NIST: Important Considerations for the Certification Body Designating Authority

Japan MRA Workshop

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Department of Commerce

United States

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NIST

- National Institute of Standards and Technology

NIST

- U.S. Designating Authority (DA)* under multiple conformity assessment Telecom Mutual Recognition Agreements (MRAs)

- Designate
  - Accredited **Testing Laboratories** to foreign MRA partners

- Designate
  - Accredited **Certification Bodies** to foreign MRA partners and the FCC
  - Accredited **Notified bodies** to the EU*

Key Stakeholders in the MRAs

Manufacturer

Testing Laboratory

Certification Body or Notified Body

Accreditation Body

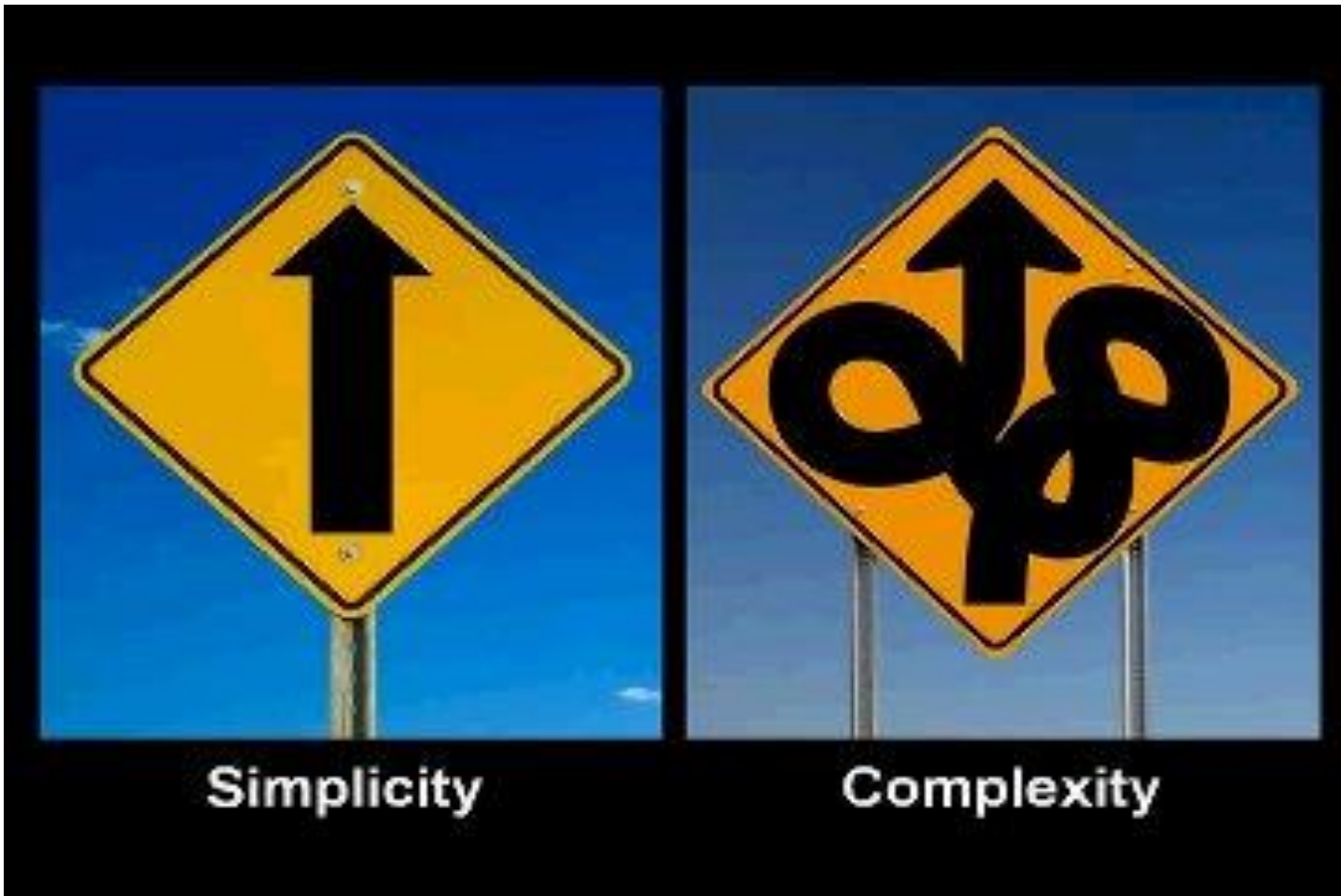Designating (or Notifying) Authority

Regulator

Consumer

Goals

Compliant product placed
on the market in a timely manner

Confidence in the conformity assessment process

Transparency of requirements

NIST - U.S. CB/NB Designating Authority

Economy	Type of CAB	# of US CABs Recognized
United States – FCC	Certification Bodies	21
Japan - MIC	Certification Bodies	6
Europe - EC	*Notified Bodies*	9 RED 9 EMCD 18 R&TTED
Canada - ISED	Certification Bodies	20
Hong Kong - OFCA	Certification Bodies	4
Singapore - IMDA	Certification Bodies	3

Simplicity

Complexity

Test Lab Designation

CB/NB Designation

Key Activities for Test Lab Designation

○ NIST verifies that the Test Lab:

- Maintains ISO/IEC 17025 Accreditation

- Is accredited for appropriate **Test Methods/Standards** required by the regulator

- Updates the Scope of Accreditation when **Test Methods/Standards** change

Key Activities for CB/NB Designation

NIST Verifies that the CB/NB:

Maintains ISO/IEC 17065 (or other) accreditation for the CB/NB activities and updates the Scope as required.

- Maintains ISO/IEC 17025 accreditation (where applicable) for the appropriate test methods/standards to support the certification activities and updates the scope as required.

- Meets specific **regulator** requirements
  - Level of NIST (DA) involvement in checking these requirements and the types of documents that must be submitted for NIST review differ by Economy and Regulator

Types of Documents Reviewed by NIST Prior to Designation of CBs

- Scope and Certificate of Accreditation
- ISO/IEC 17065 Accreditation Assessment Report and Deficiency report & resolution of deficiencies
- Certification procedures
- Market Surveillance procedures and reporting of results
- Contractual arrangements with testing laboratories
- Contractual arrangements with clients
- Understanding of labelling requirements
- Certificate template

Managing Designations:
Importance of Regulator Scheme Documents

- Regulator Scheme Documents
  - Publications explaining requirements and procedures
  - May include publication of a technical checklist for the assessors
- Benefits
  - Transparency of requirements to all stakeholders
    - CBs/NBs
    - Accreditation Bodies
    - Designating/Notifying Authorities
  - Consistent application of the regulator's requirements
  - Mechanism for announcing and tracking changes to requirements
  - Technical assessor checklist can be used to improve consistency and thoroughness of the accreditation body assessments.

Regulator/Authority Scheme Documents

Economy	Main Top Tier References	NIST
United States	FCC TCB Program Roles and Responsibilities AB TCB Checklist FCC Knowledge Database	No additional documents needed
Japan	Telecommunications Business Law Radio Law	*NIST Japan Criteria for Designation Document*

Regulator/Authority Scheme Documents

Economy	Main Top Tier References	NIST
Europe*	EMCD Directive + AB NB Checklist RED Directive + AB NB Checklist EC Directive Management Groups (EMC WP/TCAM) Blue Guide Notified Body Group Documents (REDCA & EUANB)	*NIST RED Application Document* *NIST EMCD Application Document*

Regulator/Authority Scheme Documents

Economy	Main Top Tier References	NIST
Canada	CB-01, CB-02, and CB-03 CB-02 Checklist for Recognition	No additional documents *All CB-02 Documents must be reviewed by NIST and provided to ISED for review.*
Hong Kong	OFCA MRA 002 AB FCB Checklist	No additional documents needed
Singapore	IMDA MRA REC SCHEME Checklist for ISO/IEC 17065	No additional documents needed

Example for the United States
Topics Covered in FCC Scheme Document

- Accreditation
- TCB Scope of Accreditation
- Explanation and amplification of ISO/IEC 17065 clauses for the FCC Equipment Authorization Program
- Impartiality
- Location of TCB

- TCB Testing Capability
- Certification Body Personnel
- Key Employee List
- Employee Training
- Test Procedures
- Dismissals
- Record Retention
- Post Market Surveillance

Example for Canada
Topics Covered in ISED Scheme Documents

- Accreditation
- CB Scope of Accreditation
- Technical Competence Requirements
- Test Lab Requirements
- Administrative and Operational Requirements
- CB Restrictions

- Market Surveillance/product audit requirements
- Certificate requirements
- Record Retention
- List of products that the CB has certified
- Compliance with RSP-100
- Documents to be send to Designating Authority in CB-02 Checklist

Managing Designations:
CBs – Requirements for Test Labs

- Is the CB required to maintain an affiliated ISO/IEC 17025 Accredited laboratory?
  - If yes, what is the required Scope of Accreditation, if any?
- When accepting test data from other testing laboratories to support the certification decisions (and/or NB Type Examination Decision), what are the requirements of the labs?
  - Does that lab need to maintain accreditation?
  - If so, by which accreditation bodies?
  - Does that lab's scope have to include specific test methods?
  - Are there any other requirements that apply?

Managing Designations:
CBs – Requirements for Test Labs

Three Examples

United States

Canada

Europe

CBs – Requirements for Test Labs
Example for the United States

TCB's affiliated testing laboratory	TCB must have an affiliated ISO/IEC 17025 accredited testing laboratory Laboratory must have a specific list of "core" test methods
TCB acceptance of test data to support certification	Effective July 13, 2017, the TCB may only accept test data from other **FCC recognized testing laboratories** that are accredited and FCC recognized for an appropriate scope of test methods .

CBs – Requirements for Test Labs Example for Canada

CB's affiliated testing laboratory	CB must have an affiliated ISO/IEC 17025 accredited testing laboratory **registered with ISED** CB may have contractual arrangements with other **ISED registered** testing laboratories. The Scope of Accreditation of the affiliated laboratory <u>and</u> the contracted laboratory must contain all the RSS and BETS standards to support the certification Scope.
CB acceptance of test data to support certification	CB may only accept test data from test labs that are **registered with ISED**

NBs – Requirements for Test Labs
Example for Europe

○ Test reports are submitted by the manufacturer as part of the technical documentation reviewed by the NB.

○ There is no requirement that test reports must be issued by an accredited testing laboratory.

NBs may not reject technical documentation simply because the test reports were issued by non-accredited testing laboratories.

US-EU MRA
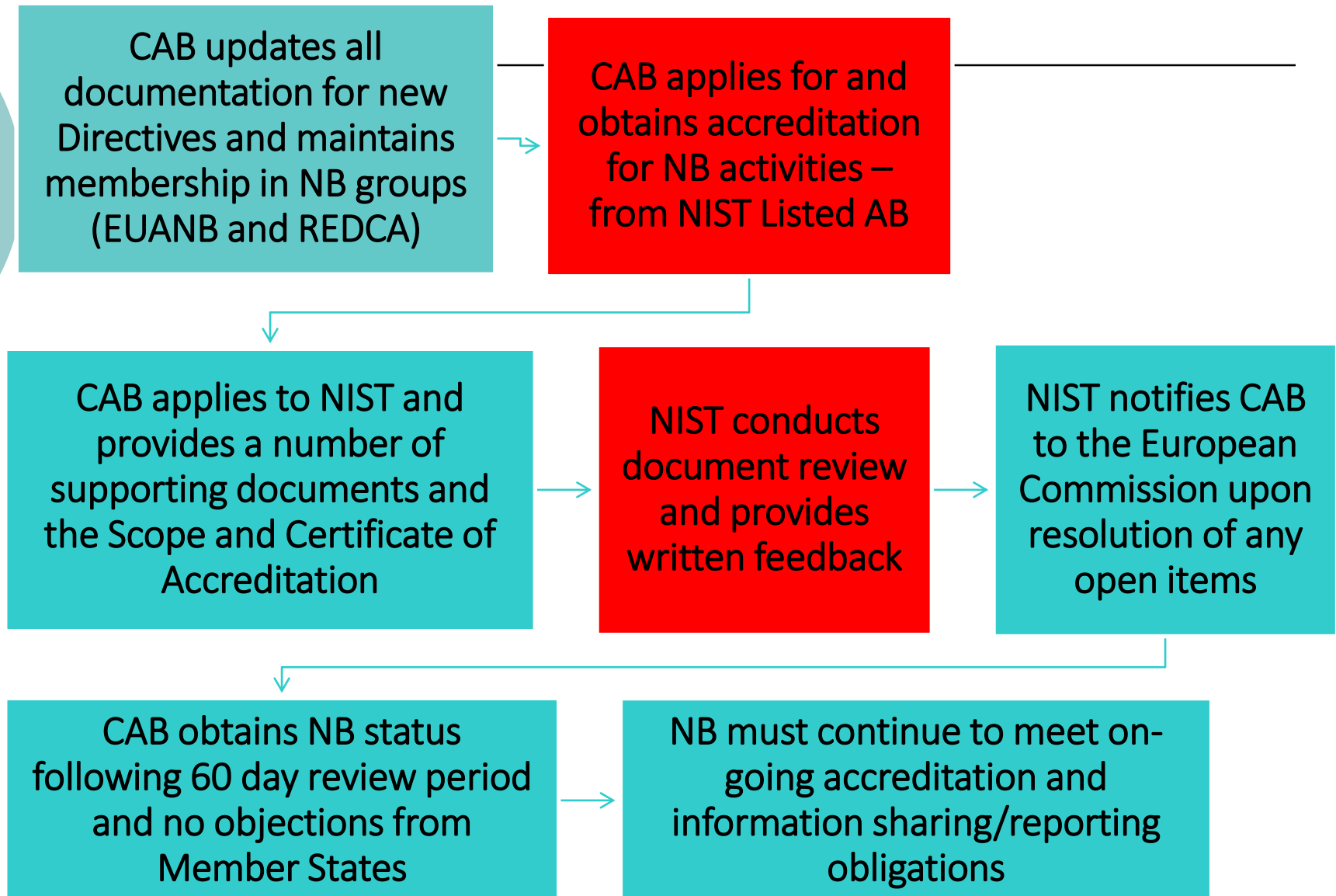## US CABs: Transition to the New Directives

EMC Directive (2014/30/EU)

Radio Equipment Directive (2014/53/EU)

Status of US CABs - Notified Bodies for EU

○ 23 U.S. CABs had Notified Body status for the EMC Directive (2001/108/EC) – all expired on <u>April 20, 2016</u>

○ 18 U.S CABs have Notified Body status for the R&TTE Directive - status expires on <u>June 13, 2017</u>

○ **Updated Directive**: EMC Directive (2014/30/EU)
  ● 9 US CABS are now EMCD NBs

○ **New Directive:** Radio Equipment Directive (2014/53/EU)
  ● 9 US CABS are now RED NBs

Obtaining NB Status - Process Used by NIST

CAB updates all documentation for new Directives and maintains membership in NB groups (EUANB and REDCA)

CAB applies for and obtains accreditation for NB activities – from NIST Listed AB

CAB applies to NIST and provides a number of supporting documents and the Scope and Certificate of Accreditation

NIST conducts document review and provides written feedback

NIST notifies CAB to the European Commission upon resolution of any open items

CAB obtains NB status following 60 day review period and no objections from Member States

NB must continue to meet on-going accreditation and information sharing/reporting obligations

US Accreditation Bodies (ABs) for NBs

- Must be qualified by NIST and become NIST-Listed

- Assessors must attend NIST training

- Assessors must use technical checklists provided

- Stay current with the latest information (through NIST) and provide it to the assessors

NIST NB Application Document Review
Key Findings by NIST:

○ Not updating Terminology

  ● NB Opinion changes to *EU Type Examination Certificate*

○ Not creating a procedure for and template for the new Evaluation Report requirement

○ Not documenting and disclosing to clients the information sharing obligations

  ● Also not disclosing participation in the new NB Certificate Database in accordance with NB Group procedures

○ Not properly documenting Employee Training for new Directives

NIST NB Application Document Review
Key Findings by NIST:

- Including NB activity for fixed installations when this is not covered by NBs (EMCD)

- Not documenting and providing a procedure on how to stay up to date with standards development activities – which ones and how?

- Not <u>removing</u> from prior documentation the reference to manufacturers being allowed to include the NB number next to the CE mark - <u>this is not allowed under the Module B for RED</u>

- Not providing sufficient unique details in the NB evaluation procedures; restating the Directive requirement is not sufficient

Current NBs for the New Directives

- European Commission publishes lists of NBs

  - [NANDO list of NBs for new EMC Directive](#)

  - [NANDO List of NBs for the new RED](#)

Japan-US

Japan-US MRA Timeline

Timeline and Status
February 2007 – Japan-US MRA Signed
November 2010 – NIST begins to accept U.S. CB applications
March 2011 – First 2 RCBs from U.S. are recognized by MIC
Today – 6 U.S. RCBs are recognized by MIC (1 new in 2017)
American Certification Body, Inc. (ACB, Inc.) Bay Area Compliance Laboratories, Corp. (BACL) Curtis-Straus, LLC MiCOM Labs SIEMIC, Inc. UL Verification Services, Inc.

RCB – NIST Criteria for Designation

- NIST Criteria for Designation
  - Published Document: *Criteria for Designation of U.S. Conformity Assessment Bodies under the U.S.-Japan Mutual Recognition Agreement* – Oct. 1 2012 (V2)
- Covers
  - Scope of the MRA
  - Applicable Laws and Ordinances
  - Test Methods Notified by MIC
  - Requirements for U.S. CAB Designation
  - Application Checklist
  - Excerpts of Information on Affidavit
  - Excerpts on Technical and Educational Requirements for the Radio Law
  - Information on Additional Resources

RCBs – Accreditation Requirements

The U.S. RCB must

- Be accredited to ISO/IEC 17065 (by September 15, 2015) for one or more US-Japan MRA scopes and must:
  - Have expert knowledge in Japan's laws, ordinances, technical regulations, and administrative requirements
  - Meet educational and experience requirements for personnel
  - Demonstrate the capability to access MIC requirements and obtain English translations

RCBs - Laboratory & Test Method Requirements

The U.S. RCB must

- Have an ISO/IEC 17025 lab that is accredited for
  - For relevant MIC test methods; or
  - For test methods that are equal to or surpass the MIC test methods
    - Procedures for determining equivalency
    - Maintain records of equivalency determination
- Contractual arrangements with other labs are acceptable
- Maintain procedures for acceptance of test data from other labs

RCBs – Designation & Recognition Processes

- NIST **reviews** all documents submitted and prepares
  - Designation letter, Nomination form
  - Joint Committee Decision form
- NIST **designates** CAB – all documents are sent to MOFA & MIC
- MIC **recognizes** CAB as RCB and notifies NIST
  - Publication in Gazette
  - RCB number assigned
- NIST confirms recognition to RCB
- NIST provides the Excel Spreadsheet for periodic reporting of certified products
- RCBs must address any market surveillance issues
- RCBs get reassessed every two years

Review

- The Designating Authority serves as a bridge between the CB, AB and Regulator

- The Regulator determines the level of the DA's involvement in reviewing supporting CB documents

- All parties (CBs, ABs and DA) can improve in their roles when they have access to up-to-date comprehensive Regulator Scheme Documents that clearly identify all the requirements that must be met

Most Important Goal

Compliant product placed
on the market in a timely manner

Questions?

Thank you.

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Questions about MRAs
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