Understanding the Types of Reference Materials, Their Differences, and Their Uses

Matthew Sica
Technical Program Manager

Who Are We?

Perry Johnson Laboratory Accreditation is cross-sector accreditation body recognized in the areas of testing, calibration and medical laboratories, inspection bodies, reference material producers and proficiency test providers

ISO/IEC 17025

ISO/IEC 17020

ISO 15189

ISO/IEC 17043

ISO 17034

Governmental/
Industry Schemes

TESTING

Comparison of known to determine an unknown

REFERENCE MATERIAL

- Generic Term
- Various Forms
- Various Uses

Definitions

- **RMs**
  - Homogenous
  - Fit for use
  - Product Info Sheets
- **CRMs**
  - Characterized
  - Certificate
  - Associated Uncertainty
  - Metrologic Traceability

Forms of Reference Materials

Pure Substances

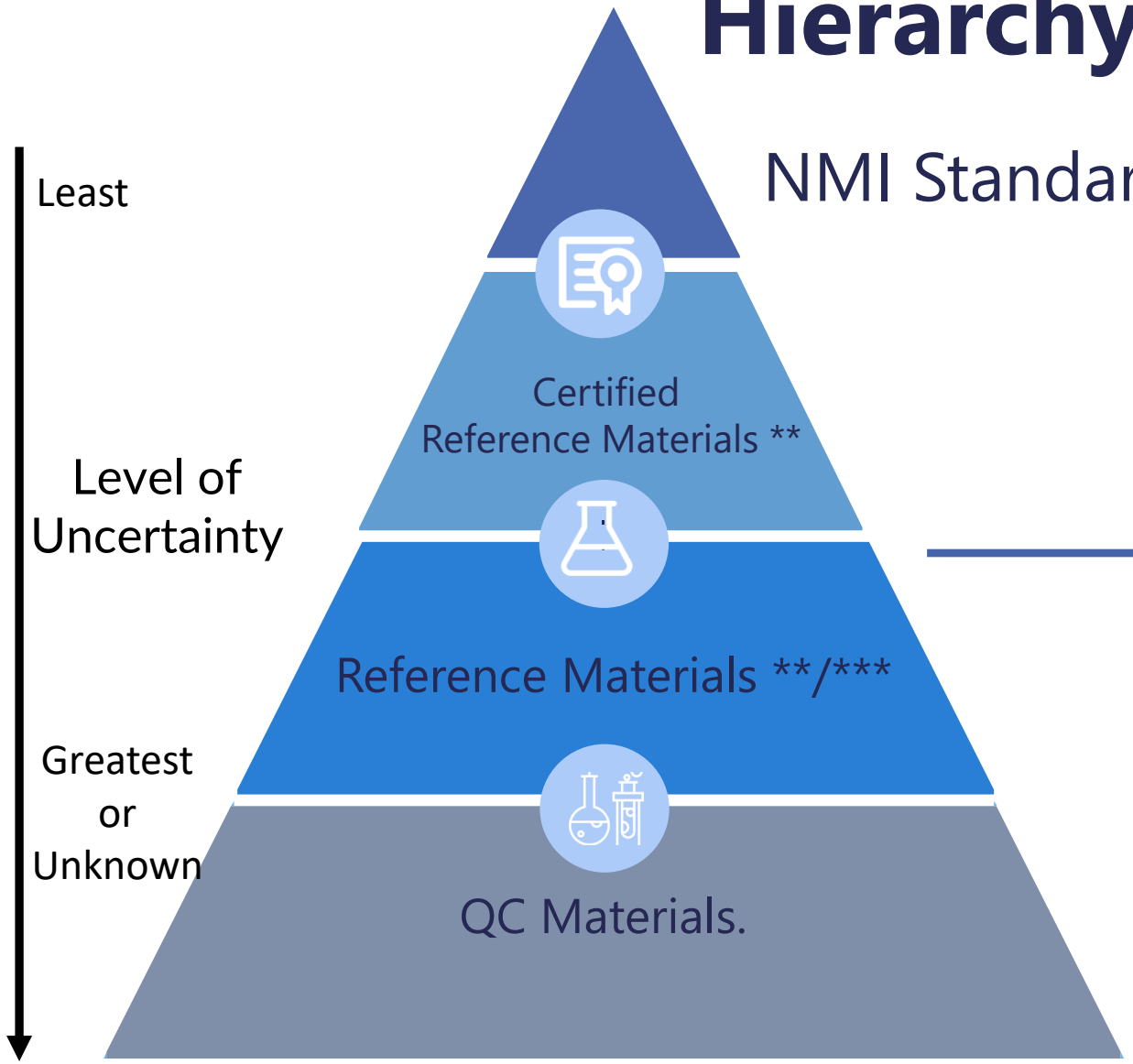
Standard solutions or gases

Matrix Reference Materials

Physical/Chemical Reference Materials

Reference Objects/ Artifacts

Hierarchy of Reference Materials



Metrological Traceability

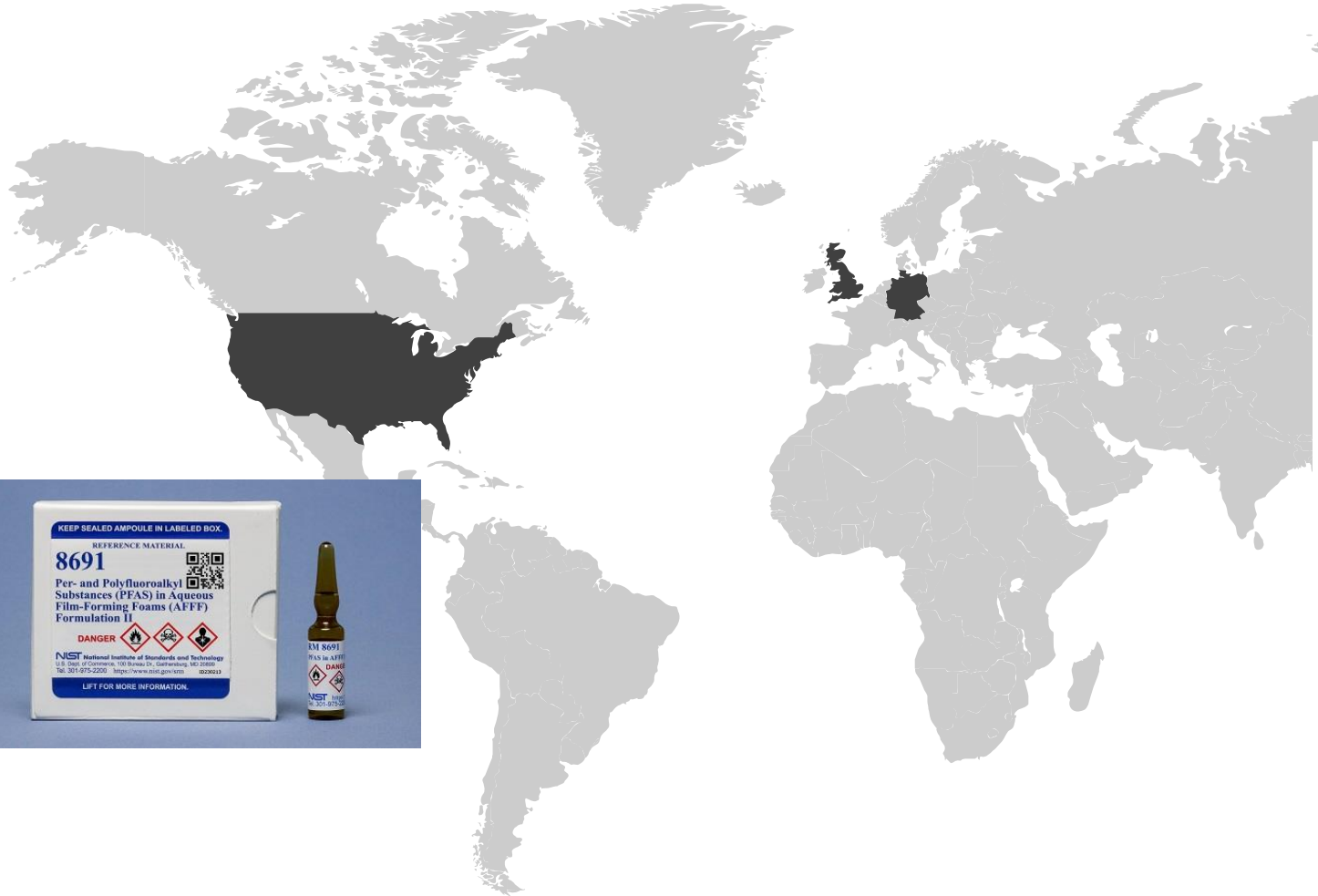
Yes

No

** Accredited Providers

*** Competent Producers

NMI Primary Standards



JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFICATE OF ANALYSIS

ERM®- EC681m

LOW-DENSITY POLYETHYLENE

	Mass Fraction		
	Uncertainty [2]	Unit
	1.2	mg/kg
	0.08	g/kg
	5	mg/kg
	0.06	g/kg
	1.9	mg/kg
	0.8	mg/kg
	2.5	mg/kg
	0.10	g/kg
	7	mg/kg
	6	mg/kg
	0.04	g/kg

lards of accuracy. The given values represent the unweighted ach set being obtained in a different laboratory and/or with a nd its uncertainty are traceable to the International System of

ertified value with a coverage factor $k = 2$ corresponding to a dance with ISO/IEC Guide 98-3, Guide to the Expression of

ıg for Cl and 60 mg for all other elements.

gned:

Prof. Dr. Hendrik Emons
European Commission
Joint Research Centre
Institute for Reference Materials and Measurements
Retieseweg 111
B-2440 Geel, Belgium

All following pages are an integral part of the certificate.
ERM®-EC681m
Page 1 of 3

National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material® 914b

Creatinine

This Standard Reference Material (SRM) is certified as a neat chemical material of known purity. It is intended to be used as a primary measurement standard for calibration of clinical measurement laboratory procedures to determine quantities of creatinine. A unit of SRM 914b consists of 10 g of high-purity crystalline creatinine.

Certified Creatinine Mass Fraction: 99.9 % ± 0.1 %

A NIST certified value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been investigated or taken into account [1]. The measurand is the mass fraction of creatinine (expressed as percent) [2] and the uncertainty is expressed as the 95 % confidence interval ($U_{95\%}$) [3,4]. Metrological traceability of the certified value is to the SI through practical realization of measurement units for specific amount of substance (mol/g) and mass fraction (%). The certified value was determined using a quantitative ^{1}H nuclear magnetic resonance spectroscopy (^{1}H-qNMR) primary ratio measurement procedure [5,6].

Expiration of Certification: The certification of **SRM 914b** is valid, within the measurement uncertainty specified, until **31 May 2028**, provided the SRM is handled and stored in accordance with the instructions given in this certificate (see "Instructions for Storage and Use"). The certification is nullified if the SRM is damaged, contaminated, or otherwise modified.

Maintenance of SRM Certification: NIST will monitor this SRM over the period of its certification. If substantive technical changes occur that affect the certification, NIST will notify the purchaser. Registration (see attached sheet or register online) will facilitate notification.

Overall direction and coordination of the technical activities were under the chairmanship of M.A. Nelson of the NIST Chemical Sciences Division.

Analytical measurements at NIST were performed by M.A. Nelson of the NIST Chemical Sciences Division and C. Salazar Arzate of Centro Nacional de Metrología (CENAM), México.

Statistical analysis was provided by B. Toman of the NIST Statistical Engineering Division.

Support aspects involved in the issuance of this SRM were coordinated through the NIST Office of Reference Materials.

Carlos A. Gonzalez, Chief
Chemical Sciences Division

Steven J. Choquette, Director
Office of Reference Materials

Gaithersburg, MD 20899
Certificate Issue Date: 21 November 2018

PJLA

Perry Johnson Laboratory Accreditation, Inc.

Reference Materials

Fit for intend use

Homogenous

Stable

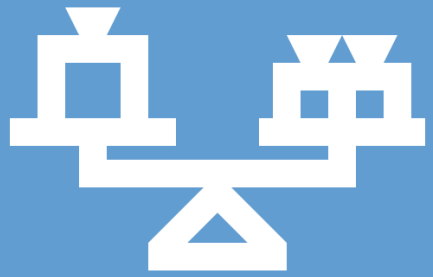
May or may not be Accredited

Features of RMs

- Property value, may be assigned through preparation
- Product Information Sheet
- ISO 17034 accredited or competent provider
  - May or may not be tested
  - No certified value
  - No uncertainty statement
  - No metrological traceability

Certified Reference Materials

Characterized by Metrologically Valid Procedures

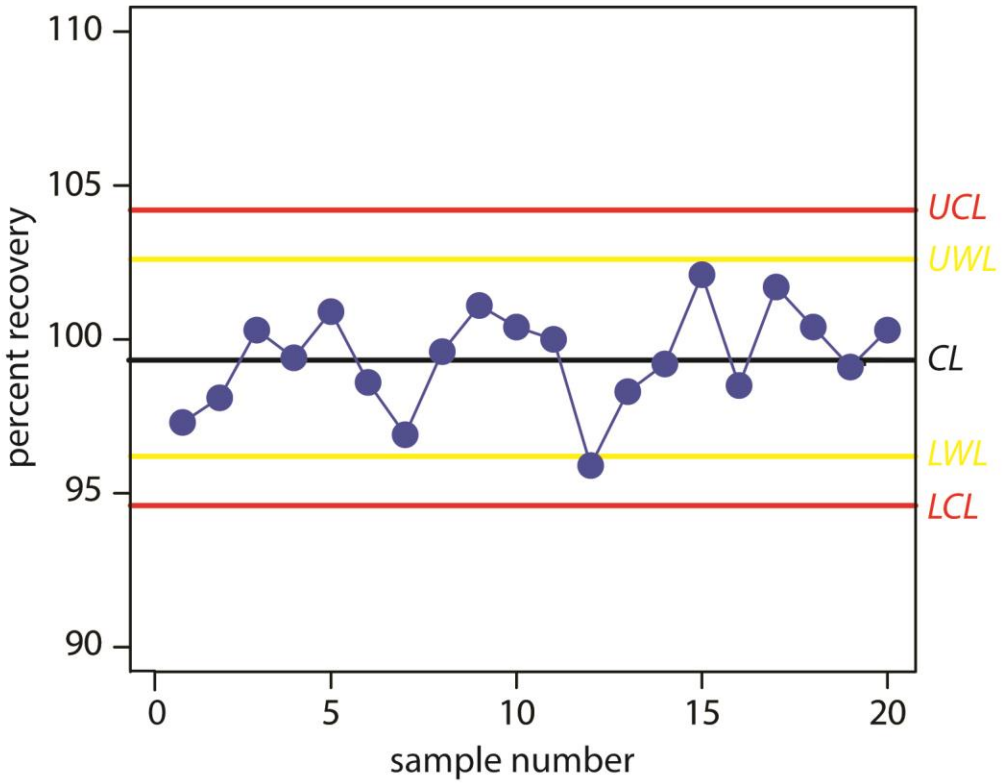


Metrologic Traceability

Associated Uncertainty

Accredited Producer

Quality Control Materials



Uncharacterized RM

- No property value
- Focus on preparation
- Fit for purpose

Features of QCMs

- Prepared in lab from stock chemicals
  - Weight/Volume prep
  - Volume/Volume prep
- Prepared from in-house materials
  - Matrix (in lab)

  - No certified value
  - No uncertainty statement
  - No metrological traceability

Summarizing Types

RMs

NMI Standards | CRMs | RMs | QCMs

National Metrology Institutes → Accredited Producers → Accredited Producers or Competent Producers → In-house Materials

Most Characterized

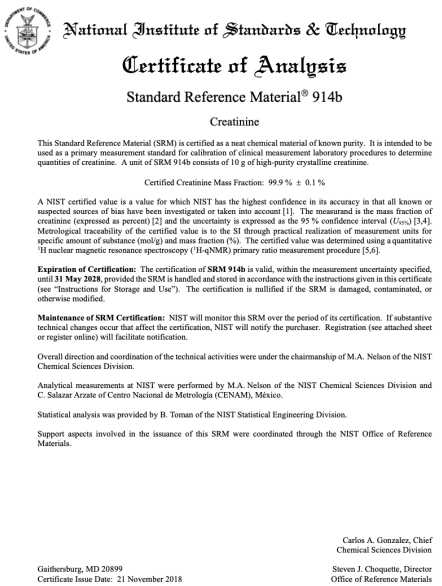
Least Uncertainty

Least Characterized

Greatest Uncertainty

What information is available

Property	NMI	CRM	RM	QCM
Identity	Yes	Yes	Yes	Yes
Content	Yes	Yes	Yes, but	Maybe, but
Homogeneity	Yes	Yes	No	No
Stability	Yes	Yes	No	No
Uncertainty	Yes	Yes	No	No
Traceability	Yes	Yes	No	No



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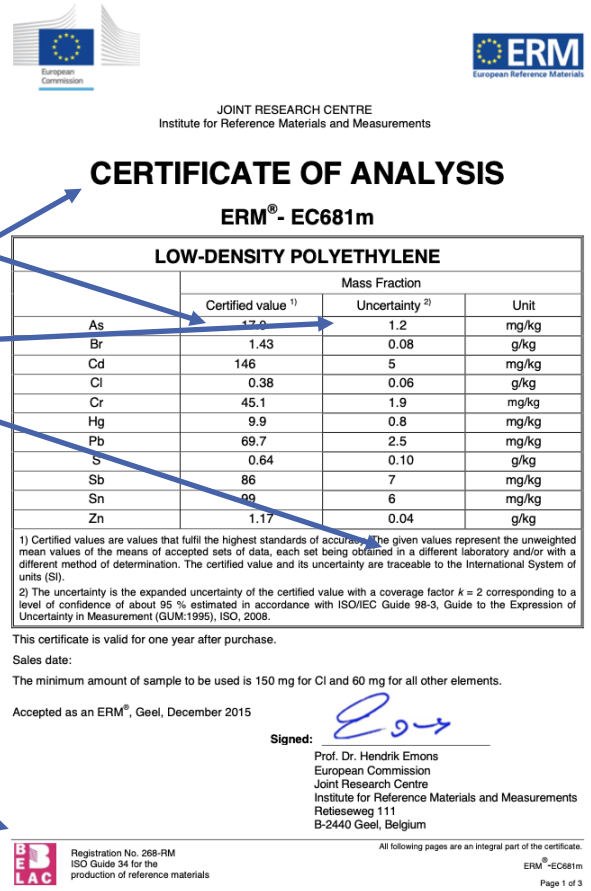
Carlos A. Gonzalez, Chief
Chemical Sciences Division

Gaithersburg, MD 20899
Certificate Issue Date: 21 November 2018

Steven J. Choquette, Director
Office of Reference Materials

Features of CRM Certificate

- Certified value (at least one)
- Metrological traceability
- Statement of Uncertainty
- Certificate (CRM Certificate)
- ISO 17034 (ISO Guide34)* accredited provider



JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFICATE OF ANALYSIS

ERM®- EC681m

LOW-DENSITY POLYETHYLENE

	Mass Fraction		
	Certified value [1]	Uncertainty [2]	Unit
As	17.9	1.2	mg/kg
Br	1.43	0.08	g/kg
Cd	146	5	mg/kg
Cl	0.38	0.06	g/kg
Cr	45.1	1.9	mg/kg
Hg	9.9	0.8	mg/kg
Pb	69.7	2.5	mg/kg
S	0.64	0.10	g/kg
Sb	86	7	mg/kg
Sn	99	6	mg/kg
Zn	1.17	0.04	g/kg

1) Certified values are values that fulfil the highest standards of accuracy. The given values represent the unweighted mean values of the means of accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The certified value and its uncertainty are traceable to the International System of units (SI).

2) The uncertainty is the expanded uncertainty of the certified value with a coverage factor $k = 2$ corresponding to a level of confidence of about 95 % estimated in accordance with ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 150 mg for Cl and 60 mg for all other elements.

Accepted as an ERM®, Geel, December 2015

Signed:

Prof. Dr. Hendrik Emons
European Commission
Joint Research Centre
Institute for Reference Materials and Measurements
Retieseweg 111
B-2440 Geel, Belgium

Registration No. 268-RM
ISO Guide 34 for the
production of reference materials

All following pages are an integral part of the certificate.
ERM®-EC681m
Page 1 of 3

* Based on Product Expiry

Putting it together

EPA 200.8

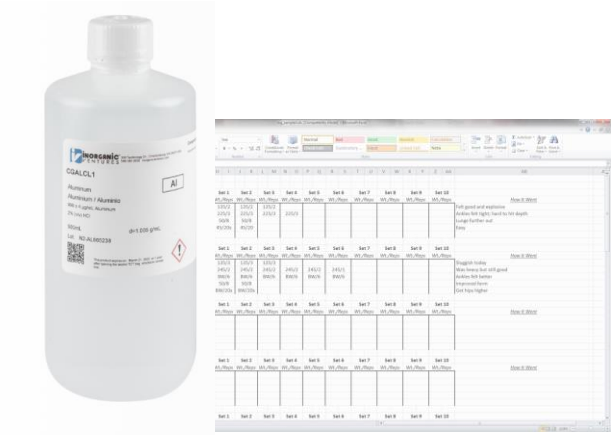
7.3 Standard Stock Solutions - Stock standards may be purchased from a reputable commercial source or prepared from ultra high-purity grade chemicals or metals (99.99-99.999% pure). All salts sh[illegible] otherwise specified. Stock solutio[illegible] stock standards when succeeding c[illegible] stock standards can not be verified [illegible]

7.3.1 Aluminum solution, stock 1 mL = 1000 µg Al: Pickle aluminum metal in warm (1+1) HCl to an exact weight of 0.100 g. Dissolve in 10 mL conc. HCl and 2 mL conc. nitric acid, heating to effect solution. Continue heating until volume is reduced to 4 mL. Cool and add 4 mL reagent grade water. Heat until the volume is reduced to 2 mL. Cool and dilute to 100 mL with reagent grade water.

QCM

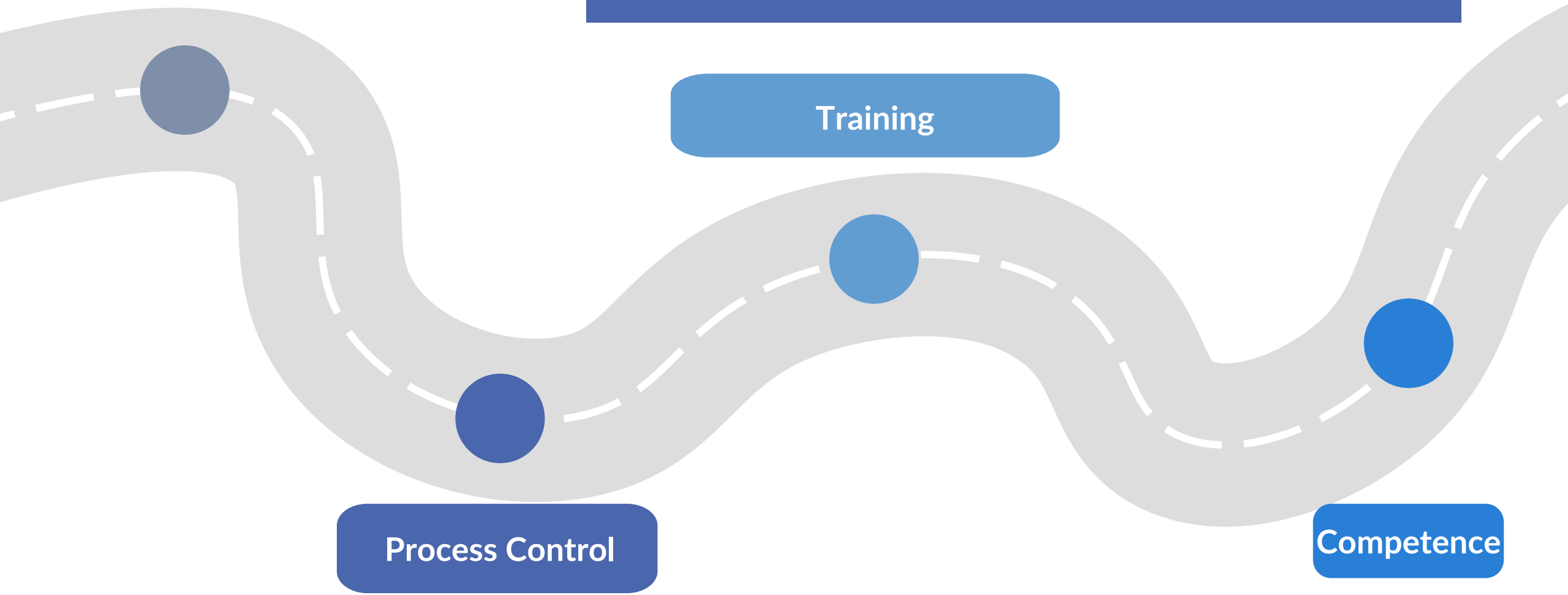
RM

CRM

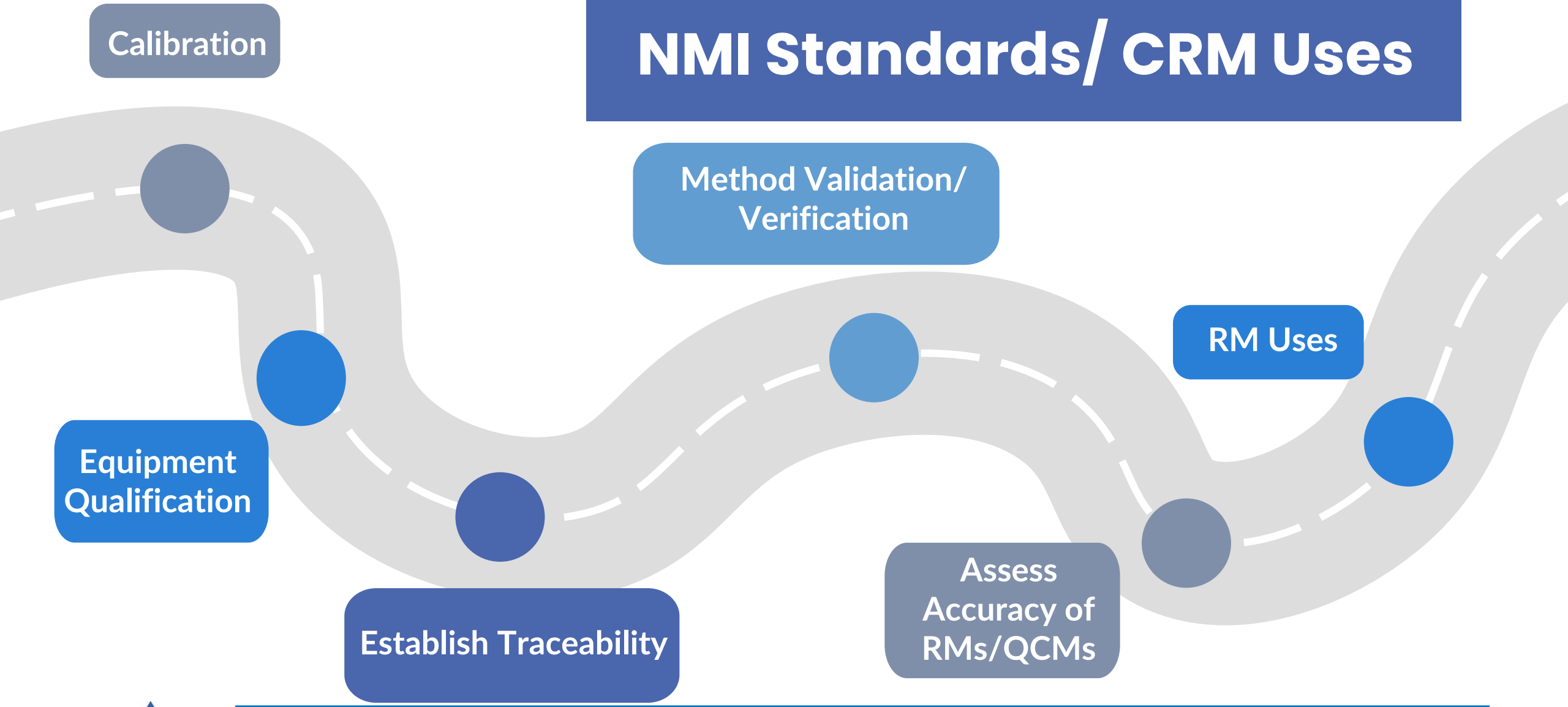


RM/QCM Uses

Method Development / Method Optimization



NMI Standards/ CRM Uses



Summary

NMI Standards

CRMs

Certificate
Characterized
Associated Uncertainty
Metrologic Traceability

Establish Traceability
Calibration
Method Val/Ver
Equipment Qual
Assess Quality of RMs/QCMs

RMs

Homogenous
Fit for use
Product Info Sheets

Method Dev/Opt
Process Control
Training
Competence

QCMs

Lab Prepared
Fit for use

QUESTIONS?

How to Keep In Touch With Us

755 West Big Beaver Road, Suite 1325
Troy, Michigan 48084
1-877-369-5227

Matthew Sica
Technical Program Manager
msica@pjlabs.com

www.pjlabs.com