



Public Health
England

Dealing with uncertainties within a regulatory framework

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Introduction

- Uncertainties always present when estimating radiation exposures
- Importance of these uncertainties depends on the likely level of exposure
- Greater understanding of the uncertainties will provide greater confidence in the results
- Regulatory authorities typically require that an appropriate level of caution be applied to an assessment
- UK guidance states that the scale of uncertainties and variabilities in the assessment should be reviewed
- But what should the regulators do with information provided by such reviews?



Background

Euratom BSS – assessment needs to be carried out in realistic way –
in practice what does this mean?

UK guidance says

- Sufficient caution should be retained to provide confidence that actual doses will be below dose limit
- Level of caution between doses assessed prospectively and retrospectively should not exceed a factor of about ten

Will examine how uncertainty and variability currently being addressed

Will look at a case study to provide a practical example



Issues

Is it mixture of conservative and realistic assumptions or is it mainly conservative assumptions with a few more realistic ones thrown in ?

Where both types of assumptions are present, the assessment must err on the side of conservatism, but reviewers should be aware that this could obscure areas of uncertainty.

Identifying what is a “conservative” assumption or approach may not be obvious.

It may therefore be necessary for assessments to adopt realistic assumptions because of competing processes. In other words, what is conservative with respect to one process may not be conservative with respect to another competing process.



Terminology

Important to have a common understanding (speak same language) so stakeholders can make informed decisions.

Uncertainty is a measure of the lack of knowledge of the system under investigation and it can be improved with better knowledge e.g. the extent of the knowledge on the parameters used in dose calculations.

Variability generally refers to genuine differences between individuals, and variation in time and space e.g. transfers of radionuclides in different environments or behaviour or characteristics, such as the amounts of different foods consumed by different people.



UK assessment approach

Graded or tiered approach

Stage 1 – Initial radiological assessment using default data. If assessed dose above dose criteria, then proceed to Stage 2.

- Stage 2 – Initial radiological assessment using refined data such as information on dispersion conditions such as site height or flow rate. If assessed dose still above dose criteria, then proceed to Stage 3.
- Stage 3 – Undertake a site-specific assessment.



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Case Study

PHE was asked to assess dose from discharges of NORM radionuclides into estuarine environment





Stages of assessment

Stage 1 - Initial radiological assessment using default data – done using methodology and spreadsheet provided by UK Environment Agency Initial Radiological Assessment Tool (IRAT) – doses greater than dose criterion of $300 \mu\text{Sv y}^{-1}$

Stage 2 - Initial radiological assessment using refined data – looked at data for specific exposure groups – for example ruled out some exposure groups which did not exist in local area – occupational fishermen - again doses greater than dose criterion

Move to Stage 3 – site-specific assessment



Site specific assessment

Determine appropriate exposure groups and associated habit data

Doses still above dose criterion

Identify parameters whose uncertainty likely to have largest impact on dose

- Review of volumetric flow between estuarine model compartments – trying to reduce model uncertainties
- Radiochemical analysis of samples to lower limits of detection for ^{210}Po
- More realistic sampling regime - previously only sampled all plants running which is only 50% of time
- Assessment used highest activity concentrations in the sample



Refinement of assessment

- Review of volumetric flow rate
 - Previously assumed net volumetric flow 10%, modelling exercise found it to be 50%
 - This change has greatest impact on dose
- Assessment used highest activity concentrations in the sample
 - On advice of the regulator used the mean activity concentration with 2 Standard Deviations to provide an estimate of uncertainty on the measurements

Doses reduced approximately by factor of 10



Regulatory challenges

For the case study parameters were reviewed to make sure that more realistic

Is there unconscious bias – do we just look at the parameters likely to try the dose drive downwards?

Difficult to generate specific guidance

Pragmatic approach is to tackle on case by case basis



Regulatory challenges

If in doubt ask for more information

But are there requests always proportionate?

Law of diminishing returns – does it provide better answer?

Typical response is to request more information– which may add months to processes and still not resolve uncertainties

Know when additional information will help resolve uncertainties versus accepting the risk of making decisions under uncertainty



Conclusions

Uncertainties (and variability) will always exist

They become more relevant as progress through the tiered approach

We need to understand which are important

That will depend on specifics and hence address on a case-by-case

But that should be done in a consistent manner whilst allowing for
necessary flexibility and taking a proportionate approach related to
the risk

And in a way that clearly communicates to decision-makers and
stakeholders how been addressed - in doing so will also met the
needs of the regulator



Points to consider

Have we improved the value of the answer or just given the impression of doing so?

Is there unconscious bias – do we just look at the parameters likely to try the dose drive downwards?