



IMDRF

International Medical
Device Regulators Forum

Updates of International Medical Devices Regulators Forum (IMDRF) activities

November, 2014

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Management Committee

The current members are:

- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Russia
- United States of America



IMDRF

International Medical
Device Regulators Forum

Management Committee

Official Observers:

- World Health Organization (WHO)
- APEC Life Sciences Innovation Forum,
Regulatory Harmonization Steering
Committee (RHSC)

Affiliate Organizations as Invited Observers:

- Asian Harmonization Working Party (AHWP)
- Pan American Health Organization (PAHO)



IMDRF

International Medical
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Management Committee

The roles of IMDRF Chair and Secretariat rotate annually:

2012 – Australia, Therapeutic Goods Administration (TGA)

2013 – European Union, EU Commission DG Sanco

2014 – US, Food and Drug Administration

2015 - Japan



IMDRF Work Items

- Implementation of a UDI system (completed)
- Recognized Standards Report (completed)
- Medical Device Single Audit Program (MDSAP)
- National Competent Authority Report (NCAR) Exchange
- Regulated Product Submission (RPS)
- Software as a Medical Device (SaMD)
- New Work Group – Patient Registries



Completed IMDRF Work Items

- IMDRF/UDI WG/N7FINAL:2013 – “UDI Guidance - Unique Device Identification (UDI) of Medical Devices”
- IMDRF/ Standards/N15FINAL:2014 Informational Document - IMDRF Recognized Standards Report



Documents issued in 2014 (1/2)

- Technical Documents
 - Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations (N12)
 - MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization (N11)
 - In Vitro Diagnostic Medical Device Market Authorization Table of Contents (N13)
 - Non-In Vitro Diagnostic Device Market Authorization Table of Contents (N9)



Documents issued in 2014 (2/2)

- Information Documents
 - MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes
 - Points to Consider in the use of the IMDRF Table of Content for Medical Device Submissions pre-RPS
 - RPS Beta Testing Document



Summary of on-going activities (1/2)

- **MDSAP**: Development of an audit report guidance (N24) and a regulatory authority assessment method guidance (N8)
- **NCAR**: Public consultation for a reporting guidance (N14)
- **RPS**: Summarization of ToCs and Beta-testing activities, and survey for common data elements



Summary of on-going activities (2/2)

- **SaMD**: Development of a document for quality management systems for SaMD
- **Patient Registries**: New activity approved in Sep. 2014
- **Others**:
 - Development of an information document on the use of international standard ISO 14155
 - Discussion of new work item proposal on Adverse Event Terminology and Coding



Medical Device Single Audit Program (MDSAP)

The Work Group will develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The document will be applicable to competent authority auditing groups/inspectionates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program.



MDSAP Working Group

Final Documents from November 2013

IMDRF MDSAP WG N3 – *“Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”*

IMDRF MDSAP WG N4 – *“Competency and Training Requirements for Auditing Organizations”*

IMDRF MDSAP WG N5 – *“Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations”*

IMDRF MDSAP WG N6 - *“Regulatory Authority Assessor Competency and Training Requirements”*



MDSAP N11

- This document defines:
 - The process and lifecycle for recognizing, maintaining, or ceasing recognition of an Auditing Organization.
 - The process of managing, grading, and closure of assessment nonconformities issued to an Auditing Organization; and,
 - The outcomes of an initial, surveillance, or re-recognition assessment process of an Auditing Organization.



MDSAP N11

**IMDRF/MDSAP WG /N11FINAL:2014 –
“MDSAP Assessment and Decision
Process for the Recognition of an
Auditing Organization”**

Posted on WWW.IMDRF.ORG



MDSAP Overview Diagram

- IMDRF MDSAP WG produced a one page flow diagram to respond to the request of an IMDRF delegation for an overview document/diagram.
- Published the Diagram on the IMDRF website

MDSAP WG/N22FINAL:2014 – Information Document

*“MDSAP: Overview of Auditing Organization
Assessment and Recognition Decision Related
Processes”*



MDSAP N8

- The purpose of this document is to provide Regulatory Authority Assessment Method Guidance that was extracted out of the PD1 version of IMDRF MDSAP N5.
- The Working Group received many comments to reduce the size and scope of N5 PD1 into two separate documents.
- MDSAP N8 was approved as a separate document in Brussels in 2013.



MDSAP N8 Timeline

- Redraft N8 in Fall 2014
- Face to Face meeting in late January/early February to produce a Proposed Document
- Submit to Management Committee for Spring 2015 IMDRF Meeting in Japan.
- Seek public comments in April and May
- Face to Face meeting June/July 2015 to produce Proposed Final document for Fall 2015 IMDRF Management Committee Meeting



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MDSAP Work Item Extension

The Working Group has received comments requesting that IMDRF also draft a Audit Report guidance document such that Auditing Organization could draft and issue a harmonized single report to the medical device manufacturers under the MDSAP scheme.



MDSAP N24 Audit Report Guidance - Timeline

- Draft in Fall 2014
- Face to Face meeting in late January/early February to produce a Proposed Document
- Submit to Management Committee for Spring 2015 IMDRF Meeting in Japan.
- Seek public comments in April and May
- Face to Face meeting June/July 2015 to produce Proposed Final document for Fall 2015 IMDRF Management Committee Meeting



MDSAP N24

- A draft document has already been prepared as part of the Work Item Extension request
- The Working Group will work on this concurrently with N8
- Goal end of 2015 - 2016.



NCAR WG: Key features

- **SCOPE:**

exclusive focus on info exchange on serious public health issues

Concerns:

- **criteria, procedures & forms** for exchange
- **requirements for participation**



NCAR WG: Reporting guidance

Interactive information exchange on:

-significant concerns OR potential trends that have not yet resulted in recalls or FSCAs.

May entail exchange of confidential information



NCAR WG: Reporting guidance

Unchanged:

- reporting criteria,
- format for information exchange.

Clarified:

- **membership:** limited to MC members.



NCAR WG: Reporting guidance

Addressed:

confidentiality

NCARs marked "confidential" may only be shared with NCAR participants covered by confidentiality arrangements with authoring NCA.



NCAR WG: Reporting guidance

Clarified:

Report Exchange Method:

- email exchange system maintained,
- **exchange procedure** and **secretariat role** revisited to take account of confidential data exchange.



NCAR WG: Work Plan

Sept. 2014 to March 2015

1. N14 completion
 - ▶ Until December 8, 2014:
Public consultation
 - ▶ mid Nov.2014 – end Jan. 2015:
Review comments & Finalise N14.



RPS Table of Contents (ToC) Update

- IVD and nIVD Table of Contents (ToC) documents (version 1) were endorsed by the MC at the teleconference on June 30th, 2014.
- An additional document entitled “Points to Consider” was also endorsed. This document clarifies how to use the ToC documents.
- These documents are available on the IMDRF website.



Classification Matrices

- Not all headings in ToCs are required for all submission types and/or jurisdictions
- ToC documents are intended to work together with a separate document created by and for each participating jurisdiction – the classification matrix
- Defines whether, for given submission type, a heading and associated content is required, not required, optional or conditionally required
- Classification matrices are to be made available on each jurisdiction/regulatory authority's websites.
- With introduction of RPS message standard, publishing/viewing tools should display what is appropriate for a particular jurisdiction



Example of Classification Matrix

		CIV New	
		Classification	Condition
CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION			
CH6B.1	Chapter ToC	R	
CH6B.2	Quality management system information	NR	
CH6B.3	Management responsibilities information	NR	
CH6B.4	Resource management information	NR	
CH6B.5	Product realization information	NR	
CH6B.6	Device Specific Quality Plan	R	
CH6B.6.1	Design and development information	NR	
CH6B.6.2	Purchasing information	NR	
CH6B.6.3	Production and service controls information	R	
CH6B.6.4	Control of monitoring and measuring devices information	NR	
CH6B.7	QMS measurement, analysis and improvement information	NR	29



RPS ToC: Next Steps

- Classification Matrices will be posted on regional websites
- Each regulator will be free to pilot the new ToCs using real submissions and translate documents as structures will be stable
- Development of training material, Qs and As and exchange of information on implementation plans will be coordinated – survey is currently being undertaken
- Anticipate potential refinement of ToCs within approximately 18 months based on real life experience
- Ongoing discussions regarding the filing of electronic (pre-RPS) versions of ToCs compliant device applications
- Regulators should be consulted on specific implementation plans



RPS ToC: Summary

- Piloting, training and elaboration of Qs & As will be important to the successful use of the new ToC structures for IVD and nIVD applications
- ToCs developed with aim of supporting RPS compliant applications; classification matrices meant to provide clarity in pre-RPS environment
- Transition rules will vary from regulator to regulator. Consult the relevant regulatory authority for further information



RPS Beta Test: Recap

- Beta Testing Objective (Phase 1):
 - Assess RPS Standard fitness for use with device submissions
 - Identify areas where the RPS standard may not meet device requirements and provide input to the HL7 standard
- If RPS is found to be suitable for device business requirements, Phase 2 of RPS Work Item, if endorsed by IMDRF MC, would focus on implementation



Software Tool versus Message Standard

- **Tool:** a business need that can be met with functionality built into publishing and reviewing software tools
- **Message:** Information that must be contained in the RPS message to support the business process
 - The RPS message carries information that software tools can use to enable software functionality
 - Business requirements may be met through tools if the RPS message carries the necessary information to do so



Tool Requirement Example

- Reviewers want to see all documents related to a manufacturing facility grouped together
 - The RPS message allows documents to be tagged with keywords. The tool can then display all documents with the same keyword together
 - All of the required information is in the message, but the use of the keywords for grouping content for display is a tool requirement



Beta Testing Status

- Initial plan to complete testing by July 15 was delayed because changes to the RPS model were not available
- A revised testing approach will allow us to comment on the HL7 RPS Ballot by Sept 8th



RPS Common Data Elements

- RPS Work Item Extension endorsed by the IMDRF MC that will:
 - Identify and define common data elements and a structure to support device identification for regulatory purposes at different stages of the product lifecycle. This work will also cover the harmonization of definitions of data fields and sets of UDIDs (Phase 1)
 - Evaluate whether an existing electronic exchange format could accommodate the transmission of device identification information or whether a new data exchange message would be required (Phase 2)



RPS Common Data Elements

- Work under this third RPS work stream has started
- Initial step – survey of common data elements that are currently collected/captured by IMDRF members to identify a device through its lifecycle (pre-market/post market) and also those that may be contemplated due to proposed revisions in some regulatory frameworks
- Phase I work is projected to be completed by September 2015.



SaMD: Goals

- International convergence and common understanding of Software as a Medical Device (SaMD):
 - Generic types of SaMD
 - Generic risks of SaMD that affect public health
 - Expectations of controls required to minimize generic risk
- Establish a framework for regulators to incorporate converged controls into their regulatory paths or classifications.



Framework Overview

SaMD definition statement:

- Significance of recommendation
- Context of use



Risk Categorization

9 criteria based on definition statement



4 Categories based on similarity of impact



General and Special Controls Considerations

Type

IV

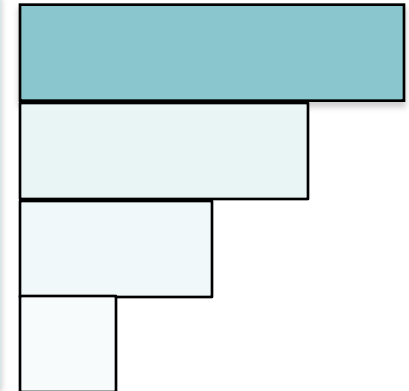
III

II

I

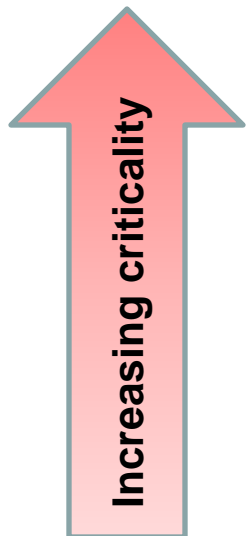
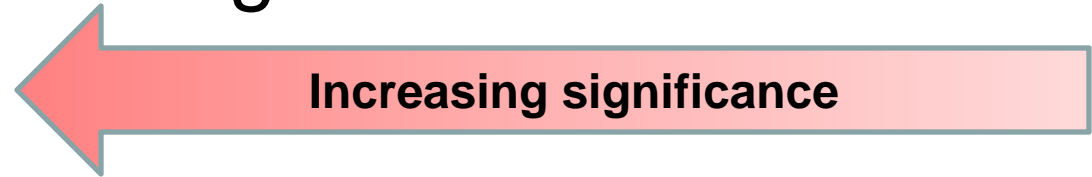
Common process expectation

Level of Risk





SaMD Categorization

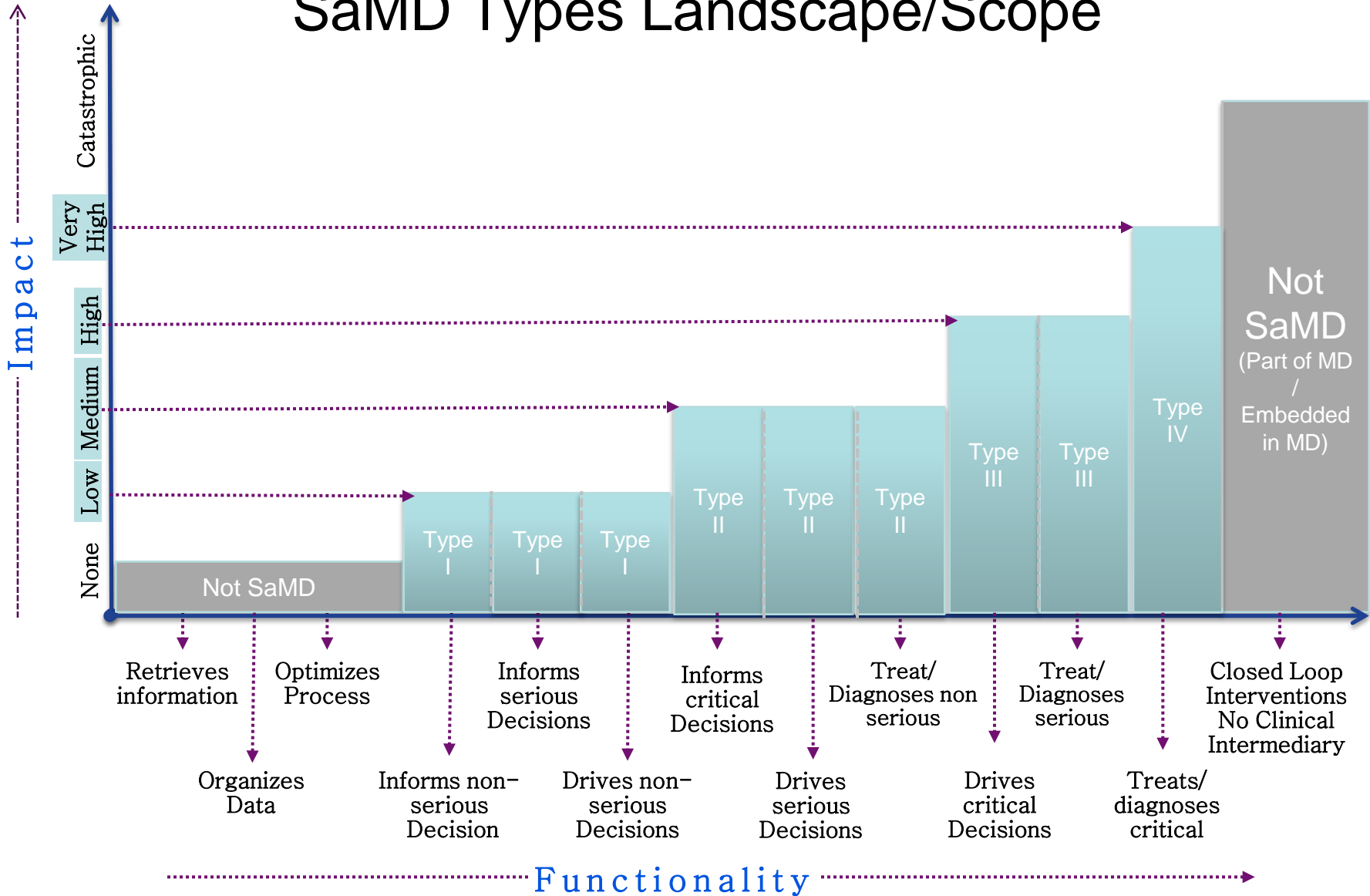


State of Healthcare Situation or Condition	Significance of Information Provided by SaMD to Healthcare Decision		
	Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
Critical	IV	III	II
Serious	III	II	I
Non-Serious	II	I	I



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SaMD Types Landscape/Scope





NWIP - Quality Management Systems for Software as a Medical Device (SaMD)

Scope

- Translate and adapt existing quality management system requirements to common software practices
- Explain how quality system requirements are applicable and adapted to typical software development, maintenance and management practices.

Rationale -- The scope and complexity of the quality management system are influenced by the range of different SaMD types, software development practices, maintenance practices, and other quality processes that are unique to software. there is no clear guidance on, how should a developer of SaMD follow and comply QMS requirements, examples of issues include

- software quickly using modules, how should a develop comply with regulatory expectations?
- some of the processes used to develop SaMD are automated, what expectations are reasonable for the principles outlined in the quality systems regulations and standards?

Proposed Timeline

- Publish Proposed Document for Public Comment in April and May 2015.
- Publish Final Document in October 2015



SaMD: Summary and Next Steps

- Published Final Document IMDRF/WG/N12 R10 in September 2014
- Approved by MC to begin development of new work item (Guidance on Quality Management Systems for Software as a Medical Device (SaMD))



New Work Group Patient Registries

Approved Work Item:

Integrating Patient Registries and Innovative
Tools for Enhanced Medical Device
Evaluation and Tracking



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Thank you

Acknowledgment of the very hard work performed and the outstanding results by IMDRF Working Group representatives.



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References



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IMDRF ORIGINS

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.



IMDRF

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Origins

It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.



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Management Committee

The IMDRF Management Committee, composed of regulatory officials, provides guidance on strategies, policies, directions, membership and activities of the Forum. Furthermore, the Management Committee oversees Working Groups which draw upon expertise from various stakeholder groups such as industry, academia, healthcare professionals, consumer and patient groups.



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Mission

The mission of the International Medical Device Regulators Forum (IMDRF) is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.



“Regulatory convergence”

“Regulatory convergence” (hereinafter “convergence”) is meant to represent a voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures. The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.



IMDRF Objectives

The objectives underpinning the goals of IMDRF are to:

- Accelerate international medical device regulatory convergence
- Support innovation and timely access to safe and effective medical devices globally
- Promote open discussion and the sharing of best practices among regulatory authorities responsible for medical device regulation



IMDRF Objectives

- Facilitate frequent exchange of policy and regulatory information of common interest to regulatory authorities
- Provide opportunities to identify commonalities and develop approaches to overcome unnecessary regulatory barriers
- Promote prospective convergence in areas of advanced and innovative technologies



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IMDRF Objectives

- Enhance communication, information sharing and scientific exchange among regulators and a broad range of stakeholders
- Establish develop dialogue with other relevant organizations.



IMDRF Work Items

- Specific tasks to be completed in a 18-24 month period with public consultation
- Avoid work items that involved legislative changes, as they are not typically solely within the control of the respective regulator and cannot typically be accomplished within 18 – 24 months.



IMDRF Work Items

Implementation initiatives:

- All jurisdiction are expected to implement the outputs of agreed upon Final IMDRF work items.
- MC member organizations may, in ***exceptional cases***, decide to opt-out of or delay involvement in implementation initiatives or involvement in the development of technical documents.