider selecting five (5) items or test entire population

Selecting a Sample

When selecting the sample, the CSF Assessor should follow procedures that ensure the sample is free of any bias or preference. The principal methods for selecting a sample are:

- **Random Selection:** Selection using a structured technique like a random number generator
- **Systematic:** Selecting every nth item
- **Haphazard:** No structured selection technique

In general, random selection is the most unbiased method to use when testing IT controls, although in many instances systematic or haphazard selection might be more appropriate. When using a haphazard approach, it is best to select a purposive sample of a typical instance or other method that provides a sample result that is objective and defensible.

For example, assume the CSF Assessor is reviewing access privileges granted to users. The CSF Assessor obtains a list of all user IDs, noting that there are 1,500 IDs. By using a random number generator, the CSF Assessor gets 25 numbers between 1 and 1,500. The CSF Assessor would then select those corresponding user IDs from the list of all IDs and review the users for appropriateness of access based upon their job descriptions and responsibilities.

If using systematic selection, the CSF Assessor might divide the population by 25, resulting in 25 groups of 60 items (1,500 / 25 = 60). To establish a starting point the CSF Assessor needs to randomly select a number between 1 and 60. If we assume that the number chosen was 39, the 39th user in the list of 1,500 users would be selected as the first item in the sample. The next item would be the 99th user (39 + 60). The next item would be the 159th user, etc.

An example of where haphazard selection might be an appropriate method is selecting a sample of completed user access request forms to determine if appropriate approvals were obtained before granting access. The population consists of hardcopy documents that have been centrally stored, the size of the population is not known, and there is no numbering system on the forms themselves. In such a situation the CSF Assessor might pull 25 documents at random (haphazardly) from the file.

Control Exceptions or Deviations

Dealing with control exceptions or deviations is a matter of judgment. The first step when encountering an exception should be determining what caused the exception. For example, if the CSF Assessor determines that the item causing the exception does not possess the characteristics of the population being tested and should not have been included in the population, selecting a replacement item may be an acceptable approach.

If there is an exception, the CSF Assessor must determine the reason for the exception and determine if it is likely to occur again. If it appears to be an isolated occurrence, the CSF Assessor would document the reason for such a conclusion and can consider selecting and testing additional items (e.g., 15 additional items). Assuming that no further exceptions are encountered, there may be a basis for concluding the control is operating effectively.

An unexpected high rate of exceptions might suggest the control is not operating effectively. The CSF Assessor may then conclude that exceptions similar to the failed item(s) exist in the population and therefore additional testing is not warranted. When such situations exist, identifying alternate controls (see *Alternate Control Identification and Selection*) may be an option. If alternate controls exist, they can be selected from the CSF where included or submitted to HITRUST's Alternate Controls Committee for approval.

Document findings

Once controls are assessed through interviews, examination of documentation and testing, the Assessor is in a position to document findings based on the results of these activities, which will ultimately be submitted to HITRUST.

Alternate Control Identification and Selection (Step 7)

Overview

The CSF is designed to establish appropriate levels of safeguards related to the protection of health information based on regulatory requirements and risks. It does not take into account environment or situation--specific limitations or circumstances. Given existing infrastructure, technologies and business environments, meeting the CSF requirements may not always be possible or practical. HITRUST defines a process that allows for alternate controls

to provide a means for organizations to meet the requirements of the CSF as they continually improve their security and compliance stance. This process is overseen by the Alternate Controls Committee (ACC) that serves to review, document, approve, and maintain acceptable alternate controls.

Identifying and Selecting Alternate Controls

Once the initial assessment is completed, the assessor can return to any non-compliant areas to determine if any alternate controls are identified and documented within the CSF by HITRUST. If so, the assessor should use the information gathered to determine if the organization or system meets the requirements of the alternate control. If an approved alternate control is implemented with no findings, the gap will be closed.

Alternate Control Requests

The alternate control request process has been established as a mechanism to allow organizations to address control deficiencies with respect to either organizational or system requirements of the CSF by proposing alternate controls to mitigate the risk.

If no existing approved alternate control exists, or if the existing one(s) are not appropriate for the organization, the control deficiency should be documented and an alternate control proposed through an alternate control request. Alternate control requests should be submitted to *ACC@HITRUSTalliance.net*, at which point it is assigned a number and tracked by the ACC throughout the review and decision-making process as outlined in the *Risk Analysis Guide for HITRUST Organizations and Assessors*. Once a request is approved or disapproved, the ACC chairperson will notify the submitter and provide the results of the review to HITRUST management. Approved controls will be used in place of the original required controls when the organization submitting the alternate control request undergoes a validated assessment. Approved alternate controls are also available for general use without the need for further consideration by or action from the ACC.

Reporting and Remediation

Reporting (Step 8)

Develop Remediation Guidance

Following the CSF assessment, the organization should develop recommendations to properly treat and manage the identified areas of non-compliance with the CSF. A remediation task should include the suggested steps that the organization should implement to mitigate the risk of an identified gap. A remediation task may consist of process improvements or implementation of technical solutions. The suggested remediation tasks should be formally documented and tailored to the organization's environment.

Submit Information to HITRUST

Using MyCSF, the organization or CSF Assessor—depending on the type of assessment performed: self or validated—should submit the completed baseline questionnaire, along with description of scope, overview of the organization's security program, testing performed, and corrective action plans to HITRUST. HITRUST will generate a CSF Self Assessment, CSF Validated or CSF Validated with Certification report outlining strengths (CSF Validated and Certified only) and potential exposures (all assessments) within the organization's information security program. The report will include a score for each domain in the MyCSF questionnaire. Additional information on the CSF Assurance Program and HITRUST Validated or Validated with Certification reports can be found in the *HITRUST CSF Assurance Program Requirements* document.

Socializing the Report

The CSF assessment of the organization and systems should conclude with the delivery of a report by the CSF assessor project coordinator to executive management. If the organization chose to have HITRUST generate the CSF Validated or CSF Validated with Certification report, the project coordinator can use this document. If the organization chose to generate its own report prior to pursuing further reporting from HITRUST, the report document should include the following sections:

- The organization's and business units' level of compliance against the CSF requirements
- The systems' level of compliance against the CSF requirements
- Recommendations to remediate controls, if any

The report should be socialized with all relevant stakeholders as determined by the project coordinator. A presentation should be made to management and key stakeholders (e.g., business unit coordinators, department directors, system owners) to highlight the assessment and provide an opportunity to discuss the results of the assessment and next steps, if any.

Management's Response

After socialization, management should agree on the specific actions to be taken based on the findings and any recommended remediation guidance. In some cases, an alternate control may be implemented or awaiting approval by HITRUST, or the cost to remediate an issue may greatly exceed the potential risk. Thus, it is possible that no action may be taken based on the recommendation. Ultimately, it is the responsibility of management, not the Assessor, to approve and implement the appropriate controls.

Sharing the Report

If the organization procured a HITRUST Self Assessment, CSF Validated or CSF Validated with Certification report, the report may be shared with the organization's third parties in accordance with a signed participation agreement.

Remediation (Step 9)

A detailed CAP addressing each identified deficiency or gap should be tracked following the assessment. At a high level, the CAP should reflect management's decisions and contain the following:

- Control Gap Identifier
- Control Gap
- HITRUST CSF Control Mapping
- Point of Contact
- Scheduled Completion Date
- Corrective Actions
- How Identified (e.g., Assessment, CSF Assessor)
- Date Identified
- Status of Corrective Action

The individual(s) responsible for the corrective actions should periodically report back to management to provide status updates, notifications of modifications to the agreed-upon timelines and any other factors that may affect the organization's compliance.

By clearly outlining the remediation effort in a detailed work plan, the organization will have a firm understanding of the scope, timing, roles, and responsibilities of the effort.

Risk Acceptance

Consistent with NIST SP 800-30 r1, HITRUST allows organizations to accept rather than mitigate control gaps when the control has an average score of three (3) or better, as—given the correlation between maturity and risk—the risk associated with such a control may be considered relatively low. When an organization chooses to accept risk, the analysis submitted in MyCSF to support the selection must show the residual risk for all the requirement statements supporting the control evaluation is less than 20 using the following risk formula:

$$R = L \times I = [(100 - MS) / 100] \times [(IR - 1) \times 25]$$

where, R = risk, L = likelihood, I = impact, MS = HITRUST CSF control maturity score, and IR = impact rating.

For a list of impact ratings for the CSF controls and more information on how risk can be accepted, refer to Appendix A of the *Risk Analysis Guide for HITRUST Organizations and Assessors*, available in the downloads section of the HITRUST website.

HITRUST

Health Information Trust Alliance

855.HITRUST
(855.448.7878)
www.HITRUSTalliance.net