



# Outsourcing IT Under BAA: Exploring Cloud Certification for Healthcare

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FedRAMP

## Conclusions

Effectiveness  
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# Introductions: Who I am

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20 years in IT

- Information Security assessment and audit, architecture, management
- Compliance and Risk Management / GRC
- Software and Product Development

Multi-sector experience

- Healthcare
- Pharmaceutical
- Financial
- Federal
- Energy and Utility
- Retail

International scope

- Privacy in EMEA and APAC
- Cross-border data flows



# Introductions: What I do

## 2002 – 2012

building consolidated information security, availability, quality, and privacy audit and assessment programs for multi-national corporations



## 2012 - Present

hosting services for Healthcare and Pharmaceuticals





# Introductions: What this is about

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Commonalities between the HIPAA Security rule and common information security certification standards.



More precisely: how these certification standards, as applied to conventional IT Hosting architectures, could be leveraged to demonstrate compliance with HIPAA Security requirements.



Four certification standards:

- SSAE 16 SOC 2
- ISO 27001
- PCI DSS
- FedRAMP





# Introductions: Why talk about this?

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The economics work



The Cloud, alongside mobile technology, is the next step in computing evolution



Security is the #1 concern among customers when considering the Cloud and other IT hosting services





# Approach: Context

Common basic IT hosting services: colocation, managed hosting, Cloud

Business Associate is willing to sign BAA

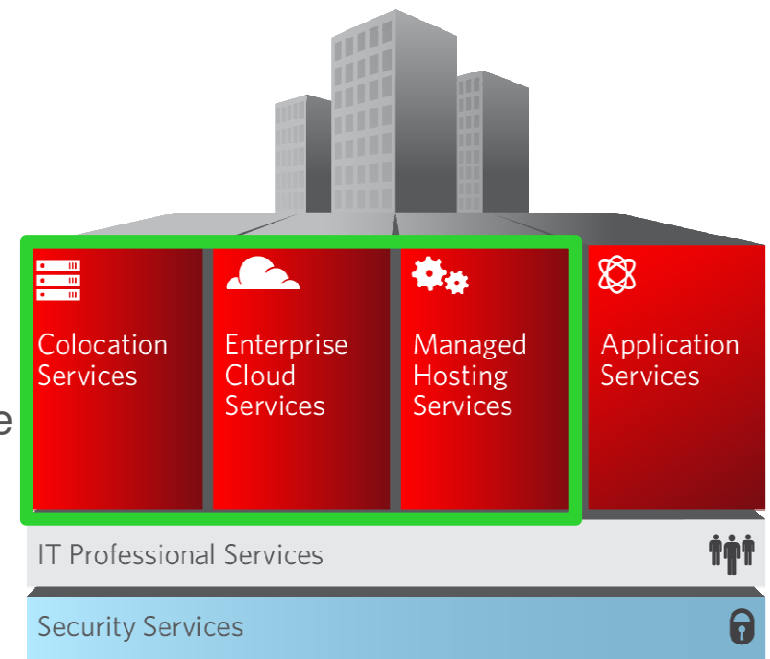
## Authorizations

- 1) No authorization to access, use, or disclose ePHI
- 2) Only authorized access to information systems containing ePHI to perform routine administrative tasks

Business Associate responsibilities do not include applications or data

Services located in U.S. jurisdictions

ePHI does not traverse national boundaries





# Approach: Methods

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## ***Methodology comparison***

Is the certification process rigorous enough to also meet the audit protocol as specified by the ONC?

**Sufficient**

**Potential**

**Insufficient**

## ***Evidence comparison***

If a service provider is awarded certification X, could the evidence contained in the working papers of that certification also be used during a HIPAA Security audit?

**Supportive**

**Interpretive**

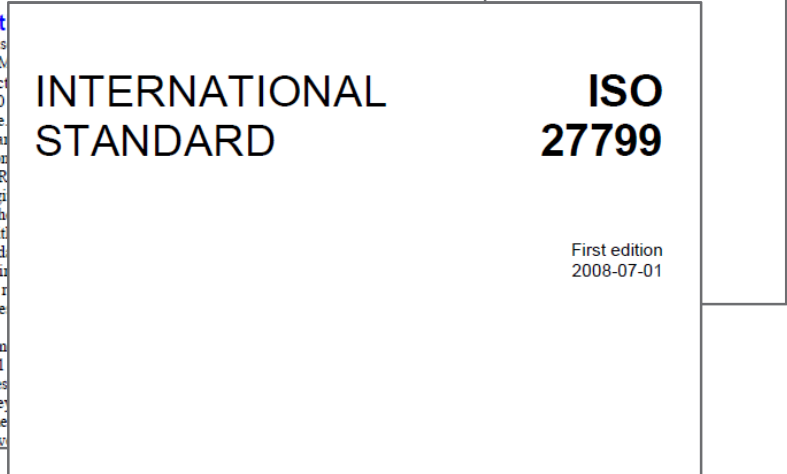
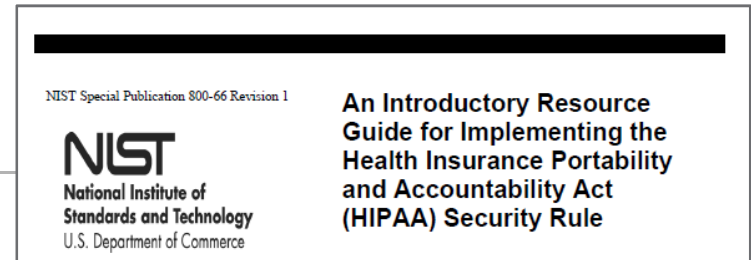
**Inadequate**





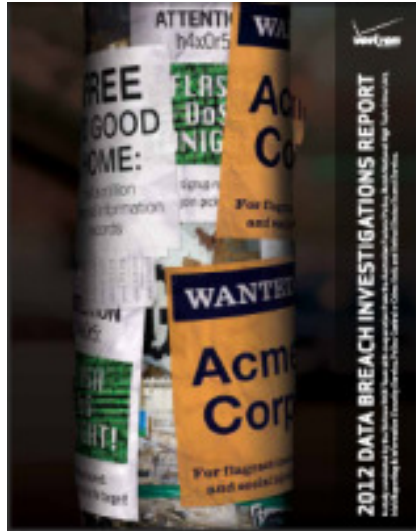
# Approach: Literature

- Prevalent guidance informed the general risk analysis
  - CMS HIPAA Security Series
  - NIST 800-66 (2008)
  - ISO 27799 (2008)
- Verizon HIPAA Security Office risk requirements
- Verizon Data Breach Investigative Report





# Approach: Literature Data Breach Investigative Report (DBIR)



Released annually, since 2008

Provides insight into data breaches from 2004 to present

Spans more than 2,000 data breaches, totaling over one billion compromised records



Australian  
Federal Police



Dutch National  
High Tech  
Crime Unit



Irish Reporting  
& Information  
Security Service



Police Central e-Crime  
Unit of the London  
Metropolitan Police



United States  
Secret Service

**2013 Data Breach Investigations Report (DBIR) Developed in Cooperation with International Crime Agencies**

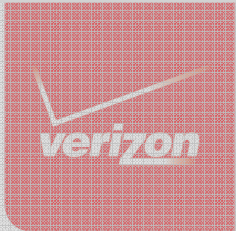


# Findings: SSAE 16 SOC 2 Type II



Certifiers	Certified Public Accountants (CPA)
Validity Period	6 months to 1 year
Used by	IT Service Organizations

Methodology	Evidence
Type I: Single point-in-time <b>Type II: Continuous over reporting period</b>  SOC 1: Operational Assurance <b>SOC 2: Conformance with Trust Services Criteria</b> SOC 3: Auditor’s Statement	



## Findings: SSAE 16 SOC 2 Type II

Certifiers

Certified Public Accountants (CPA)

The following principles and related criteria have been developed by the AICPA and CPA Canada for use by practitioners in the performance of trust services engagements:

- **Security.** The system is protected against unauthorized access (both physical and logical).
- **Availability.** The system is available for operation and use as committed or agreed.
- **Processing integrity.** System processing is complete, accurate, timely, and authorized.
- **Confidentiality.** Information designated as confidential is protected as committed or agreed.
- **Privacy.** Personal information is collected, used, retained, disclosed, and destroyed in conformity with the commitments in the entity's privacy notice and with criteria set forth in generally accepted privacy principles issued by the AICPA and CPA Canada.

period

• Security

3.12 Encryption or other equivalent security techniques are used to protect transmissions of user authentication and other confidential information passed over the Internet or other public networks.

3.13 Procedures exist to identify, report, and act upon system confidentiality and security breaches and other incidents.



# Findings: SSAE 16 SOC 2 Type II



Certifiers	Certified Public Accountants (CPA)
Validity Period	6 months to 1 year
Used by	IT Service Organizations

## Methodology

Type I: Single point-in-time  
**Type II: Continuous over reporting period**

SOC 1: Operational Assurance  
**SOC 2: Conformance with Trust Services Criteria**  
 SOC 3: Auditor’s Statement

## Evidence

SOC 1: ToE’s policies and procedures  
 SOC 2: Trust Services Principles

- **Security**
- **Availability**
- Processing Integrity
- **Confidentiality**
- Privacy (GAAP)

SOC 3: Same as SOC2

**Sufficient**

**Interpretive**



# Findings: ISO 27001



Certifiers	Accredited Auditors
Validity Period	3 years
Used by	Information Security Management

## Methodology

## Evidence

Statement of Applicability

Point-in-time audit

Review of ISMS inputs and outputs over reporting time period

Review of risk management practices

ISO/IEC 27002:2005 establishes guidelines and general principles for initiating, implementing, maintaining, and improving information security management in an organization. The objectives outlined provide general guidance on the commonly accepted goals of information security management. ISO/IEC 27002:2005 contains best practices of control objectives and controls in the following areas of information security management:

- security policy;
- organization of information security;
- asset management;
- human resources security;
- physical and environmental security;
- communications and operations management;
- access control;
- information systems acquisition, development and maintenance;
- information security incident management;
- business continuity management;
- compliance.

The control objectives and controls in ISO/IEC 27002:2005 are intended to be implemented to meet the requirements identified by a risk assessment. ISO/IEC 27002:2005 is intended as a common basis and practical guideline for developing organizational security standards and effective security management practices, and to help build confidence in inter-organizational activities.



# Findings: ISO 27001



Certifiers	Accredited Auditors
Validity Period	3 years
Used by	Information Security Management

## Methodology

## Evidence

Statement of Applicability

Point-in-time audit

Review of ISMS inputs and outputs over reporting time period

Review of risk management practices

ISO 27001:2013 - Information technology— Security techniques — Information security management systems — Requirements

ISO 27002: 2005 - Information technology – Security techniques – Code of practice for information security management

**Potential**

**Interpretive**



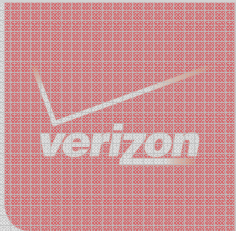


# Findings: PCI DSS



Certifiers	Qualified Security Assessors (QSA)
Validity Period	1 year
Used by	Payment Card Industry

Methodology	Evidence
Annual self-assessment	
Annual audit for high-risk providers <ul style="list-style-type: none"><li>• Interviews</li><li>• On-site Inspection</li><li>• Document review</li></ul>	
Quarterly scans of cardholder environment	



# Findings: PCI DSS

## PCI Data Security Standard – High Level Overview

<b>Build and Maintain a Secure Network and Systems</b>	<ol style="list-style-type: none"><li>1. Install and maintain a firewall configuration to protect cardholder data</li><li>2. Do not use vendor-supplied defaults for system passwords and other security parameters</li></ol>
<b>Protect Cardholder Data</b>	<ol style="list-style-type: none"><li>3. Protect stored cardholder data</li><li>4. Encrypt transmission of cardholder data across open, public networks</li></ol>
<b>Maintain a Vulnerability Management Program</b>	<ol style="list-style-type: none"><li>5. Protect all systems against malware and regularly update anti-virus software or programs</li><li>6. Develop and maintain secure systems and applications</li></ol>
<b>Implement Strong Access Control Measures</b>	<ol style="list-style-type: none"><li>7. Restrict access to cardholder data by business need to know</li><li>8. Identify and authenticate access to system components</li><li>9. Restrict physical access to cardholder data</li></ol>
<b>Regularly Monitor and Test Networks</b>	<ol style="list-style-type: none"><li>10. Track and monitor all access to network resources and cardholder data</li><li>11. Regularly test security systems and processes</li></ol>
<b>Maintain an Information Security Policy</b>	<ol style="list-style-type: none"><li>12. Maintain a policy that addresses information security for all personnel</li></ol>

environment



# Findings: PCI DSS



Certifiers	Qualified Security Assessors (QSA)
Validity Period	1 year
Used by	Payment Card Industry

## Methodology

Annual self-assessment

Annual audit for high-risk providers

- Interviews
- On-site Inspection
- Document review

Quarterly scans of cardholder environment

**Insufficient**

## Evidence

### PCI Data Security Standard – High Level Overview

<b>Build and Maintain a Secure Network and Systems</b>	1. Install and maintain a firewall configuration to protect cardholder data
	2. Do not use vendor-supplied defaults for system passwords and other security parameters
<b>Protect Cardholder Data</b>	3. Protect stored cardholder data
	4. Encrypt transmission of cardholder data across open, public networks
<b>Maintain a Vulnerability Management Program</b>	5. Protect all systems against malware and regularly update anti-virus software or programs
	6. Develop and maintain secure systems and applications
<b>Implement Strong Access Control Measures</b>	7. Restrict access to cardholder data by business need to know
	8. Identify and authenticate access to system components
	9. Restrict physical access to cardholder data
<b>Regularly Monitor and Test Networks</b>	10. Track and monitor all access to network resources and cardholder data
	11. Regularly test security systems and processes
<b>Maintain an Information Security Policy</b>	12. Maintain a policy that addresses information security for all personnel

**Inadequate**



# Findings: FedRAMP



Certifiers	FedRAMP Accredited Assessors
Validity Period	At most 3 years
Used by	US Federal Agencies

## Methodology

## Evidence

### Security Assessment

- Documenting security controls
- Security testing

### On-going Assessment and Authorization

- Continuous monitoring
- Plan of Action and Milestones



## FedRAMP Control Quick Guide

Control requirements are identified in the FedRAMP SSP

ID	Family	Class	Low Count	Moderate Count
AC	Access Control	Technical	11	17 (24)
AT	Awareness and Training	Operational	4	4
AU	Audit and Accountability	Technical	10	12 (9)
CA	Certification, Accreditation, and Security Assessment	Management	6 (1)	6 (2)
CM	Configuration Management	Operational	6	9 (12)
CP	Contingency Planning	Operational	6	9 (15)
IA	Identification and Authentication	Technical	7 (2)	8 (10)
IR	Incident Response	Operational	7	8 (4)
MA	Maintenance	Operational	4	6 (6)
MP	Media Protection	Operational	3	6 (5)
PE	Physical and Environmental Protection	Operational	11	18 (5)
PL	Planning	Management	4	5
PS	Personnel Security	Operational	8	8
RA	Risk Assessment	Management	4	4 (5)
SA	System and Services Acquisition	Management	8	12 (7)
SC	System and Communications Protection	Technical	8 (1)	24 (16)
SI	System and Information Integrity	Operational	5	12 (9)

### Legend:

Count = # of controls (#of enhancements)

Impact Level: L = Low / M = Moderate

Enhancements: (#, #)

Additional FedRAMP Requirements = ★

FedRAMP Guidance = G

Note: Controls and Enhancements added by FedRAMP are in Bold.

### Access Control (AC)

Control #	Control Name	Control Baseline		Additional Req.
		Low	Moderate	
AC-1	Access Control Policy and Procedures	L	M	
AC-2	Account Management	L	M (1,2,3,4,7)	★
AC-3	Access Enforcement	L	M (3)	★
AC-4	Information Flow Enforcement		M	
AC-5	Separation of Duties		M	
AC-6	Least Privilege		M (1,2)	★ G
AC-7	Unsuccessful Login Attempts	L	M	
AC-8	System Use Notification	L	M	★ G
AC-10	Concurrent Session Control		M	
AC-11	Session Lock		M (1)	G
AC-14	Permitted Actions Without Identification/Authentication	L	M (1)	
AC-16	Security Attributes		M	★
AC-17	Remote Access	L	M (1,2,3,4,5,7,8)	★ G
AC-18	Wireless Access	L	M (1,2)	
AC-19	Access Control for Mobile Devices	L	M (1,2,3)	★
AC-20	Use of External Information Systems	L	M (1,2)	
AC-22	Publicly Accessible Content	L	M	

### Awareness and Training (AT)

Control #	Control Name	Control Baseline		Additional Req.
		Low	Moderate	
AT-1	Security Awareness and Training Policy and Procedures	L	M	
AT-2	Security Awareness	L	M	
AT-3	Security Training	L	M	
AT-4	Security Training Records	L	M	

### Audit and Accountability (AU)

Control #	Control Name	Control Baseline		Additional Req.
		Low	Moderate	
AU-1	Audit and Accountability Policy and Procedures	L	M	
AU-2	Auditable Events	L	M (3,4)	★ G
AU-3	Content of Audit Records	L	M (1)	★ G
AU-4	Audit Storage Capacity	L	M	
AU-5	Response to Audit Processing Failures	L	M	
AU-6	Audit Review, Analysis, and Reporting	L	M (1,3)	
AU-7	Audit Reduction and Report Generation		M (1)	
AU-8	Time Stamps	L	M (1)	★ G
AU-9	Protection of Audit Information	L	M (2)	
AU-10	Non-Repudiation		M (5)	★
AU-11	Audit Record Retention	L	M	★
AU-12	Audit Generation	L	M	

### Certification, Accreditation, & Sec. Assessment (CA)

Control #	Control Name	Control Baseline		Additional Req.
		Low	Moderate	
CA-1	Security Assessment and Authorization Policies and Procedures	L	M	
CA-2	Security Assessments	L (1)	M (1)	
CA-3	Information System Connections	L	M	
CA-5	Plan of Action and Milestones	L	M	
CA-6	Security Authorization	L	M	G
CA-7	Continuous Monitoring	L	M (2)	

### Configuration Management (CM)

Control #	Control Name	Control Baseline		Additional Req.
		Low	Moderate	
CM-1	Configuration Management Policy and Procedures	L	M	
CM-2	Baseline Configuration	L	M (1,3,5)	★ G
CM-3	Configuration Change Control		M (2)	★
CM-4	Security Impact Analysis	L	M	
CM-5	Access Restrictions for Change		M (1,5)	
CM-6	Configuration Settings	L	M (1,3)	★ G
CM-7	Least Functionality	L	M (1)	★ G
CM-8	Information System Component Inventory	L	M (1,3,5)	★ G
CM-9	Configuration Management Plan		M	

### Contingency Planning (CP)

Control #	Control Name	Control Baseline		Additional Req.
		Low	Moderate	
CP-1	Contingency Planning Policy and Procedures	L	M	
CP-2	Contingency Plan	L	M (1,2)	★
CP-3	Contingency Training	L	M	
CP-4	Contingency Plan Testing and Exercises	L	M (1)	★
CP-6	Alternate Storage Site		M (1,3)	
CP-7	Alternate Processing Site		M (1,2,3,5)	★
CP-8	Telecommunications Services		M (1,2)	★
CP-9	Information System Backup	L	M (1,3)	★
CP-10	Information System Recovery and Reconstitution	L	M (2,3)	★

### Identification and Authentication (IA)

Control #	Control Name	Control Baseline		Additional Req.
		Low	Moderate	
IA-1	Identification and Authentication Policy and Procedures	L	M	
IA-2	Identification and Authentication (Organizational Users)	L (1)	M (1,2,3,6)	★
IA-3	Device Identification and Authentication		M	★
IA-4	Identifier Management	L	M (4)	★
IA-5	Authenticator Management	L (1)	M (1,2,3,6,7)	G
IA-6	Authenticator Feedback	L	M	
IA-7	Cryptographic Module Authentication	L	M	
IA-8	Identification and Authentication (Non-Organizational Users)	L	M	



# Findings: FedRAMP



Certifiers

FedRAMP Accredited Assessors

Validity Period

At most 3 years

Used by

US Federal Agencies

## Methodology

### Security Assessment

- Documenting security controls
- Security testing

### On-going Assessment and Authorization

- Continuous monitoring
- Plan of Action and Milestones

## Evidence

The evidence section displays several screenshots from the FedRAMP Control Quick Guide. The main screenshot shows a table of controls with columns for ID, Family, Control Name, Level, and Status. Below this are several smaller tables for specific control families: Access Control (AC), Configuration Management (CM), Contingency Planning (CP), Identification and Authentication (IA), Incident Response (IR), Maintenance (MA), Mobile Protection (MP), Physical and Environmental Protection (PE), Planning (PL), Personnel Security (PS), Risk Assessment (RA), System and Services Acquisition (SA), Systems and Communications Protection (SC), and Systems and Information Integrity (SI). Each table lists control IDs, names, and their current status (e.g., 'Met', 'Not Met', 'In Progress').

**Sufficient**

**Interpretive**



# Findings: Summary View

Standard	Methodology	Evidence
SSAE 16 SOC 2	Sufficient	Interpretive
ISO 27001	Potential	Interpretive
PCI DSS	Insufficient	Inadequate
FedRAMP	Sufficient	Interpretive



## Conclusions: Effectiveness

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As they exist, prevalent information security certification standards are insufficient to address all HIPAA Security requirements.

Appropriate interpretation of existing certification standards *should* be sufficient





## Conclusions: Opportunity

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Establish information security baseline for IT hosting in healthcare

Improve consistency of security posture across hosting providers serving covered entities

Standardize method to report information security posture

Reduce barriers for outsourcing IT hosting functions to covered entities by increasing confidence in the security of these functions