United States Transuranium and Uranium Registries
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Data Quality Objectives Supporting U.S. Transuranium and Uranium Registries Mission

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SAC Meeting 2020: *Recommendation #4*

The SAC is pleased with the progress made in creating a Data Quality Assurance Plan (DQAP) to guide USTUR operation. The SAC urges the completion of the DQAP at the earliest possible date. Consideration should be given to

(a) measurement of all analytes/matrices performed both on-site and off-site,

(b) Measurement Quality Objectives (accuracy, precision, sensitivity, selectivity, and completeness) linked to the DQAP decision needs,

(c) quality tolerance limits for different quality measurement parameters linked to various Measurement Quality Indicators, and

(d) data verification and validation objectives and practices to verify that Measurement Quality Objectives are met.

USTUR Mission: *Statement of the Problem*

The USTUR's mission is to:

- Follow up occupationally-exposed individuals (volunteer Registrants) by studying the biokinetics (deposition, translocation, retention, and excretion) and tissue dosimetry of uranium and transuranium elements, such as plutonium, americium, curium, and neptunium
- Obtain, analyze, preserve, and make available for future research, materials from individuals who had documented intakes of uranium and transuranium elements
- Apply USTUR data to refine dose assessment methods in support of reliable epidemiological studies, radiation risk assessment, and regulatory standards for radiological protection of workers and the general public

The goal of this DQO report is to determine an optimal tissue sample collection and data analysis techniques to meet mission statement objectives

Goal of the DQO: *Principal Study Questions*

1. Tissue samples

   What tissue samples are collected at the autopsy?

2. Activities

   For the radionuclide of concern for a particular case, what are the activities in dosimetrically important organs and tissues?

3. Uncertainties

   What is an acceptable relative uncertainty in USTUR activity measurements?

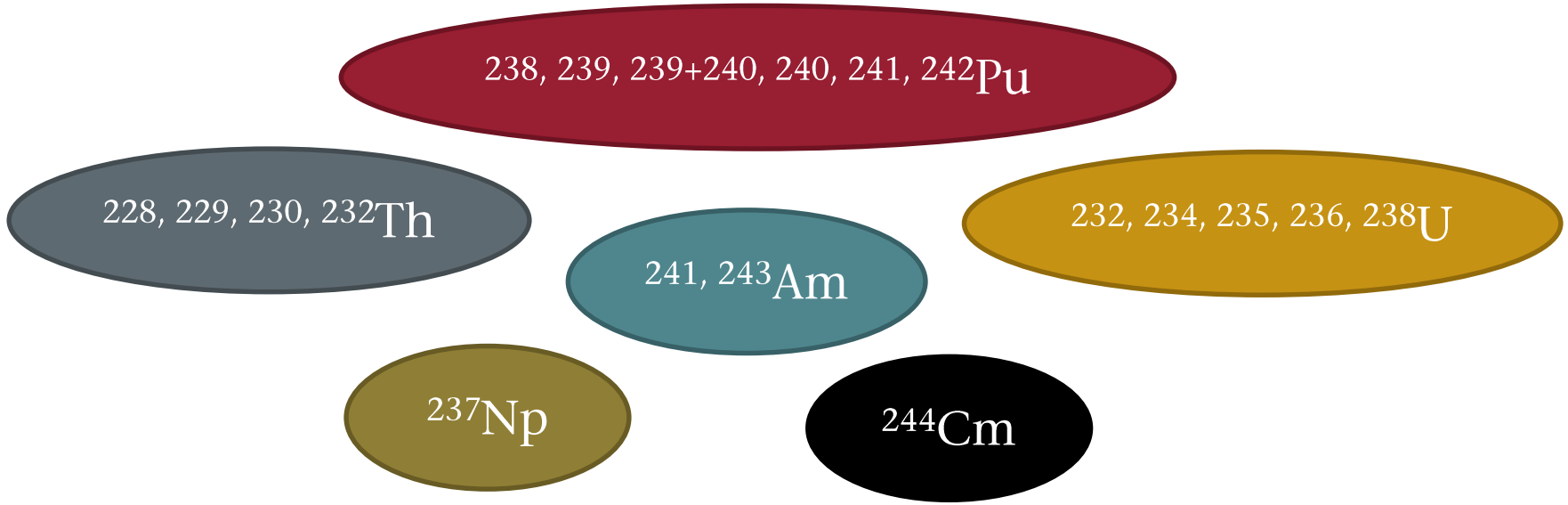
DQO Document Overview: *Updates*

- The goal of the DQO was revised to redefine study questions geared towards tissue collection, activities, and uncertainties
- Sample collection inputs include masses, tracking, radiochemical analysis on-site and off-site
- Measurement Quality Objectives (MQO)
- Laboratory performance indicators and tolerance limits
- Quality control limits, tolerance limits, and DQ acceptance criteria
- Assessment: verification, validation, and quality assessment

Measurement of Analytes & Matrices

- Sample processing: on-site, off-site

- Radiochemical analysis: on-site, off-site



Measurement Quality Objectives

Measurement results and the combined standard uncertainty of the measurement results are the principal products of USTUR's radiochemistry laboratory

Measurand – the quantity intended to be measured

- True but unknown activity in the USTUR tissue, organ or other sample

Laboratory Performance Indicators

- Critical Value
- *MDA* (minimum detectable amount)
- $MQA_{10\%}$ (minimum quantifiable amount with relative uncertainty u_R = 10%)
- Evaluation of uncertainties

MQOs:

- Accuracy
- Precision
- Representativeness
- Completeness
- Sensitivity

Evaluating Activity on a Planchet

Using 74 Bq activity threshold for becoming a USTUR Registrant as a starting point

- through inhalation and/or wounds
- various chemical forms of the principal radionuclides

The ideal objective:

- ensure that the predicted activity on a planchet for an intake of ≥74 Bq 50 years earlier can be detected with 10% relative uncertainty under realistic conditions

Tolerance Limits: *Predicted MDA & MQA*

- N_B = 15 counts in 300,000s assumed (background tolerance limit)

MDA = 0.44 mBq

Radio-nuclide	Tissue or organ	Systemic uptake	Inhalation	
			Nitrate	Dioxide
Pu-239	Lungs			
Pu-239	Liver			
Pu-239	Skeleton			
Pu-239	Other soft tissues			
Am-241	Lungs			
Am-241	Liver			
Am-241	Skeleton			
Am-241	Other soft tissues			

MQA = 3.7 mBq

Radio-nuclide	Tissue or organ	Systemic uptake	Inhalation	
			Nitrate	Dioxide
Pu-239	Lungs			
Pu-239	Liver			
Pu-239	Skeleton			
Pu-239	Other soft tissues			
Am-241	Lungs			
Am-241	Liver			
Am-241	Skeleton			
Am-241	Other soft tissues			

$f \geq 1.0$	$0.5 < f < 1.0$	$f \leq 0.5$

- f is $A_{50,predicted}$ / *MDA* or $A_{50,predicted}$ / $MQA_{10\%}$
- Green: meets *MDA* or $MQA_{10\%}$ criterion
- Yellow: within a factor of 2 below *MDA* or $MQA_{10\%}$ criterion
- Pink: "technology shortfall," more than 2× below *MDA* or $MQA_{10\%}$ criterion

MQO Justification

Uncertainty increases with decreasing activity on a planchet

- $u_R(Activity) \approx 35\%$ at the *MDA*

For

$N_B = 15$ counts

$t_B = 300{,}000$ s

$t_S = 150{,}000$ s

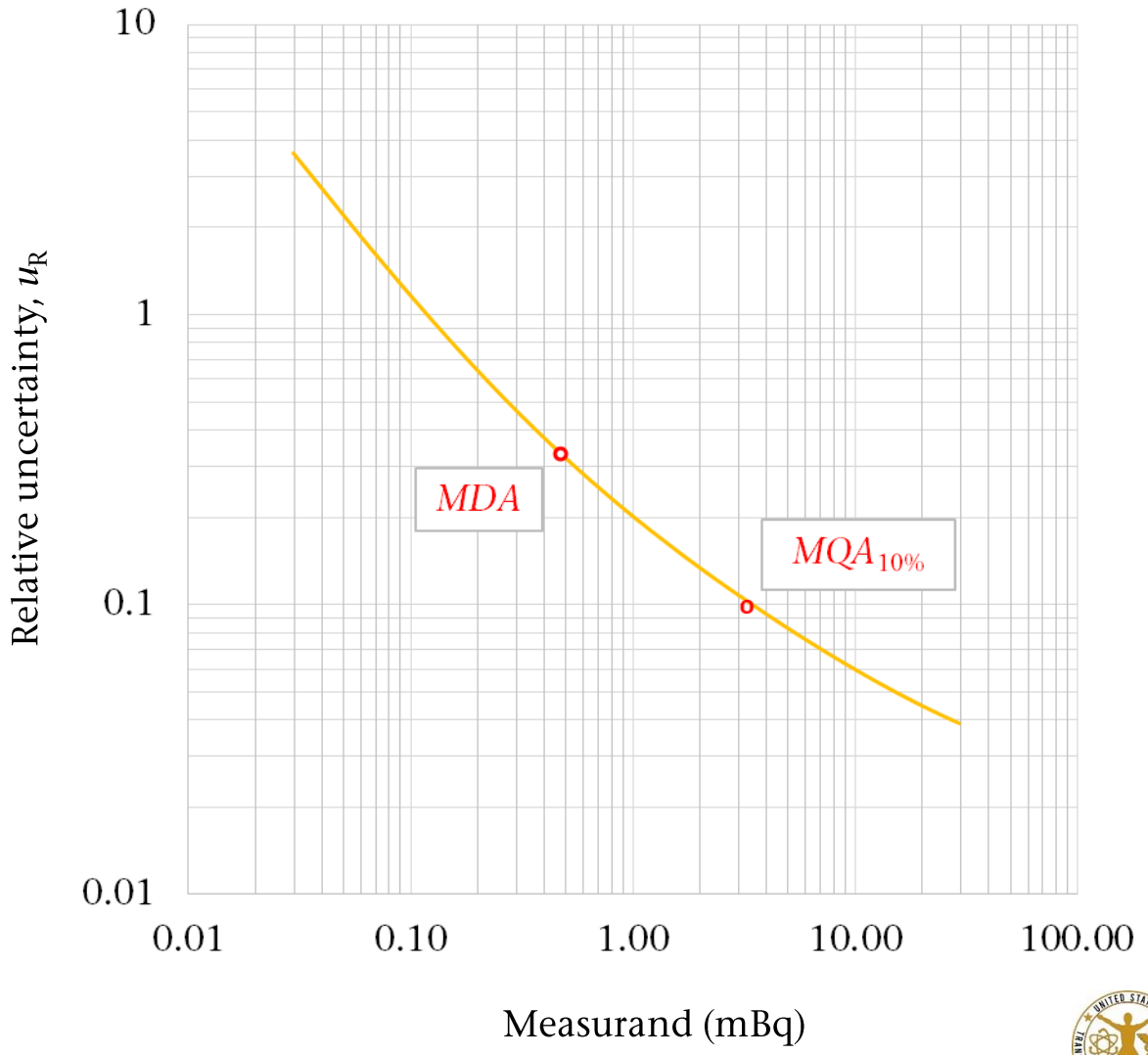
$\varepsilon = 0.25$

$f_{X,ROI} = 1$

$y_{RR} = 0.9$

the $MDA = 0.44$ mBq

the $MQA_{10\%} \sim 3.7$ mBq



An Achievable MQO

- More practical MQO is that the expected activity on a planchet should be greater than the *MDA*, rather than the *MQA* (Sensitivity MQO):

$$A_{\text{planchet}}(\text{radionuclide, chemical form, organ, route of intake}) \geq MDA(\text{radionuclide})$$

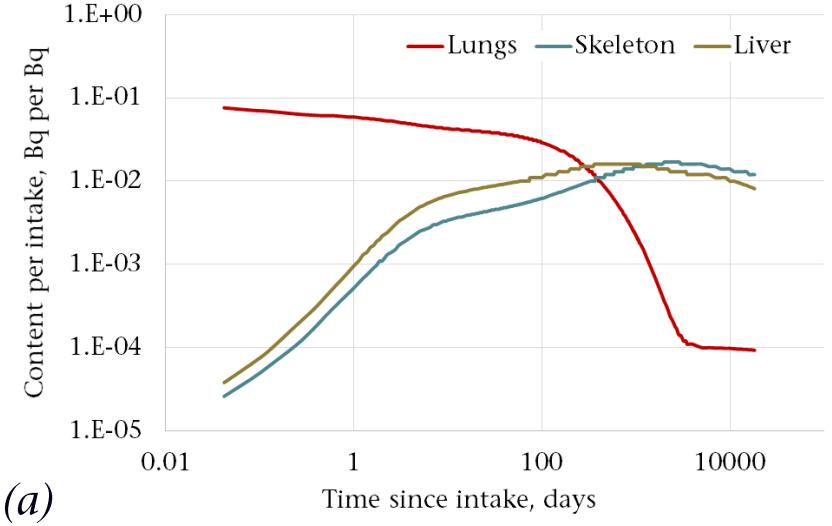
- There will be about 35% combined standard relative uncertainty rather than 10% using the $MQA_{10\%}$

Technology Shortfall

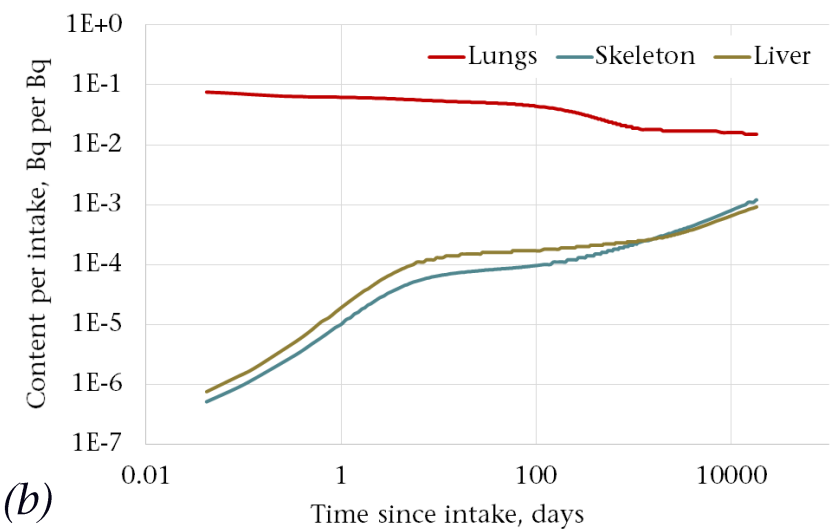
Most registrants have intakes that are sufficiently high that material can be detected in many tissues, with some notable exceptions

- 50 years after an inhalation intake of plutonium nitrate, less than 1/1000th of the initial activity in the lung remains
- Technology shortfall is not often encountered because most Registrants had intakes that exceeded 74 Bq

Tissue or organ content over time following 1 Bq inhalation intake of 5-µm ^{239}Pu nitrate (a) and oxide (b) aerosols



(a)



(b)

Managing Technology Shortfall

At least four approaches can be taken to manage technology shortfall:

- Increasing α-spectrometry counting time
- Using mass spectrometry technique
- Combining eluates from several sab-samples
- Combining counts from several sub-samples of a tissue or organ

  Lung lobes: superior, middle, inferior

  Combining counts reduces uncertainty by 40% in a typical case

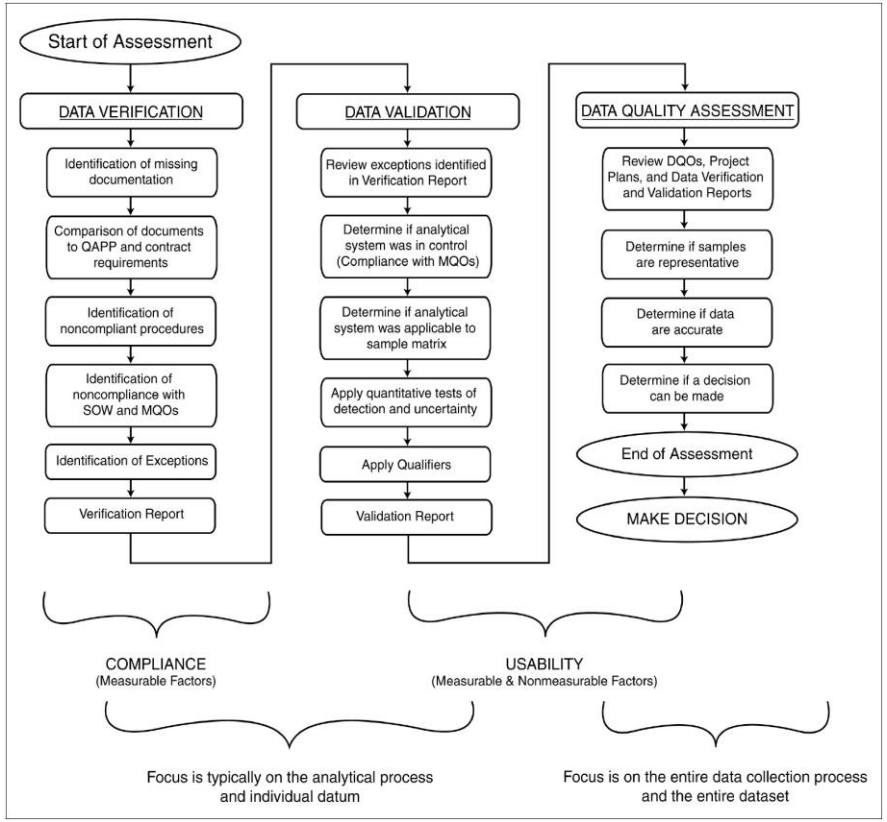
	Mass (g)	N_B	N_S	R_B (Ms^{-1})	R_S (Ms^{-1})	R_N (Ms^{-1})	$u(R_N)$	$u_R(R_N)$
Lung: superior lobe	96.03	5	9	20.0	66.7	46.7	20.5	44.0%
Lung: middle lobe	66.84	5	11	20.0	80.0	60.0	22.6	37.7%
Lung: inferior lobe	104.56	3	12	13.3	86.7	73.3	23.1	31.5%
All 3 lobes	267.43	13	32	46.7	220.0	173.3	39.2	22.6%
Approximate factor by which uncertainty in $u_R(R_N)$ is reduced:								1.6703

Verification, Validation, and Quality Assessment

MARLAP's data assessment steps applied to the USTUR DQO document

Future Work

- Accuracy and precision MQO based on 740 Bq (20 nCi) criterion, or similar
- Development of reporting templates
  - ✓ Data verification
  - ✓ Data validation
- USTUR 800: Quality Assurance Procedure



MARLAP Fig. 8-1

Thank you!