

OCR-Quality Security Risk Analysis™ By-the-Book

Steve Cagle, CEO, Clearwater

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Our Expertise & Experience

- Completely focused on healthcare cyber risk management and HIPAA compliance
- Makers of IRM | Analysis™, the leading enterprise cyber risk management software for healthcare
- **Consulting engagements in 400+ healthcare organizations**
- Successful outcomes in dozens of OCR-enforcement cases
- 100% OCR-acceptance rate of risk analysis executed with our solutions

Learning Objectives



Clarify what is and what is NOT a HIPAA Risk Analysis



Review OCR requirements for Risk Analysis



Learn how to implement nine steps of OCR's guidance on Risk Analysis using specific examples



89%

of ePHI related OCR Enforcement Actions cited <u>Risk Analysis Failure</u>



\$103.9M

\$28.7M

\$19.3M

PAID TO DATE

PAID IN 2018

PAID IN 2017

- WRONG REPORT: submission of a Non-Technical Evaluation or Technical Evaluation or something else
- 2. NOT ASSET-BASED: too many organizations treating as a checklist matter rather than a loss/harm matter
- 3. NOT COMPREHENSIVE ENOUGH: must include every asset in every LOB in every facility in every location
- 4. NOT DETAILED ENOUGH: does not have asset-threat-vulnerability scenarios
- 5. NOT FOLLOWING OCR/NIST GUIDANCE: 9 essential elements in OCR guidance
- 6. NOT ENOUGH DOCUMENTATION: little evidence of an adequate program

THERE HAVE BEEN

64

OFFICE FOR CIVIL RIGHTS

ENFORCEMENT ACTIONS

WITH MONEY PENALTIES

2016 Phase 2 Audit Results



CE Audits (166)

- Privacy and Bread
- Security (63)

BA Audits (41)

Breach and Secur

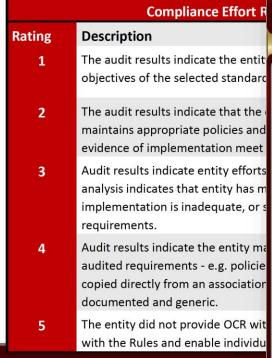
• 57%, 4s and 5s

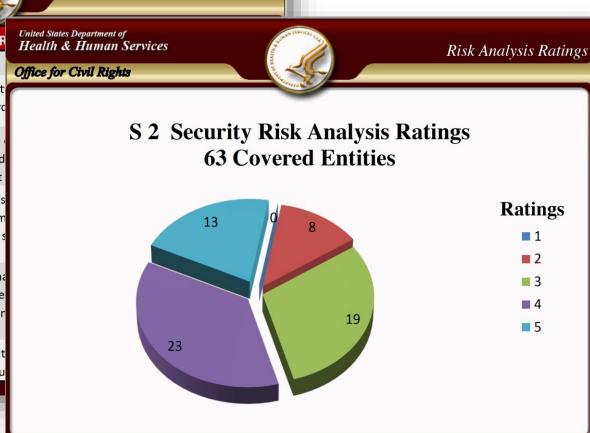
• 86%, 3s, 4s and 5s

United States Department of
Health & Human Services

Effort Ratings

Office for Civil Rights





1 = Meets

2 = Substantially Meets

5 = No Serious Effort to Comply

3 = Minimally Meets

4 = Negligible Efforts

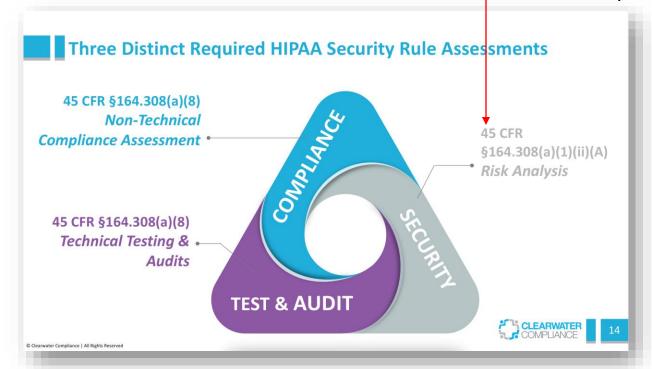
Security Evaluation v. Risk Analysis

45 C.F.R. §164.308(a)(8)

<u>Standard: Evaluation.</u> Perform a periodic technical and non-technical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, which establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.

45 C.F.R. §164.308(a)(1)(i) Standard: Security Management Process (1)(i) Standard: Security management process. Implement policies and procedures to prevent, detect, contain, and correct security violations.

- (ii) Implementation specifications:
 - (A) Risk analysis (Required). Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.





Lots of Good Assessments, Only One Bona Fide Risk Analysis!

Today's

Focus

- External Security Assessment
- Architecture Assessment
- Internal Security Assessment
- Security Rule Compliance Assessment
- Wireless LAN Security Validation
- Information Security Program Assessment
- Meaningful Use EHR Temical Controls Assessment
- Social Engineering 3sessment
- OWASP Web pplication Assessments
- NIST Carrent Profile Assessment
- oint Tactical HIPAA and Cyber Risk Management Assessment
- Strategic Enterprise IRM Program Maturity Assessment

Bona Fide, Comprehensive Risk Analysis Required at 45 CFR

§164.308(a)(1)(ii)(A) MEANS OCR Guidance and NIST SP800-30!

Guidance on Risk Analysis Requirements under the HIPAA Security Rule

Introduction

The Office for Civil Rights (OCR) is re provisions in the HIPAA Security Rule guidances will assist organizations2 in and appropriate administrative, physica protected health information (e-PHI). nput from stakeholders and the public

We begin the series with the risk analy Conducting a risk analysis is the first s that comply with and carry out the stan Security Rule. Therefore, a risk analys detail before OCR can issue meaningfo and technologies that will best protect

The guidance is not intended to provid the risk analysis requirement. Rather, i organizations working to meet these re most appropriate way to achieve comp the organization and its environment.

We note that some of the content conta of the National Institute of Standards a publishes freely available material in th only federal agencies are required to fo represent the industry standard for goo securing e-PHI. Therefore, non-federal when developing and performing com-

All e-PHI created, received, maintaine Security Rule. The Security Rule requi their environments and to implement re

Section 13401(c) of the Health Information 1 As used in this guidance the term "organizat guidance will be updated following implement The HIPAA Security Rule: Health Insurance ⁴ The 800 Series of Special Publications (SP) a specifically, SP 800-30 - Risk Management Gu (http://www.hhs.gov/ocz/privacy/hipaa/admini

NIST Special Publication 800-30

National Institute of Standards and Technology U.S. Department of Commerce Guide for Conducting Risk Assessments

JOINT TASK FORCE TRANSFORMATION INITIATIVE

INFORMATION SECURITY

Computer Security Division National Institute of Standards and Technology



Rebecca M. Blank, Acting Secretary

National Institute of Standards and Technolog



OCR-Quality Risk Analysis – Risk Management Review

The Ten Risk Analysis Key Essential Criteria Are Derived From:

- 1. the HIPAA Risk Analysis implementation specification language at 45 CFR §164.308(a)(1)(ii)(A) of the HIPAA Security Rule;
- 2. the methodology outlined in the HHS/OCR <u>"Guidance on Risk Analysis Requirements under the HIPAA Security Rule"</u>;
- 3. the underlying NIST Special Publications for performing a risk assessment and, specifically NIST SP 800-30 "Guide for Conducting Risk Assessments";
- 4. the documentation found in OCR investigation letters and "OCR Resolution Agreements / Corrective Action Plans".
- 5. the <u>"OCR Audit Protocol Updated April 2016"</u> specific to Risk Analysis and Risk Management .
- 6. our work with numerous organizations subjected to OCR enforcement actions that included reviews of organizations' risk analyses.



Rx: Your Review Plan - OCR Risk Analysis Guidance

Regardless of the risk analysis methodology employed...

- 1. Scope of the Analysis
- 2. Data Collection
- 3. Identify and Document Potential Threats and Vulnerabilities
- 4. Assess Current Security Measures
- 5. Determine the Likelihood of Threat Occurrence
- 6. Determine the Potential Impact of Threat Occurrence
- 7. Determine the Level of Risk
- 8. Finalize Documentation
- 9. Periodic Review and Updates to the Risk Assessment
- 10. Meet Emerging OCR Standard of Care (added by Clearwater)

Guidance on Risk Analysis Requirements under the HIPAA Security Rule

Introduction

The Office for Civil Rights (OCR) is responsible for issuing annual guidance on the provisions in the HIPAA Security Rule. (45 C.F.R. §§ 164.302 – 318.) This series of guidances will assist organizations in identifying and implementing the most effective and appropriate administrative, physical, and technical safeguards to secure electronic protected health information (e-PHI). The guidance materials will be developed with input from stakeholders and the public, and will be updated as appropriate

We begin the series with the risk analysis requirement in § 164.308(a)(1)(ii)(A). Conducting a risk analysis is the first step in identifying and implementing safeguards that comply with and carry out the standards and implementation specifications in the Security Rule. Therefore, a risk analysis is foundational, and must be understood in detail before CCR can issue meaningful guidance that specifically addresses safeguards and technologies that will best protect electronic health information.

The guidance is not intended to provide a one-size-fits-all blueprint for compliance with the risk analysis requirement. Rather, it clarifies the expectations of the Department for organizations working to meet these requirements. An organization should determine the most appropriate way to achieve compliance, taking into account the characteristics of the organization and its environment.

We note that some of the content contained in this guidance is based on recommendations of the National Institute of Standards and Technology (NIST), NIST, a federal agency, publishes freely available material in the public domain, including guidelines. Although only federal agencies are required to follow guidelines set by NIST, the guidelines represent the industry standard for good business practices with respect to standards for securing e-PHI. Therefore, non-federal organizations may find their content valuable when developing and performing compliance activities.

All e-PHI created, received, maintained or transmitted by an organization is subject to the Security Rule. The Security Rule requires entities to evaluate risks and vulnerabilities in their environments and to implement reasonable and appropriate security measures to

Posted July 14, 2010

Page 1



Section 13401(c) of the Health Information Technology for Economic and Clinical (HITECH) Act.
As used in this guidance the sum "expanizations" refers to covered antifics and business associates. The guidance will be updated following implementation of the final HITECH regulation.
The HIPAA Socurity Naile: Health Insurance Reform: Security Standards, February 20, 2003, 68 FR 8334.
The 500 States of Special Publications (SP) are available on the Office for Civil Rights' website—upscriftcally, SP 800-30. Risk Management Guide for Information Technology Systems.
(http://www.hisa.gov/circip/ricy/phas/hadministria/vie/curity/pulgate-security/lingal/dance-him1)

ÇCLEARWATER

Review Point 1-A: Scope of the Analysis

Asset Inventory List

Assets > Asset

To add an Asset click the New button. To edit select a row and click the Edit Button



19 assets used out of unlimited ass

+ New	<i>≱</i> Edit					Search:	
ld Jî	Asset name 1	Asset description 11	# records 🎵	Owner	11 Inherited from	Created 11	Modified 11
7355	Automated Medication Cabinet	An automated dispensing cabinet (ADC) is a computerized drug storage device or cabinet designed for hospitals.	150,000	Jon Stone		2014-08-14 10:38	2017-01-10 08:53
95	Billing Information Systems	Used for Medical Billing	16,000	Jon Stone		2011-12-27 22:08	2016-09-08 09:06
21796	CCTV - System One	Closed Circuit Television System	10,000	Brad Park		2015-06-11 09:33	2015-11-09 09:14
57	Claim Payment System	Used to adjudicate claims. Hosted in our own data center.	100,000	Claims Director		2011-12-27 22:08	2016-09-08 09:07
2626	Core HIS	Hospital information system, an enterprise resource planning system that caters to hospital needs	10,000	Jon Stone		2013-08-07 10:30	2016-09-08 09:07
2729	CT Scan	Computed axial tomography (CAT scan) or computer assisted tomography is a medical	12,000	Sam Mark		2013-08-30 12:04	2017-01-10 08:53
	Show that	at you've inclu	ded A	ALL Ir	nformation	Syste	ms

and their components with ePHI!

53267 Docume

09:59

Does It Include all ePHI Systems & Devices?

Enterprise Risk Analysis Extends Well Beyond Your EHR System



















Review Point 1-B: Scope of the Analysis



Show You Have Completed the Risk Analysis Across Your Enterprise

Ambulatory Surgical Center

7

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How "Enterprise" is Your Risk Analysis?













Hospitals

LTC Facility

ASC

CHC













Imaging Center







Rural Clinic

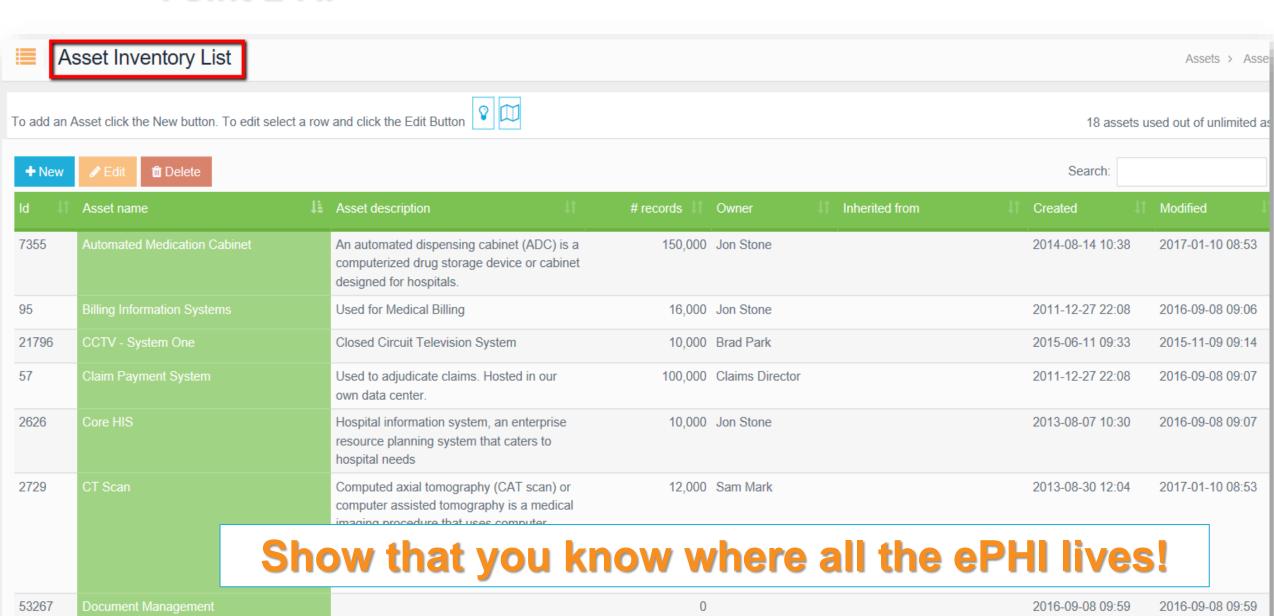
Dialysis Clinic

Behavioral

Labs

Review Point 2-A: Data Collection

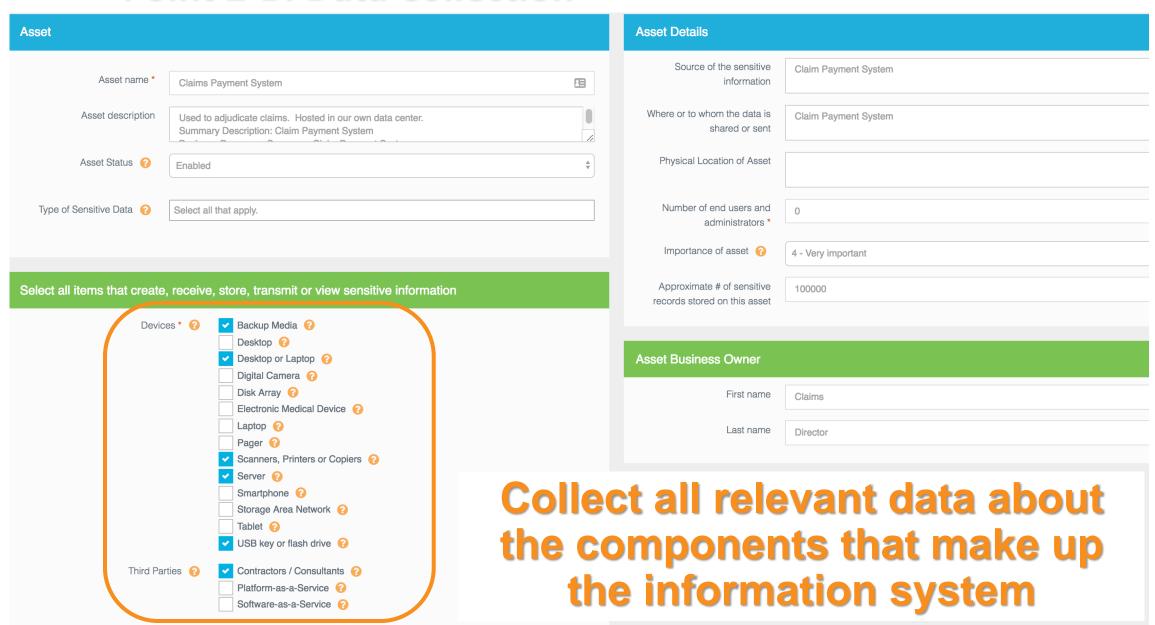




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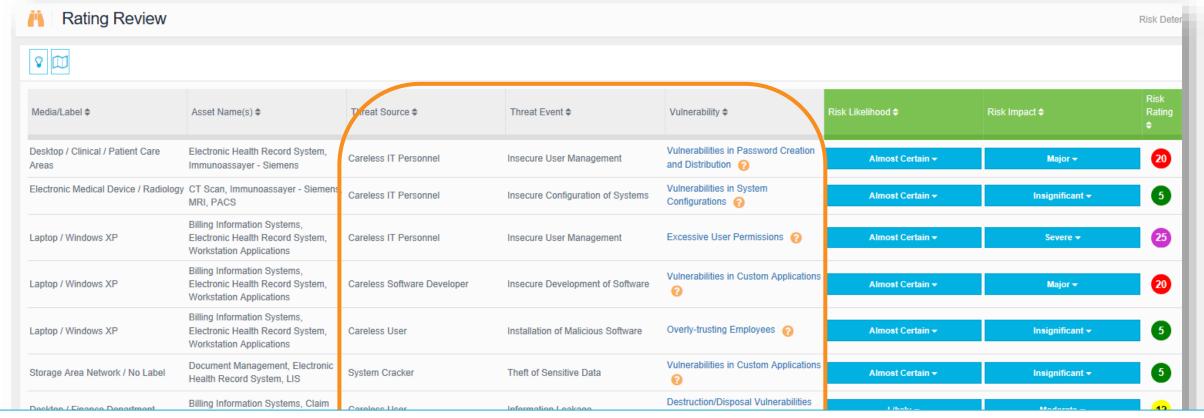


Review Point 2-B: Data Collection





Review Point 3: Identify and Document Threats & Vulnerabilities

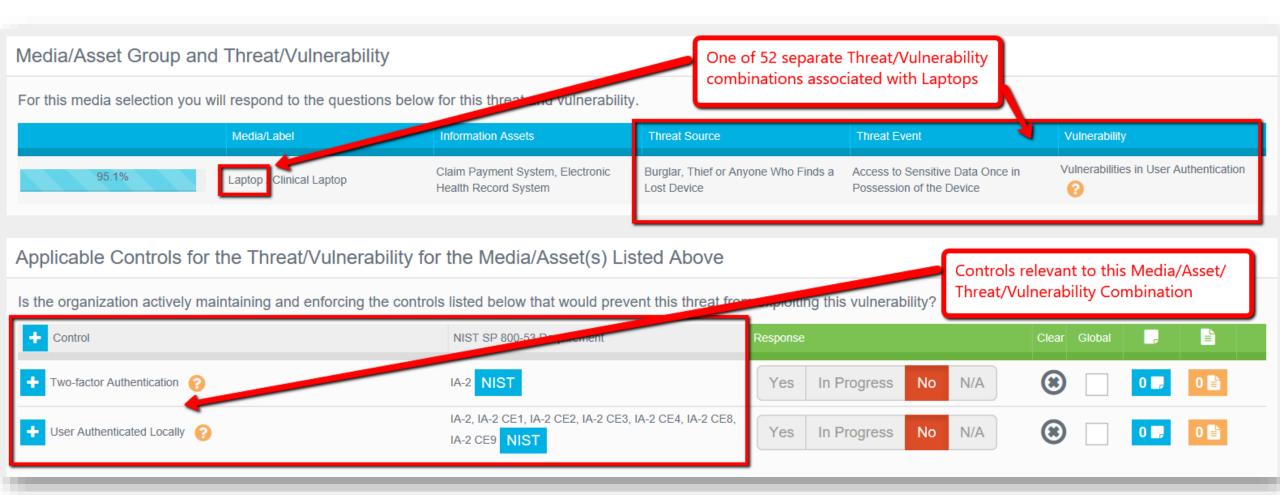


Identify all reasonably anticipated threats & vulnerabilities for each of the components that are associated with your information systems.

	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Careless Software Developer	Insecure Development of Software	Insecure Software Development Processes	Likely ▼	Major ▼	16	
	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Fire	Fire Damage to Equipment	Insufficient Fire Protection ?	Likely ▼	Severe ▼	20	
	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Careless User	Installation of Malicious Software	Overly-trusting Employees (2)	Likely ▼	Major ▼	16	
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Review Point 4-A: Assess Relevant Security Controls In Place



What controls are in place – at the Specific Asset-Threat-Vulnerability Level

Review Point 5: Determine Likelihood

Risk Likelihood

The likelihood of occurrence of a threat event initiated or caused by a threat source, combines an estimate of the likelihood of initiation or occurrence of the threat event, with an estimate of the likelihood of impact (i.e., the likelihood that the threat event results in adverse impacts). For adversarial threats, an assessment of likelihood of initiation is typically based on: (i) adversary

intent; (ii) adversary capability; and (iii) adversary target advanced persistent threat (APT). For other than adve occurrence can be estimated using historical evidence, end the likelihood that a threat event will be initiated or will occurrence (e.g., the next six months, the next year, or threached). If a threat event is almost certain to be initiated of frame, the assessment of risk may take into consideration. The likelihood of threat occurrence can also be based mission/business processes, enterprise and information systems and environments of operation (taking into consideration of deployed safeguards and countermeasures (i.e., unauthorized or undesirable behavior, detect and limit mission/business capabilities).

From NIST SP800-30, Chapter 2, Page 9

How likely is it for the threat to exploit the vulnerability?

Risk Likelihood

Rank	Description	Percent Likelihood	Example
0	Not Applicable	0% likely in the next 12 months'	Will never happen
1	Rare	5% likely in the next 12 months'	May happen once every 20 years
2	Unlikely	25% likely in the next 12 months'	May happen once every 10 years
3	Moderate	50% likely in the next 12 months'	May happen once every 5 years
4	Likely	75% likely in the next 12 months'	May happen once every year
5	Almost Certain	100% likely in the next 12 months'	May happen multiple times per year

Review Point 6: Determine Impact

Risk Impact

The level of impact from a threat event is the magnitude of harm that can be expected to result

from the unauthorized disclosure, modification, disruption, destruction, or loss of information and/or

denial of service. Such adverse impact, and hence harm, can be organizational and non-organizational stakeholders including, for emission and business owners, information owners/stewards, mission information system owners, or individuals/groups in the public or proganization—in essence, anyone with a vested interest in the organization of individuals, including other organizations in partnership with the organization infrastructure-related considerations).

From NIST SP800-30, Chapter 2, Page 9

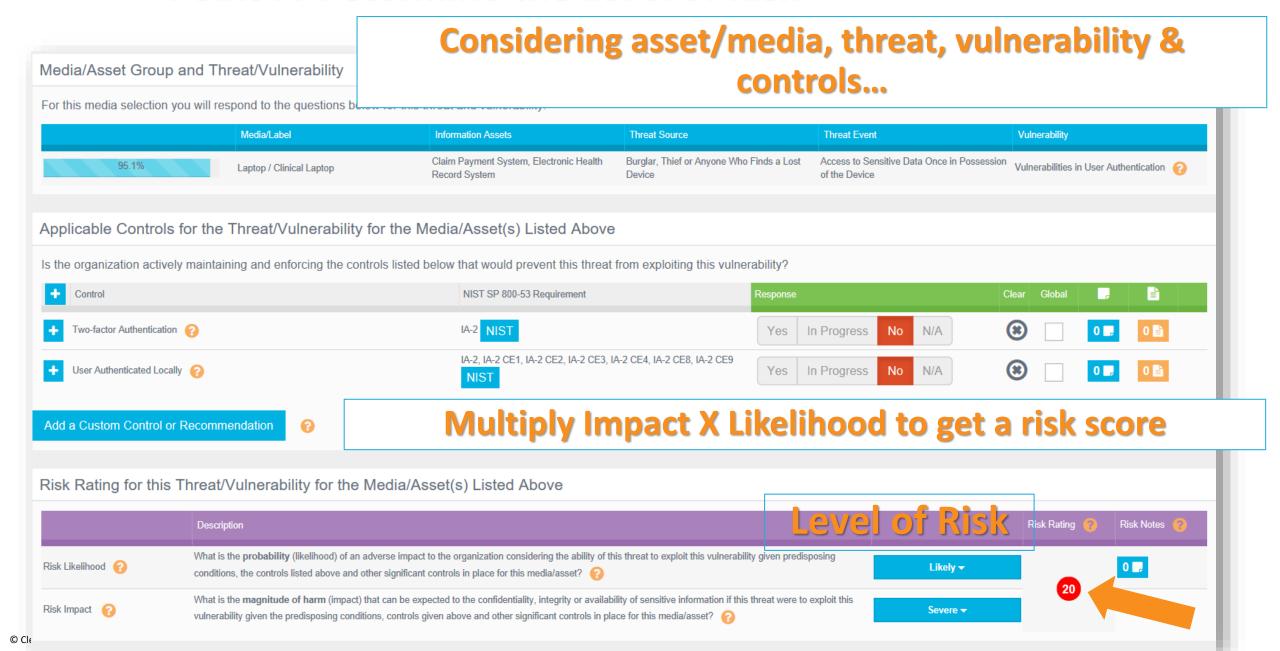
Risk Impact ×					
Rank	Description	Example	# of Records	Productivity Lost	Financial Impact
0	Not applicable threat	No impact	0	0	0
1	Insignificant	No interruption, no exposed data	0	0	0
2	Minor	Multi-minute interruption, no exposed data	0	2	20,000
3	Moderate	Multi-hour interruption, minor exposure of data	499	4	175,000
4	Major	One day interruption, exposure of data	5,000	8	2,000,000
5	Severe	Multi-day interruption, major exposure of sensitive data	50,000	24	20,000,000

What harm or loss would occur?





Review Point 7: Determine the Level of Risk

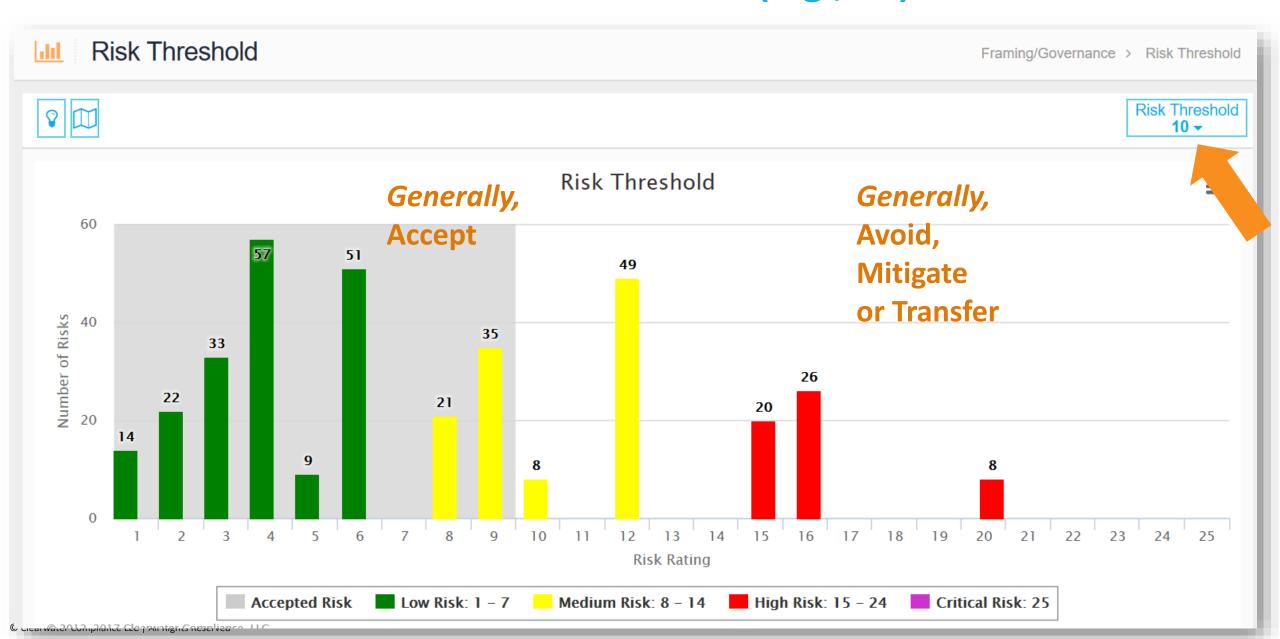


Review Point 7: Determine the Level of Risk at Granular Level

Asset	Threat Source / Action	Vulnerability	Likelihood	Impact	Risk Rating
Laptop	Burglar steals laptop	No encryption	High (5)	High (5)	25
Laptop	Burglar steals laptop	Weak passwords	High (5)	High (5)	25
Laptop	Burglar steals laptop	No tracking	High (5)	High (5)	25
Laptop	Careless User Drops	No data backup	Medium (3)	High (5)	15
Laptop	Shoulder Surfer views	No privacy screen	Low (1)	Medium (3)	3
Laptop	Lightning Strike	No surge protection	Low (1)	High (5)	5
Etc.					



Review Point 7: Establish Risk Threshold (e.g., 10)



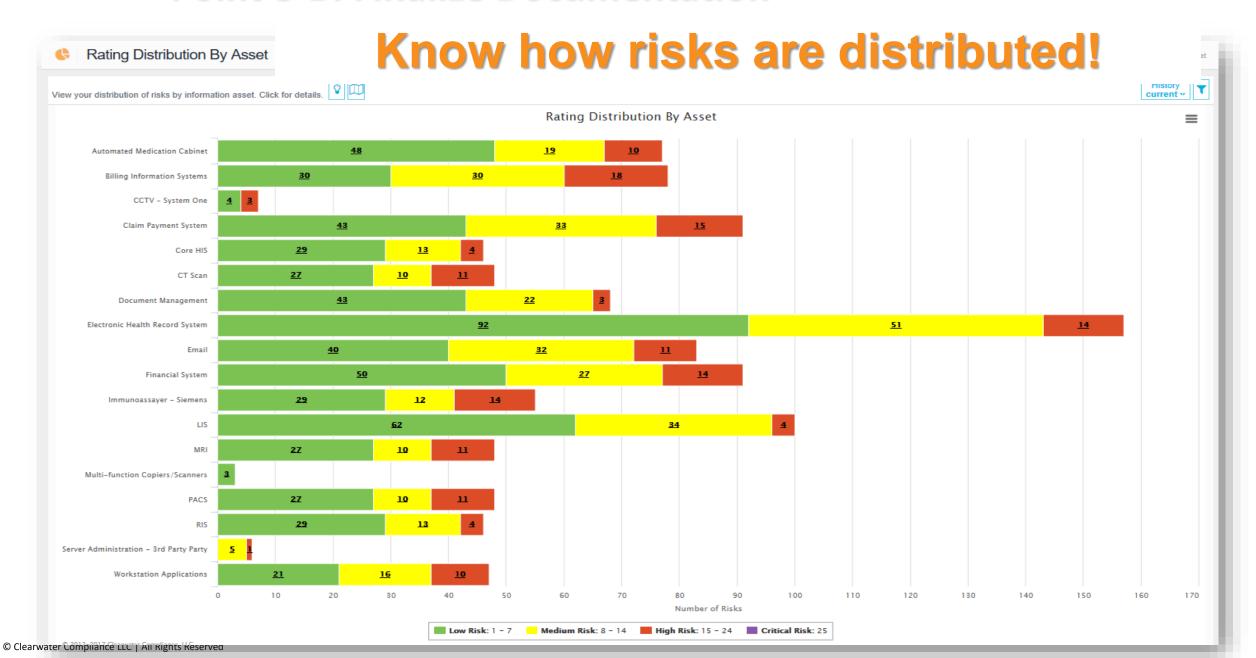


Review Point 8-A: Finalize Documentation

	Rating Review	Nov	w you	Have a	Risk R	egister		Risk De
	Media/Label 	Asset Name(s)	Threat Source	Threat Event ‡	Vulnerability ‡	Risk Likelihood ‡	Risk Impact ¢	Risk Rating
	Desktop / Clinical / Patient Care Areas	Electronic Health Record System, Immunoassayer - Siemens	Careless IT Personnel	Insecure User Management	Vulnerabilities in Password Creation and Distribution	Almost Certain ▼	Severe ▼	25
General	Zaptop / Windows XP	Billing Information Systems, Financial System, Workstation Applications	Burglar/Thief	Theft of Equipment	Physical Security Vulnerabilities ?	Likely ▼	Severe ▼	20
Avoid,	Laptop / Clinical Laptop	Claim Payment System, Electronic Health Record System	Burglar/Thief	Theft of Equipment	Physical Security Vulnerabilities ?	Likely ▼	Severe ▼	20
Mitigate Transfer	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Inclement Weather	Unavailability of Key Personnel	Lack of Key Person Redundancy / Cross-training	Likely ▼	Major ▼	16
Hallstel	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Power Outage/Interruption	Loss of Electrical Power	Insufficient Power Capacity ?	Likely ▼	Major ▼	16
	USB key or flash drive / Company Provided	Billing Information Systems	Burglar/Thief	Theft of Equipment	Physical Security Vulnerabilities ?	Moderate ▼	Severe ▼	15
	Desktop / Clinical / Patient Care Areas	Electronic Health Record System, Immunoassayer - Siemens	Burglar/Thief	Theft of Equipment	Physical Security Vulnerabilities ?	Moderate →	Major →	12
	Laptop / Windows XP	Billing Information Systems, Financial System, Workstation Applications	Careless IT Personnel	Insecure User Management	Vulnerabilities in Password Creation and Distribution	Unlikely ▼	Severe ▼	10
	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Careless IT Personnel	Insecure User Management	Excessive User Permissions ?	Moderate ▼	Moderate ▼	9
General	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Careless IT Personnel	Insecure User Management	Vulnerabilities in Password Creation and Distribution	Moderate ▼	Moderate ▼	9
Accept	Desktop / Administration	Workstation Applications	Burglar/Thief	Theft of Equipment	Physical Security Vulnerabilities ?	Moderate →	Moderate ↓	9
	Laptop / Clinical Laptop	Claim Payment System, Electronic Health Record System	Careless IT Personnel	Insecure User Management	Vulnerabilities in Password Creation and Distribution	Unlikely ▼	Major ▼	8
	Desktop / Finance Department	Billing Information Systems, Claim Payment System, Email	Burglar/Thief	Theft of Equipment	Physical Security Vulnerabilities ?	Unlikely ▼	Moderate ▼	6
© Clearwater Compliance	Desktop / Clinical / Patient Care Areas	Electronic Health Record System, Immunoassayer - Siemens	Careless IT Personnel	Insecure User Management	Excessive User Permissions ?	Unlikely ▼	Moderate ▼	6

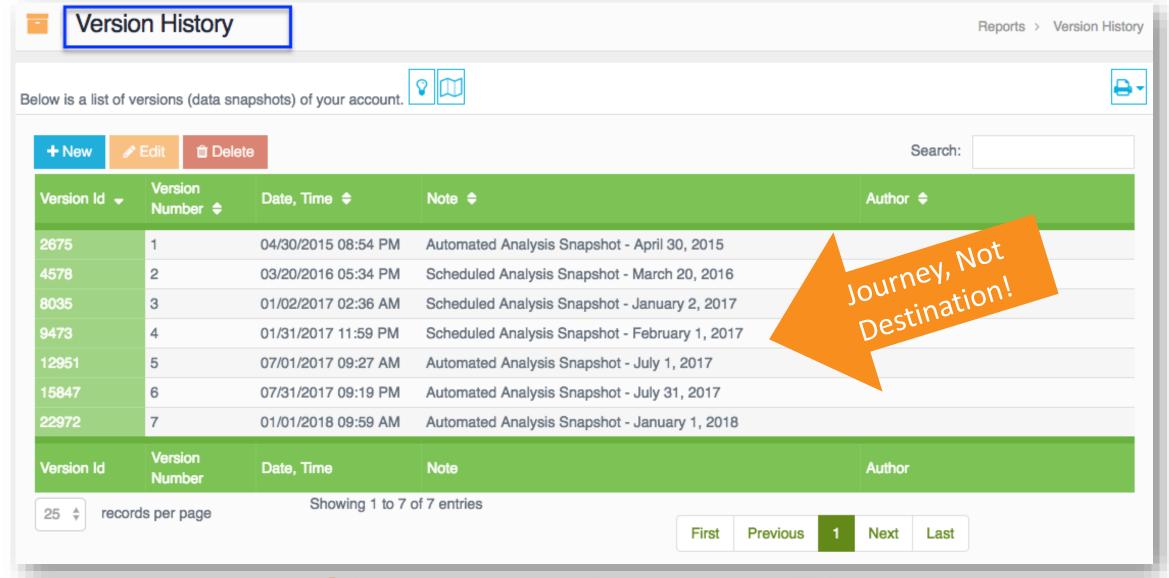
Review Point 8-B: Finalize Documentation







Review Point 9: Periodic Review and Updates



The Risk Analysis Dilemma

Assets and Media

Backup Media

Desktop

Disk Array

Electronic Medical Device

Laptop

Pager

Server

Smartphone

Storage Area Network

Tablet

Third-party service provider

Etcetera...

Threat Agent

Burglar/ Thief

Electrical Incident

Entropy

Fire

Flood

Inclement weather

Malware

Network Connectivity Outage

Power Outage/Interruption Etcetera...

Threat Actions

Burglary/Theft

Corruption or destruction of important data

Data Leakage

Data Loss

Denial of Service

Destruction of important data

Electrical damage to equipment

Fire damage to equipment

Information leakage

Etcetera...

Vulnerabilities

Anti-malware Vulnerabilities

Destruction/Disposal Vulnerabilities

Dormant Accounts

Endpoint Leakage Vulnerabilities

Excessive User Permissions

Insecure Network Configuration
Insecure Software Development

Processes

Insufficient Application Capacity

Insufficient data backup

Insufficient data validation

Insufficient equipment redundancy

Insufficient equipment shielding

Insufficient fire protection

Insufficient HVAC capability

Insufficient power capacity

Insufficient power shielding

Etcetera...

NIST SP 800-53 Controls

PS-6 a The organization ensures that individuals requiring access to organizational information and information systems sign appropriate access agreements prior to being granted access.

PS-6 b The organization reviews/updates the access agreements [Assignment: organization-defined frequency].

AC-19 a The organization establishes usage restrictions and implementation guidance for organization-controlled mobile devices.

AC-19 b The organization authorizes connection of mobile devices meeting organizational usage restrictions and implementation guidance to organizational information systems.

AC-19 d The organization enforces requirements for the connection of mobile devices to organizational information systems.

AC-19 e The organization disables information system functionality that provides the capability for automatic execution of code on mobile devices without user direction; Issues specially configured mobile devices to individuals traveling to locations that the organization deems to be of significant risk in accordance with organizational policies and procedures.

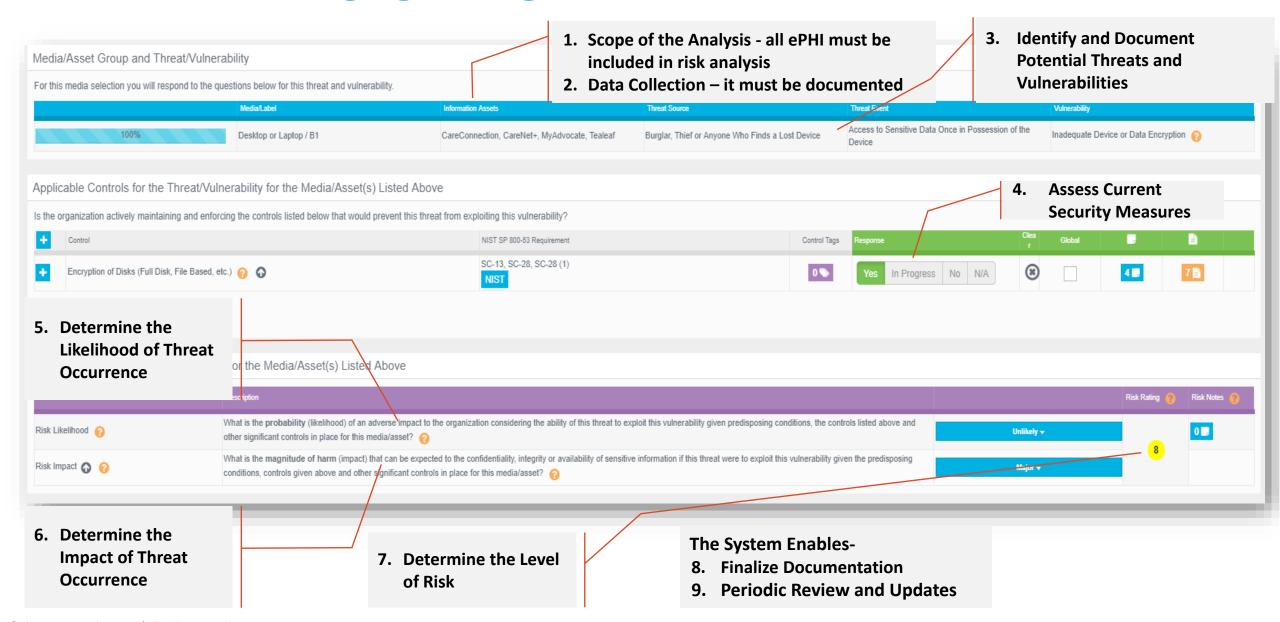
Hundreds and hundreds







Meet OCR's Emerging, Stringent Standard of Care



In Summary

Bona Fide, Comprehensive Risk Analysis Required at 45 CFR §164.308(a)(1)(ii)(A) MEANS OCR Guidance and NIST SP800-30!

- OCR has clearly defined what it expects in a risk analysis not meeting these requirements has resulted in severe penalties and reputational damage.
- A risk analysis is not a technical evaluation, nor is it a check list it's an information system based evaluation of the vulnerabilities and risk.
- A by-the-book risk analysis must follow the nine critical components described in this session and must be properly documented.
- Purpose built software can streamline the work, drive a by-the-book process, and ensure adequate documentation is on place.
- With a system in place you can effectively manage your riskiest exposures.

Key Resources

- Sample HIPAA Security Risk Analysis FOR Report
- Guidance on Risk Analysis Requirements under the HIPAA Security Rule
- NIST SP800-30 Revision 1 Guide for Conducting Risk Assessments
- NIST SP800-39-final Managing Information Security Risk
- NIST SP800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach
- The Clearwater Definition of an Information Asset

Additional Resources

- NIST SP800 53 r4 Security and Privacy Controls for Federal Information Systems and Organizations
- NIST SP800-115 Technical Guide to Information Security Testing and Assessment
- NIST SP800-34 Contingency Planning Guide for Federal Information Systems
- MU Stage 2 Hospital Core 7 Protect Electronic Health Info 2012-11-05
- NIST Risk Management Framework 2009





Questions?





Thank You!



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