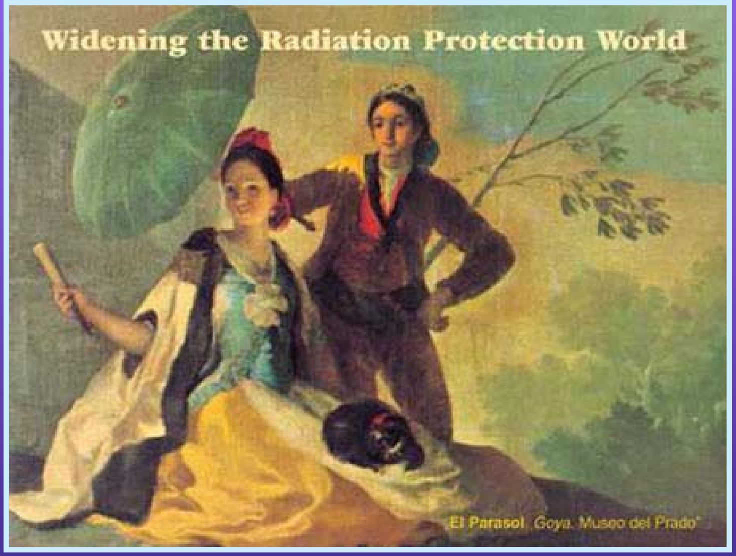
International Radiation Protection Association
11th International Congress
Madrid, Spain - May 23-28, 2004



RC-6a

Quality Assurance and the Evaluation of Uncertainties in Environmental Measurements

Dra. Lourdes Romero González

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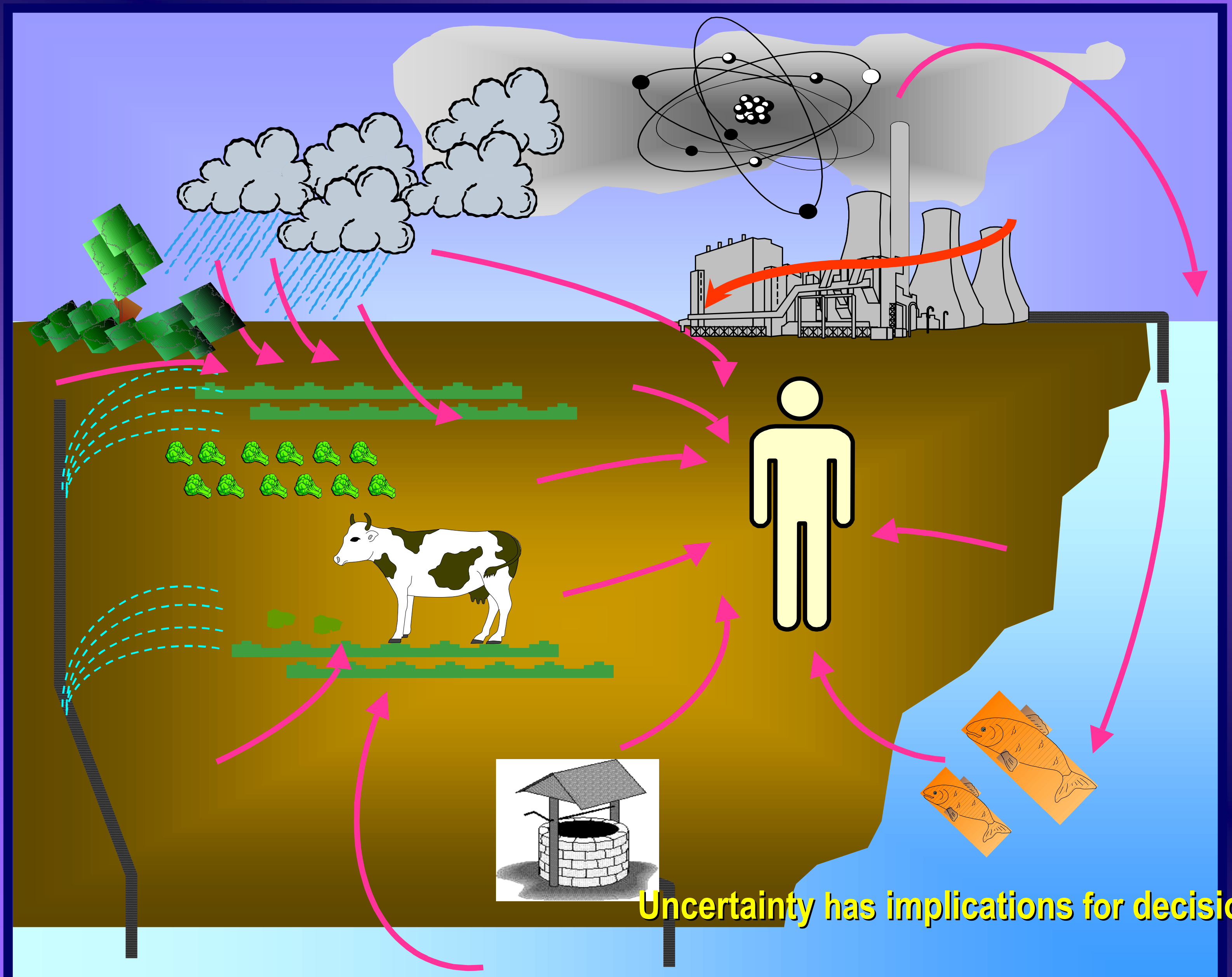
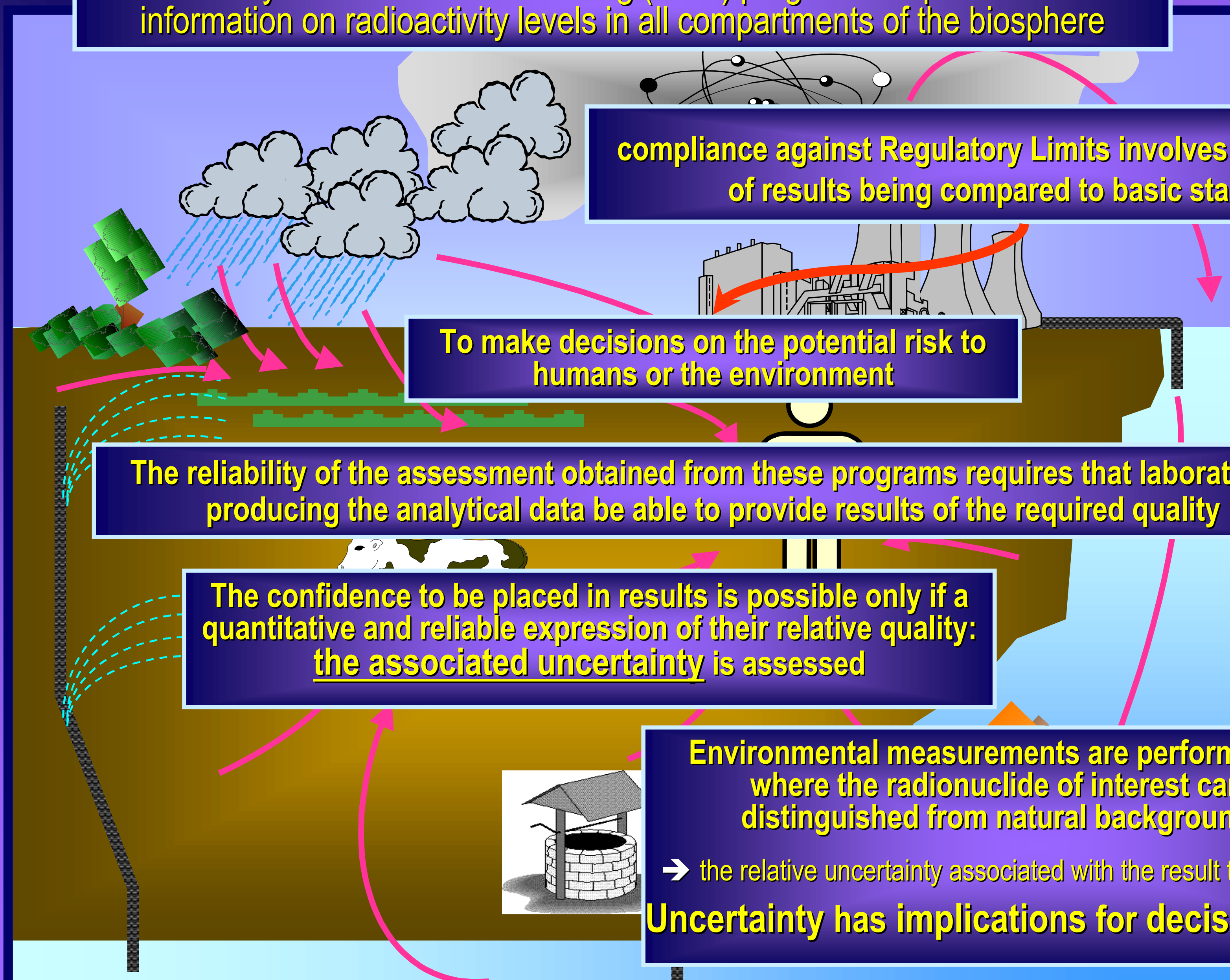
Introduction



Uncertainty has implications for decision purposes

Introduction

Radioactivity environmental monitoring (REM) programmes provide relevant information on radioactivity levels in all compartments of the biosphere



compliance against Regulatory Limits involves large number of results being compared to basic standards

To make decisions on the potential risk to humans or the environment

The reliability of the assessment obtained from these programs requires that laboratories producing the analytical data be able to provide results of the required quality

The confidence to be placed in results is possible only if a quantitative and reliable expression of their relative quality: the associated uncertainty is assessed

Environmental measurements are performed at levels where the radionuclide of interest cannot be distinguished from natural background levels

➔ the relative uncertainty associated with the result tends to increase

Uncertainty has implications for decision purposes

Introduction

The user of the data reported by a laboratory should be aware that the information provided by measurement can rarely assumed to be complete

Laboratories are increasingly requested to demonstrate not only the quality of their results, but their *fitness for purpose* by giving a measure of the confidence that can be placed on the result

the **MEASUREMENT UNCERTAINTY**

Over the years different uncertainty evaluation procedures have been developed

1993 ISO *Guide to the Expression of Uncertainty in Measurement* (*GUM*)

- established general rules for evaluating and expressing uncertainty in measurement
- promotes the achievement of international harmonization for stating formally measurement results
- making possible international comparability

1995 EURACHEM *Quantifying uncertainty in analytical measurement*
application of the concepts in the GUM to analytical measurement

many of the opinions and recommendations here expressed are the outcome of multiple review and discussions within the Working Group

GTINC

Spanish WG for the study of Uncertainties in REM sponsored by the CSN (Regulatory Body)
from which the author is the coordinator

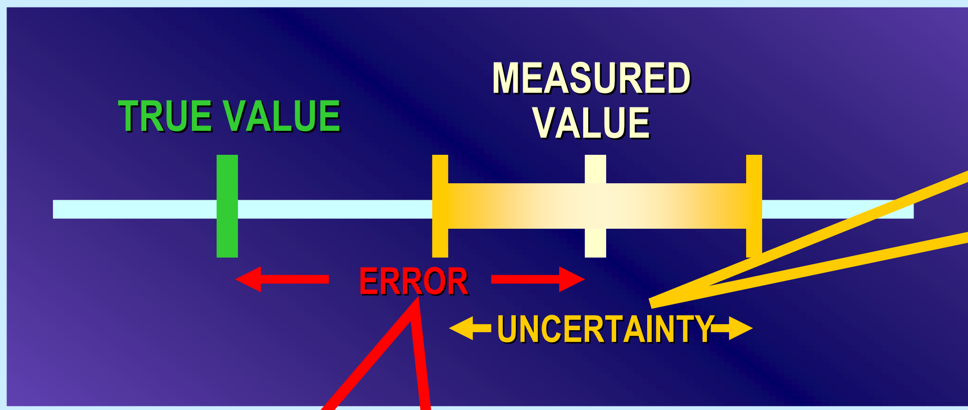
a short review of the principles and recommendations from these documents applied to Radioactive Measurements

Criteria and Recommendations for Radioactive Determinations
in compliance with
MARLAP, ISO 11843 and ISO 11929 series

Measurement uncertainty *Concepts and definitions*

any measurement result is in general a *point estimate* of the measured quantity (**measurand**)

which true value remains unknown

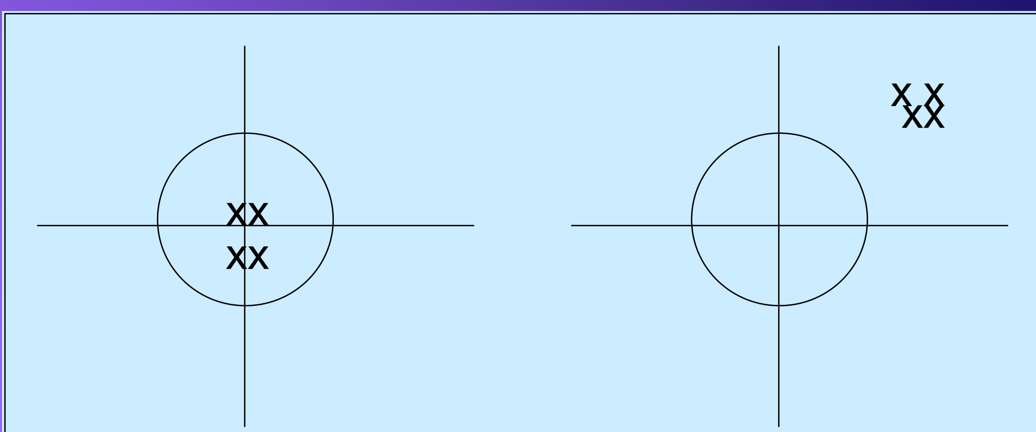


Uncertainty *of measurement* (VIM)
"A parameter associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand"

Error *of the measurement*
the difference between the measured result and the actual value of the measurand

The measured result may vary with each repetition of the measurement

should be considered random variables



Accurate and precise

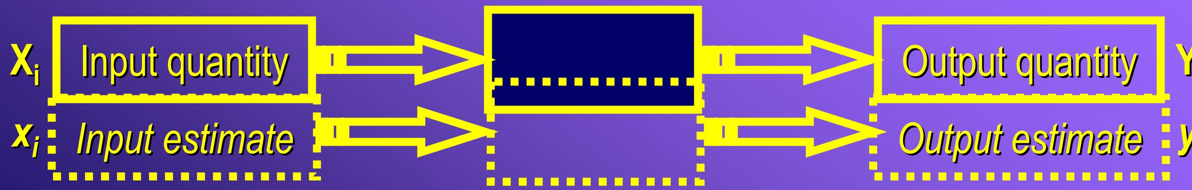
Precise but non accurate

Accuracy
the closeness of the agreement between the result of a measurement and a true value of the measurand
(a measurement is accurate if its error is small)

Precision *(not defined in VIM)*
we take as *"a quantitative indication of the variability of a series of repeatable measurement results"* (Lira,I.,2002)

Measurement uncertainty *Concepts and definitions*

The measurement model



The mensurand **Y** (*output quantity*) depends upon a number N, of *input quantities*, $(X_1,X_2,\ldots X_N)$: $\boldsymbol{Y = f(X_1,X_2,\ldots X_N)}$

When measuring, we get an estimate of **Y** (*output estimate* **y**) obtained from above using *input estimates* $\mathbf{x_i}$:

$$y_i = f(x_1,x_2,\ldots x_N)$$

The **Standard uncertainty of measurement** $\mathbf{u_c(y)}$ associated with the *output estimate* (measurement result **y**) is the standard deviation of the measurand **Y**

- To be determined from the input estimates $\mathbf{x_i}$, and their associated standard uncertainties $\mathbf{u(x_i)}$

The **Expanded uncertainty** **U** provides an interval within which the value of the measurand **Y** is believed to lie with a higher level of confidence

U is obtained by:

$$U = k \cdot u_c(y)$$

➔ The choice of the **coverage factor *k*** is based on the level of confidence desired

➔ for an approximate level of confidence of 95%, the value of ***k*** is 2

The **Combined Standard uncertainty** $\mathbf{u_c(y)}$
(total uncertainty of *y*)
is an estimated standard deviation obtained by combining all the uncertainty components $\mathbf{u(x_i)}$ evaluated using the "Law of propagation of uncertainty"

When the *input quantities* $\mathbf{X_i}$, are uncorrelated $\mathbf{u_c(y)}$, is given by:

$$u_c^2(y) = \sum_{i=1}^{N} \left(\frac{\partial f}{\partial x_i} \right)^2 u^2(x_i)$$

$\mathbf{u(x_i)}$ evaluated by using a TypeA or TypeB methods

➔ When the *input quantities* $\mathbf{X_i}$, are correlated to some degree, the covariance also has to be considered

Measurement uncertainty *Sources*

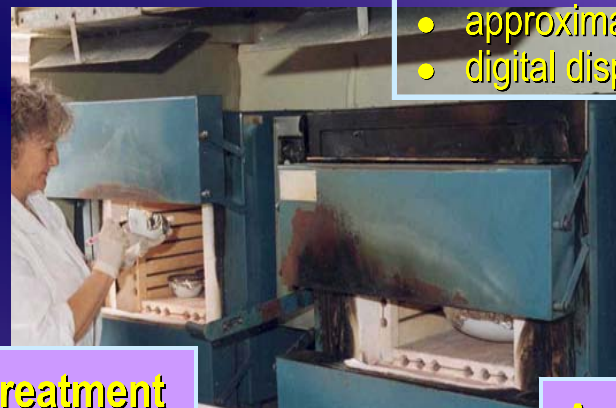
Radioactive determinations

- many analytical techniques are used before measuring
- measurement involves sophisticated instrumentation.
- specific sources due to the random nature of radioactive decay and radiation counting

Some sources are common to any analytical process:

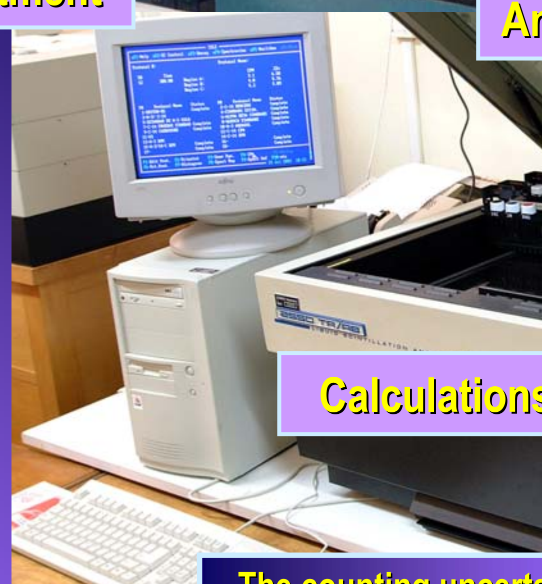
- incomplete definition of the measurand
- sampling, sub-sampling, storage conditions
- matrix effects/interferences, environmental conditions
- masses and volumetric equipment, reference values
- approximations included in the measurement method
- digital displays and rounding, ...

Sampling



Pretreatment

Analyses



Calculations

Measurement

<u>other possible causes</u>

- Radioactive standards
- Radionuclide half-life
- Counting efficiency
- Background
- Radioactive decay
- Source geometry & placement
- Variable instrument backgrounds and efficiencies
- Time measurements in decay & ingrowth calculations
- Instrument dead-time corrections
- Approximation errors in mathematical models
- Published values for half-lives & radiation emission probabilities

The counting uncertainty is the predominant source of uncertainty *at the low activity levels encountered in environmental samples*

Measurement uncertainty *Components*

In estimating overall uncertainty, it may be necessary to treat each source separately to obtain its contribution

- Each of the separate contributions to uncertainty (input estimates) is an **uncertainty component**
  - ➔ when expressed as a standard deviation, is the ***standard uncertainty*** **$u(x_i)$**

Components are grouped into two categories according to the way in which their numerical value is estimated:
Type A or a Type B method of evaluation

- "**Type A**": Uncertainty that is evaluated from the statistical distribution of series of measurements
  - can be characterised by standard deviations, s_i :

  the associated number of degrees of freedom is ν_i,

  and the standard uncertainty $u_i = s_i$

$$s_i = \left|\sqrt{s_i^2}\right|$$

- "**Type B**": Uncertainty evaluated by means *other* than the statistical analysis of a series of observations
  - The standard uncertainty is evaluated by scientific judgement based on all available information on the possible variability of the input quantity: assumed probability distributions based on experience or other information, represented by u_j
  - u_j can be characterised by a corresponding standard deviation:

$$u_j = \left|\sqrt{u_j^2}\right|$$

(since the quantity u_j like a standard deviation, the standard uncertainty is u_j.

Measurement uncertainty *Components*

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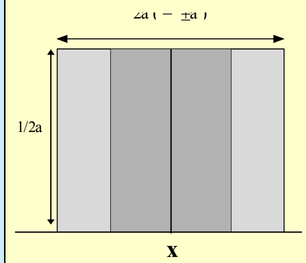
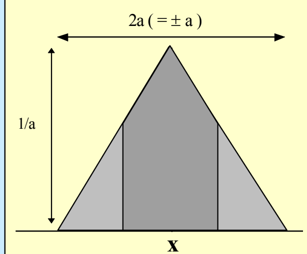
Frequent distributions used for Type B evaluation method

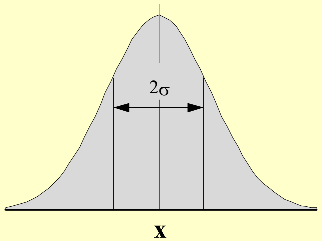
Rectangular distribution

Form	Use when:	Uncertainty
	• A certificate or other specification gives limits without specifying a level of confidence (eg 25ml ± 0.05ml) • An estimate is made in the form of a maximum range (±a) with no knowledge of the shape of the distribution.	$u(x) = \frac{a}{\sqrt{3}}$

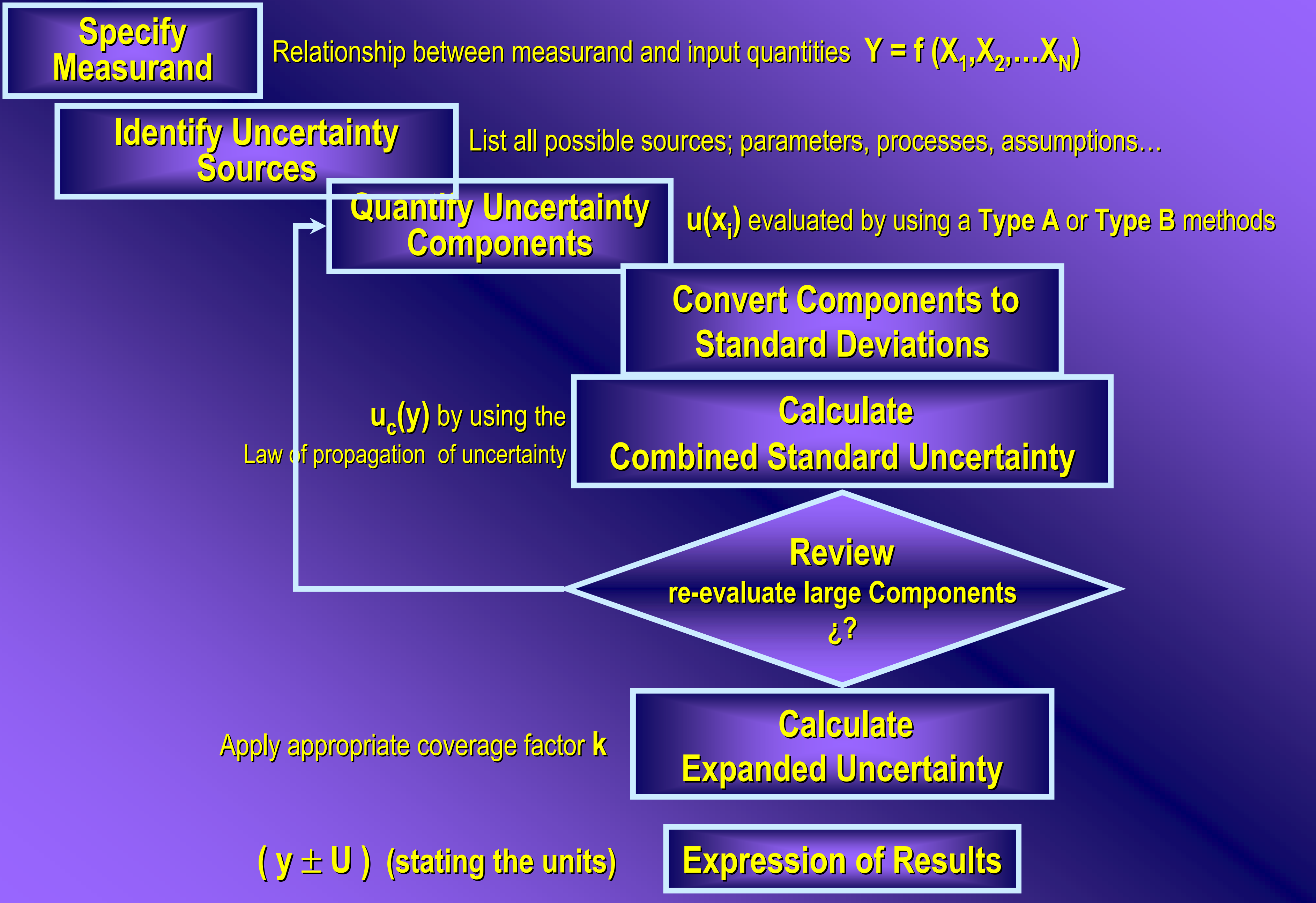
Triangular distribution

Form	Use when:	Uncertainty
	• The available information concerning x is less limited than for a rectangluar distribution. Values close to x are more likely than near the bounds. • An estimate is made in the form of a maximum range (±a) described by a symmetric distribution.	$u(x) = \frac{a}{\sqrt{6}}$

Normal distribution

Form	Use when:	Uncertainty
	• An estimate is made from repeated observations of a randomly varying process. • An uncertainty is given in the form of a standard deviation s or σ, a relative standard deviation $s/\bar{x}$, or a coefficient of variance CV% without specifying the distribution. • An uncertainty is given in the form of a 95% (or other) confidence interval **I** without specifying the distribution.	$u(x) = s$ $u(x) = s$ $u(x)=x.(s/\bar{x})$ $u(x)=\frac{CV}{100}\cdot x$ $u(x) = I/2$ (for **I** at 95%)

Process of evaluating uncertainty



Reporting Uncertainty

The information necessary to report the result of a measurement depends on its intended use

➔ Guiding principle:

to present sufficient information to allow the result to be re-evaluated (if new information become available),
to better enable statistical analyses and to observe trends in the data

ISO *Guide to the Expression of Uncertainty in Measurement* (1995)
EURACHEM/CITAC *Guide: Quantifying Uncertainty in Analytical Measurement*, EURACHEM. (2000)
EPA//DOE/DOD/NRC/NIST/USGS/FDA *Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP)* draft (2003)

References recommend that the result should be reported as expanded uncertainty U:

Result: ($y \pm U$) (stating the units)

k must always be reported and the confidence level associated to the $y \pm U$ interval

Example: The activity concentration of a radionuclide (A) in a water sample,

$$A = (0.85 \pm 0.13)\ \mathrm{Bq/m^3}\ *$$

- *The reported uncertainty is an expanded uncertainty calculated using a coverage factor of 2 which gives a level of confidence of approx. 95 %*

Rounding

➔ ***recommended by References***
uncertainties should be rounded to 2 figures, when possible

The number of significant figures that should be reported depends on the uncertainty of the result

- Round the uncertainty (standard or expanded) to either 1 or 2 significant figures and report both the measured value and the uncertainty to the resulting number of decimal places

➔ **should only be applied to final results**

Intermediate results shall be carried through all steps with additional figures to prevent unnecessary round off errors

Reporting Uncertainty

In radioactive environmental measurements it is possible to calculate results that are less than zero
although negative radioactivity is physically impossible

Negative values may occur when the measured result is less than a pre-established average background level for the particular system and procedure used

Censoring of results is ***not*** recommended,
these values should be reported to better enable statistical analyses and to observe trends in the data

All results, whether positive, negative, or zero, should be reported as obtained, together with their uncertainties [reference

ISO *Guide to the Expression of Uncertainty in Measurement* (1995)
EURACHEM/CITAC *Guide: Quantifying Uncertainty in Analytical Measurement*, EURACHEM. (2000)
EPA//DOE/DOD/NRC/NIST/USGS/FDA *Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP)* draft (2003)

Compliance against regulatory limits in REM involves that large numbers of results from environmental radioactive determinations be compared to basic standards or to be within specific limits
(The uncertainty associated to the result has obviously implications for interpretation of analytical data)

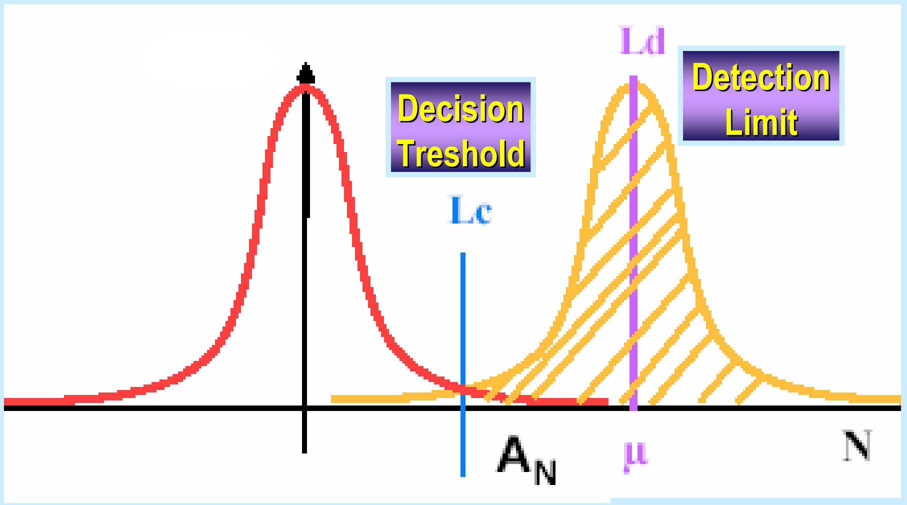
According to section 9.6 of EURACHEM :
"The uncertainty in the analytical result may need to be taken into account when assessing compliance
The LIMITS may have been set with some allowance for measurement uncertainties
Consideration should be given to both factors in any assessment"

Close to Detection/Decision Levels

Environmental measurements are frequently performed at levels where the radionuclide of interest cannot be distinguished from natural background levels
The relative uncertainty associated with the result tends to increase to the point where the (symmetric) uncertainty interval includes zero

This region is typically associated with the practical ***Limit of Detection*** for a given method

does the sample contain a positive amount of the radionuclide ?



"Conflicting region" exists some confusion due to:

- the difficulty of establishing a *Decision Threshold*
- the numerous criteria, terminology and formulation since the first articles on making a detection decision for radioactive measurements were published

All methodologies involve the principles of statistical hypothesis testing

Resume latest harmonized international criteria, terminology and definitions based on **ISO 11843 & 11929** series

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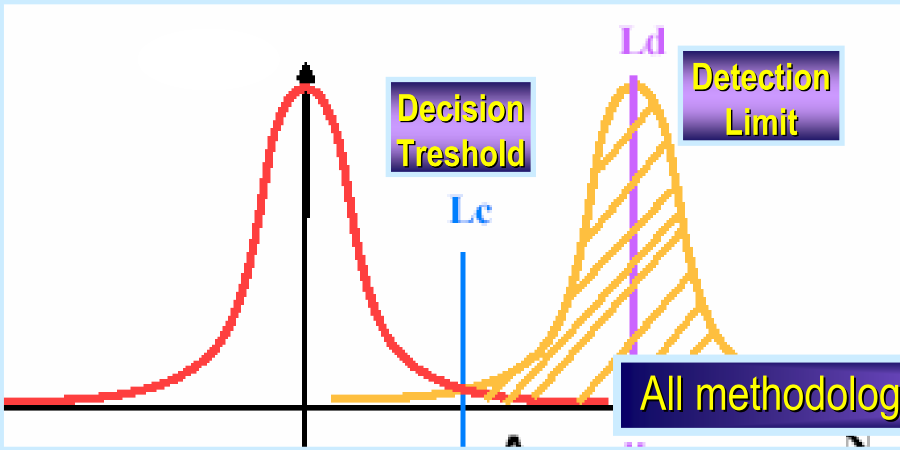

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Altshuler, B.; Pasternack, B. *Statistical Measures of the Lower Limit of Detection of a Radioactivity Counter*. Health Physics 9:293-298, **(1963)**
Nicholson, W.L. *Statistics of Net-Counting-Rate Estimation with Dominant Background Corrections*. Nucleonics 24(8):118-121, **(1966)**
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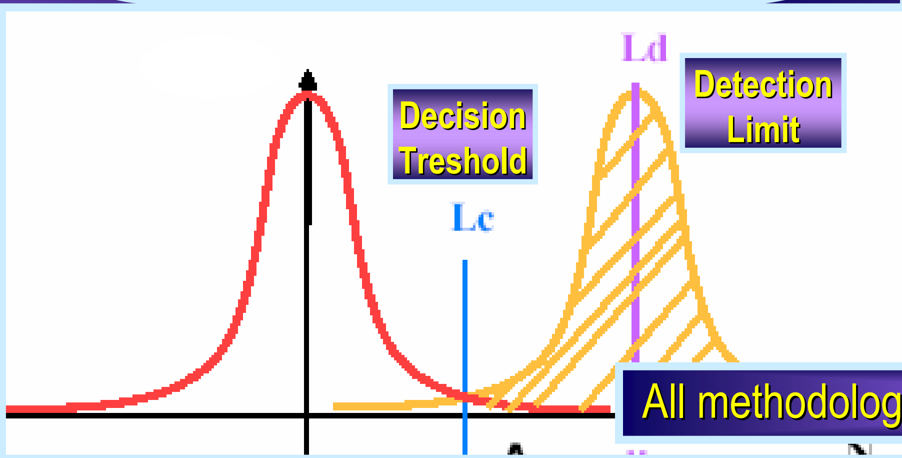

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All methodologies…

Resume latest harmonized international criteria, termi…
based on **ISO 11843 & 11929** seri…

The application of more advanced statistical technique…
i.e.: Bayesian inference, can be found in

- Incorporates scientific hypothesis in the analysis (by means of *"a priori distribution"*), resulting in a distribution of likely outcomes

Bayes, T. *An Essay Towards Solving a Problem in the Doctrine of Chance… The Philosophical Transactions* 1763. Rep Biometrika 45:293-315; (1958)
Little, R.J.A. *The Statistical Analysis of Low-Level Radioactivity in th… Presence of Background Counts*. Health Physics 43(5):693-703; (1982)
Miller, G.; Inkret, W.C.; Martz, H.F. *Bayesian Detection Analysis for Radiatio… Exposure*. Radiation Protection Dosimetry 48(3):251-256; (1993)
Miller, G.; Inkret, W.C.; Martz, H.F. *Bayesian Detection Analysis for Radiatio… Exposure, II*. Radiation Protection Dosimetry 58(2):115-125; (1995)
Miller, G.; Martz, H.F.; Schillaci, M.E.; Berry, D.A.; Inkret, W.C.; Little, … *Support for Bayesian Statistics*. Health Physics Society Newsletter 26(3):28-2… (1998)
Strom, D.J., *Introduction to Bayesian Statistics*. PNNL-SA-31527. Heal… Physics Society Annual Meeting,1999. Richland, Washington: PNL (1999)
Lira, I., *Evaluating the measurement uncertainty. Fundamentals and practical guidance*. Institute of Physics Publishing. Bristol and Philadelphia (2002)

Close to Detection/Decision Levels

Decision Threshold, R_n^*
(Critical Level (Lc) *Currie's*)

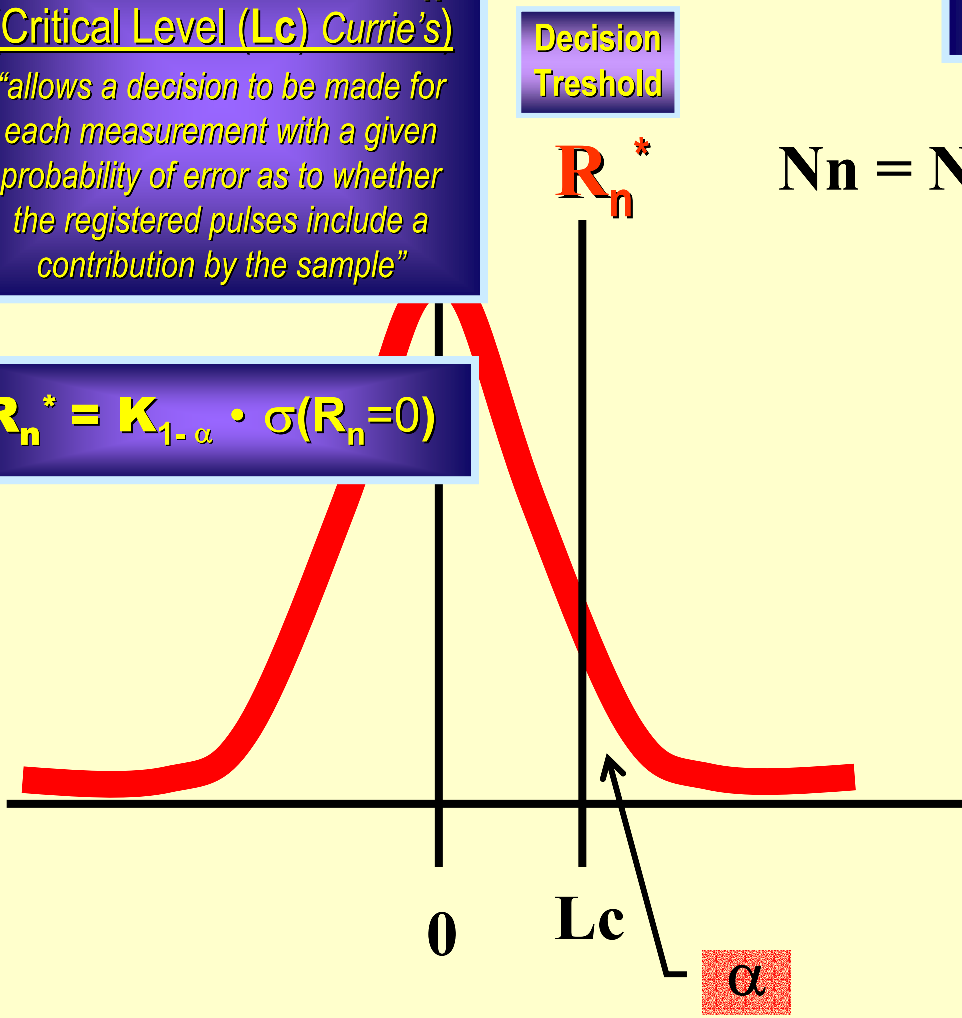
"allows a decision to be made for each measurement with a given probability of error as to whether the registered pulses include a contribution by the sample"

$$R_n^* = K_{1-\alpha} \cdot \sigma(R_n = 0)$$

Statistical concept: the lowest useable action level

Results of R_n are compared with R_n^*

$$Nn = Ns - No$$



"Critical value of a statistical test for the decision between the hypothesis $\rho_s = \rho_0$ and the alternative hypothesis $\rho_s > \rho_0$"

ρ_s = Expectation value of R_s (gross effect counting rate quotient of the number pulses N_s counted during the preselected duration of measurement t_s: $R_s = N_s / t_s$

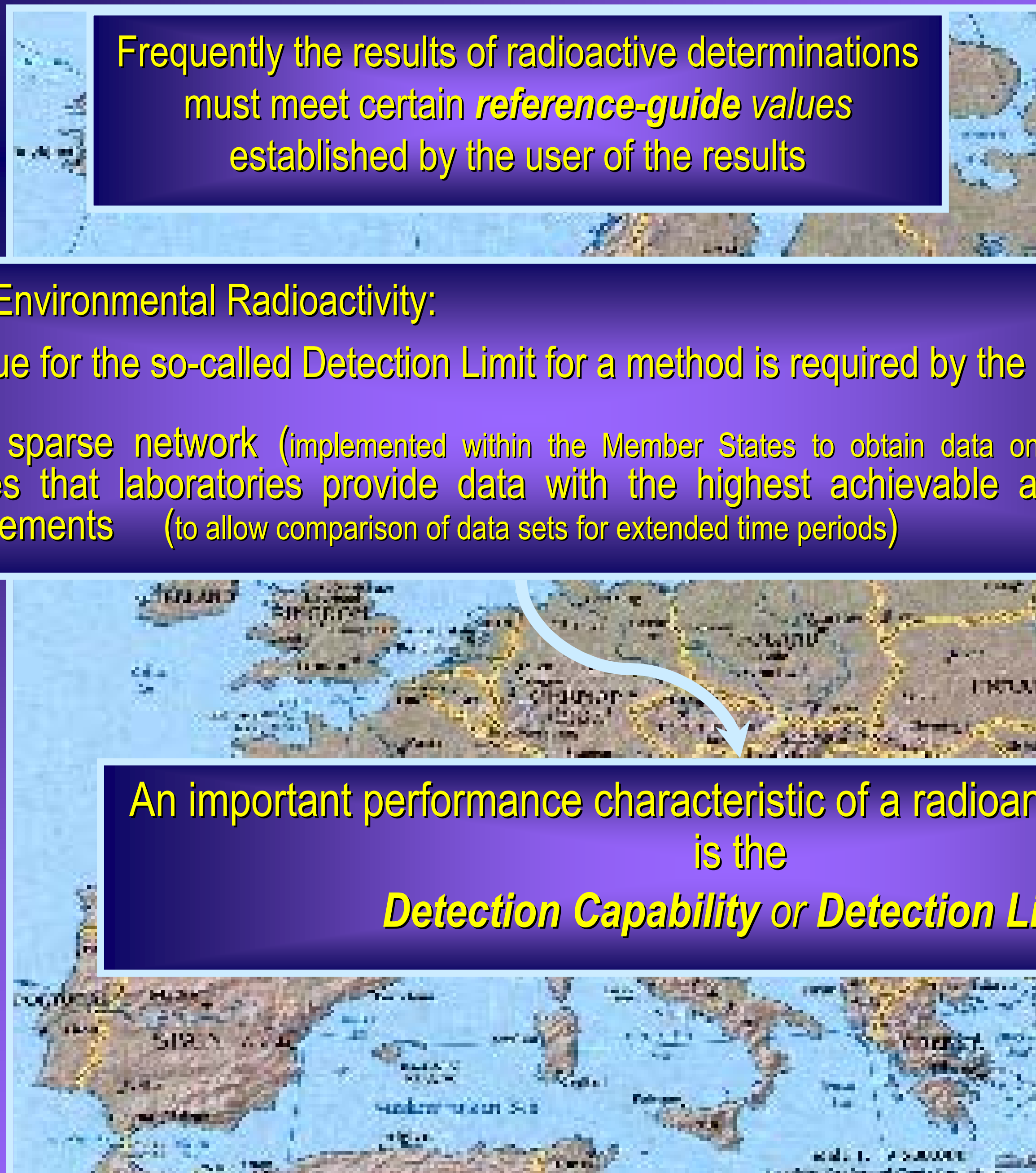
ρ_0 = Expectation value of R_0 (background effect counting rate, quotient of the pulses N_0 counted during the preselected duration of measurement t_0: $R_0 = N_0 / t_0$

R_n = net effect counting rate, $R_n = R_s - R_0$

ρ_n = Expectation value of R_n

- R_n^* is a value chosen so that results above it are unlikely to be false positive, <u>with a probability α fixed *a priori*</u>
- smaller value of α makes *type I errors (false +)* less likely, but also *type II errors (false -)* more likely (sample~blank)

Close to Detection/Decision Levels



Frequently the results of radioactive determinations must meet certain ***reference-guide*** *values* established by the user of the results

Monitoring of the Environmental Radioactivity:

- A minimum value for the so-called Detection Limit for a method is required by the Regulatory body
- The EU REM sparse network (implemented within the Member States to obtain data on **actual levels** of radioactivity) requires that laboratories provide data with the highest achievable accuracy and high sensitivity measurements (to allow comparison of data sets for extended time periods)

An important performance characteristic of a radioanalytical procedure is the

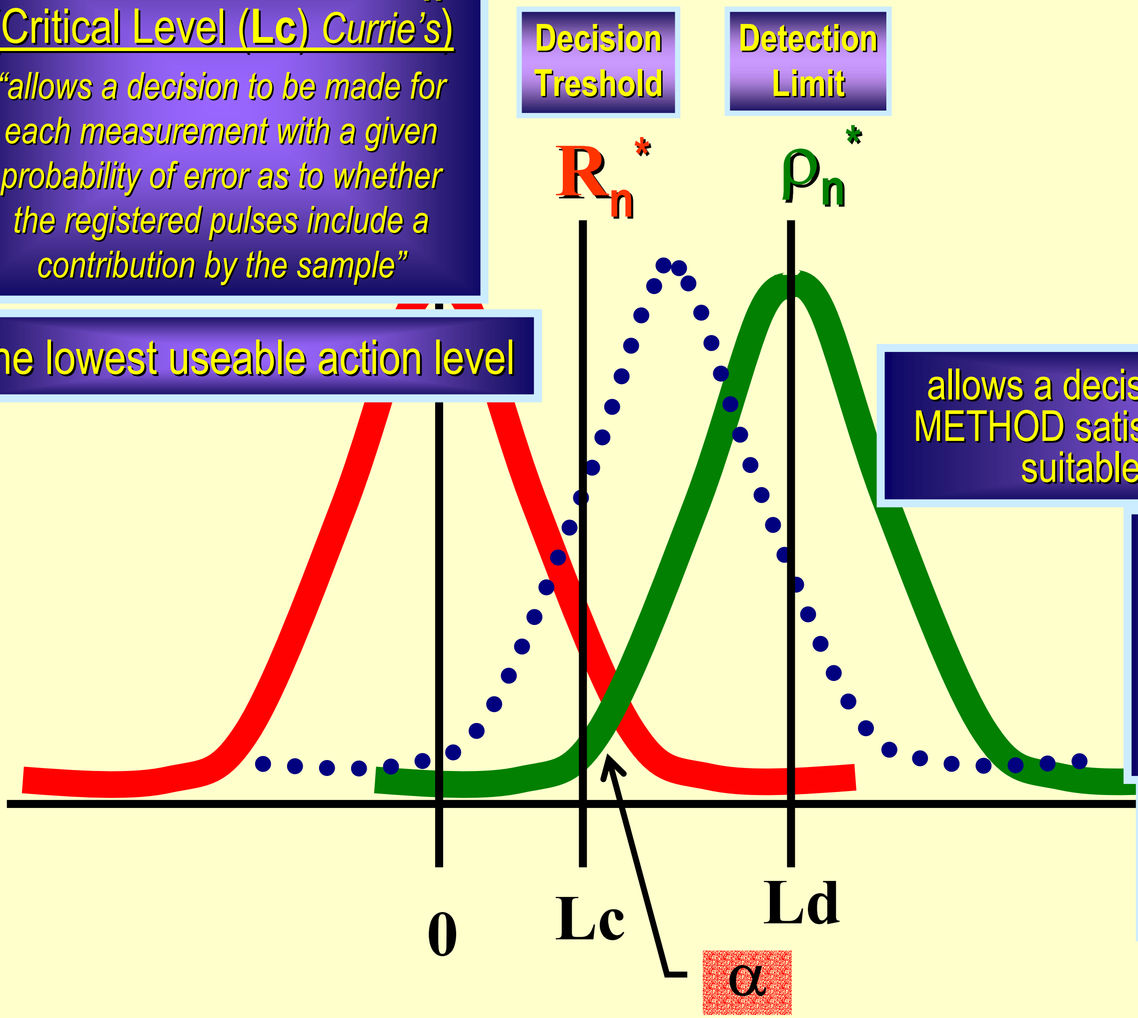
Detection Capability *or* ***Detection Limit***

Close to Detection/Decisi[...]

Decision Threshold, R_n^*
(Critical Level (Lc) *Curie's*)

"allows a decision to be made for each measurement with a given probability of error as to whether the registered pulses include a contribution by the sample"

the lowest useable action level



Detection Limit, ρ_n^*
(Detection Capability) (**Ld** *Currie's*)

"specifies the minimum sample contribution which can be detected with a given probability of error using the measuring procedure in question"

$$\rho_n^* = R_n^* + K_{1-\beta} \cdot \sigma(R_n = \rho_n^*)$$

allows a decision to be made as to whether a MEASURING METHOD satisfies certain requirements and is consequently suitable for the given purpose of measurement

Guideline Value

"Value constituted by requirements on measuring procedures arising for scientific, legal or other reasons which are specified, (i.e.: activity, specific activity, dose rate, ..."

➔ In the REM programmes this value is fixed by the Regulatory Body for specific activity in the different types of samples

ρ_s = Expectation value of $R_s = N_s / t_s$

R_n = net effect counting rate, $R_n = R_s - R_0$

ρ_0 = Expectation value of $R_0 = N_0 / t_0$

ρ_n = Expectation value of R_n

Close to Detection/Decisi

Decision Threshold, R_n^*
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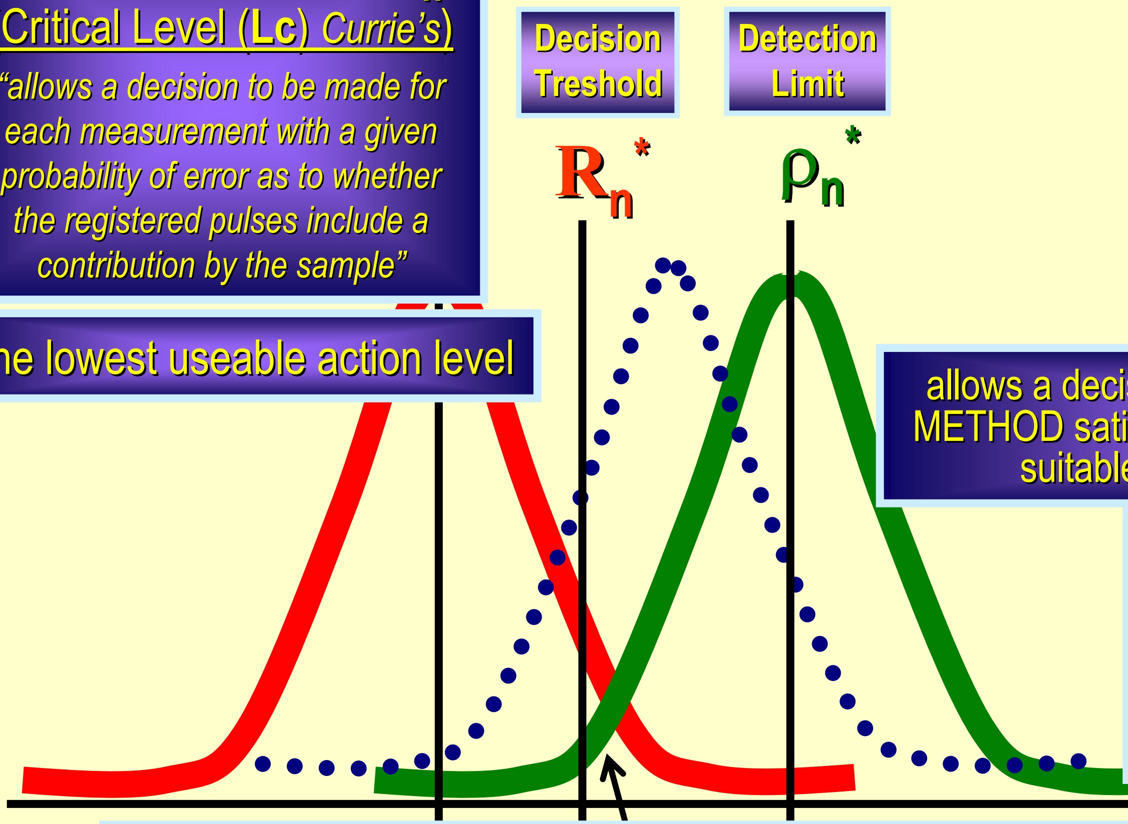

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➔ In the REM programmes this value is ... for specific ... f samples

Uses

- **DECISION THRESHOLD** R_n^* is to be compared with the **MEASURED VALUES**
- **DETECTION LIMIT** ρ_n^* is to be compared with the **GUIDELINE VALUE**

ρ_s = Expectation value of $R_s = N_s / t_s$

ρ_0 = Expectation value of $R_0 = N_0 / t_0$

R_n = net effect counting rate, $R_n = R_s - R_0$

ρ_n = Expectation value of R_n

Close to Detection/Decision Levels

To stress the significance of producing reliable measurements together with adequate uncertainty evaluation and having the "Conflicting Region" well characterized

Areas of application of the *Detection Capability* for a radiochemical procedure

- Fulfilling Safeguard agreements (Treaty on the Non-Proliferation of Nuclear Weapons, NPT)

➔ Verification activities include monitoring systems to detect the flow of nuclear material past key points (detection of very small amounts of specific radionuclides), to ensure peaceful nuclear activities

- Exemption levels, Clearance of materials,
- Cleanup of contaminated areas,
- Bioassay excreta radioanalyses (internal dosimetry)
- Waste management, ...

Expense and consequences of making incorrect decisions in REM programs

- Reporting false positive in environmental samples, can produce unnecessary costly cleanup, unnecessarily alarm public, spend money on re-sampling, analyses and further investigations
- Reporting a false negative, the consequences could affect directly the population,
  - ➔ not protective actions of public and environment would be taken
  - ➔ if later discovered can destroy trust and communication > political consequences

Final Recommendations

Documentation

THE VALUE (AND ITS UNCERTAINTY) SHOULD ALWAYS BE REPORTED

if it does not exceed the *Decision Threshold*, the comment “no detected” should be added

For established sample contributions, in addition to the measured value, confidence intervals and the confidence level shall be reported

A report on measurements shall be accompanied by details on the probabilities of error, the DECISION THRESHOLD and the DETECTION LIMIT

censoring data means

CHANGING measured results from numbers to some other form

that cannot be averaged or analyzed numerically

~~Result < ρ_n^* (Ld)~~

Final Recommendations

Measurement uncertainty

Laboratory measurements always involve uncertainty. Every measured value obtained by a radioanalytical procedure should be accompanied by an explicit uncertainty estimate

Uncertainty must be considered when:

- analytical results are used as part of a basis for making decisions
- comparing data against Regulatory Limits
- comparing data among results of laboratories from other countries

All results, (positive, negative, or zero) should be reported, together with their uncertainties

➔ The coverage factor and approximate probability should be stated with the expanded uncertainty

Assessment of measured results

MEASUREMENT RESULT shall be compared with the **DECISION THRESHOLD**

➔ If a result is greater than the *Decision Threshold* R_n^* it is assumed to be a real sample contribution

Assessment of measuring procedure

the determined **DETECTION LIMIT** shall be compared with the **GUIDELINE VALUE**

➔ If the DETECTION LIMIT ρ_n^* is greater than the GUIDELINE VALUE, the procedure is not suitable for the purpose of the measurement

Final Recommendations

At the environmental radioactivity levels, the relative uncertainty associated with the measurement result tends to increase:

- Uncertainties should be correctly assessed
- Detection/decision levels must be carefully characterized

further harmonization of criteria and terminology is needed

The radiological protection of the environment and the population requires from all states to have laboratories with Internationally comparable Quality levels

Adequate management of any eventual situation of nuclear emergency can only be assured on the basis of reliable and traceable measurements to international standards

To conclude

- Efforts should be made by the scientific community to have all involved laboratories in closer collaboration for an international harmonization of criteria and terminology
  ➔ and to diffuse this information among the **users of the results**
- To study the use of proper statistics for decision making at the "conflicting region"
  ➔ application of Bayesian Statistics

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