CATEGORY A

Qualification, Verification and Validation for the model used to evaluate radiological risk to non-human biota (ERICA Tool)

Project near surface disposal of category A waste at Dessel

QUAL-LT(BIO)

Belgian Agency for Radioactive Waste and Enriched Fissile Materials

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1	06/12/2011	Initial version submitted to the FANC as input to the discussions between the FANC and ONDRAF/NIRAS during the period before the submission of the licence application.
2	30/09/2022	Update of the report to include the revisions leading to ERICA Tool version 2.0 as released in November 2021, with a new section describing the most recent updates as well as additional scientific literature on validation and verification of the Tool, bringing it up to the level of the state of the art in 2022.

Executive summary

This report is one of a set of technical supporting documents in the safety case, submitted to the FANC in support of an application for a construction and operating licence for a near surface repository for category A waste at Dessel.

It documents the qualification, verification and validation of the ERICA assessment tool (in its current Version 2.0) to evaluate radiological risk to non-human biota within the framework of long-term safety assessments of near surface disposal of Category A waste. The model is suitably qualified, i.e. consistent with the current knowledge in the field of radiological assessment to non-human-biota. In addition, the ERICA Tool has been adequately verified, i.e. the software is a correct implementation of the conceptual description embodied in the ERICA Integrated Approach to assessing the radiological risk to biota. Lastly, the report describes the degree to which the model performance is verified, that is, the degree to which it performs accurately by documenting the comparisons that have been done between ERICA and other models and empirical results.

Samenvatting

Voorliggend rapport is één van de technische ondersteunende documenten in het veiligheidsdossier, dat aan het FANC wordt overgemaakt ter staving van de aanvraag voor een oprichtings- en exploitatievergunning voor een oppervlaktebergingsinrichting voor categorie A-afval in Dessel.

Het beschrijft de kwalificatie, verificatie en validatie van de ERICA tool (in zijn huidige versie 2.0) die gebruikt wordt om het radiologische risico naar niet-menselijke biota toe te evalueren in het kader van de oppervlakteberging van categorie A afval. Het model is voldoende gekwalificeerd, wat inhoudt dat het in overeenstemming is met de huidige kennis op het gebied van radiologische impactevaluaties voor niet-menselijke biota. Daarnaast is de ERICA Tool ook terdege geverifieerd – de software implementeert de conceptuele beschrijving uit de Geïntegreerde ERICA-Aanpak om het radiologisch risico voor niet-menselijke biota te evalueren, op een correcte manier. Tot slot beschrijft dit rapport de mate waarin de performantie van het model geverifieerd werd, d.w.z. hoe de modelresultaten zich laten vergelijken met andere modelresultaten en empirische resultaten.

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1 Introduction

ONDRAF/NIRAS is entrusted by law with developing a coherent policy for the safe management of all radioactive waste on Belgian territory and, subject to parliamentary and government review, implementing that policy consistent with royal decrees, government decisions and decisions from the regulatory body FANC.

A key part of ONDRAF/NIRAS's mission is the long-term management of all Belgian radioactive waste. The fundamental safety objective is *to protect people and the environment now and in the future from harmful effects of ionising radiation* [1, 2]. Consistent with this objective, radioactive waste must be managed so as to ensure any associated risks are as low as reasonably practicable and, in any case, consistent with legal and regulatory standards. The preferred strategy for the management of all radioactive waste is to isolate it from the accessible biosphere and to contain it, with disposal in suitable facilities being the last step in the management of solid conditioned radioactive waste [3]. Safety is the most important and driving requirement in planning and implementing waste disposal facilities.

The present report is part of the safety case, submitted to the FANC, in support of ONDRAF/NIRAS's application for a construction and operating licence for a near surface repository for category A waste on the territory of the municipality of Dessel.

1.1 Aim and context of the present report

As well as ensuring that humans are adequately protected from exposure to radioactive contaminants originating from the Dessel near surface repository, there is a need to ensure that the environment as a whole – including non-human biota species – is also adequately protected.

The ERICA Tool is a software programme with supporting databases that, together with its associated helps, guides users through the environmental risk assessment (ERA) process. It focuses on assessing the effects to non-human biota from exposure to ionising radiation. It is available for download at www.erica-tool.com.

Within the category A disposal programme, the ERICA Tool is used to assess the radiological risk to non-human biota under the reference scenario for gradual leaching [4]. The version of the ERICA Tool used to conduct the assessment is Version 2 as released in November 2021, fixing a number of issues reported on previous versions and expanding some functionalities.

The aim of the present report is to document the qualification, verification and validation of the ERICA assessment tool to evaluate radiological risk to non-human biota within the framework of long-term safety assessments of near surface disposal of Category A waste. We demonstrate that the model is suitably qualified, i.e. consistent with the current knowledge in the field of radiological assessment to non-human-biota. We also demonstrate that the ERICA Tool has been adequately verified, i.e. that the software is a correct implementation of the conceptual description embodied in the ERICA Integrated Approach to assessing the radiological risk to biota. Lastly, we establish the degree to which the model performance is verified, that is, the degree to which it performs accurately by documenting the comparisons that have been done between ERICA and other models and empirical results.

The ERICA Tool has become the European standard methodology for radiological assessment to non-human biota, and so there is already a substantial body of validation and verification work performed internationally and documented scientifically. This report will make adequate reference to the substantial publications that support the confidence-building process for this assessment tool.

It must be noted that the ERICA Tool and its associated model are not used as a stand-alone model in the assessment. The near field *reference leaching model* (peak fluxes) and *hydrogeological models* (peak flux → concentrations in groundwater / fluxes to river) provide input for assessing the impact to non-human biota. These models are essentially the same as for human impact assessment and are outside the scope of the present report.

1.2 Application of the QVV concepts in the present report

Prior to the actual conduct of analyses, suitable *models* need to be developed. As indicated in Figure 1, model development consists of several stages.

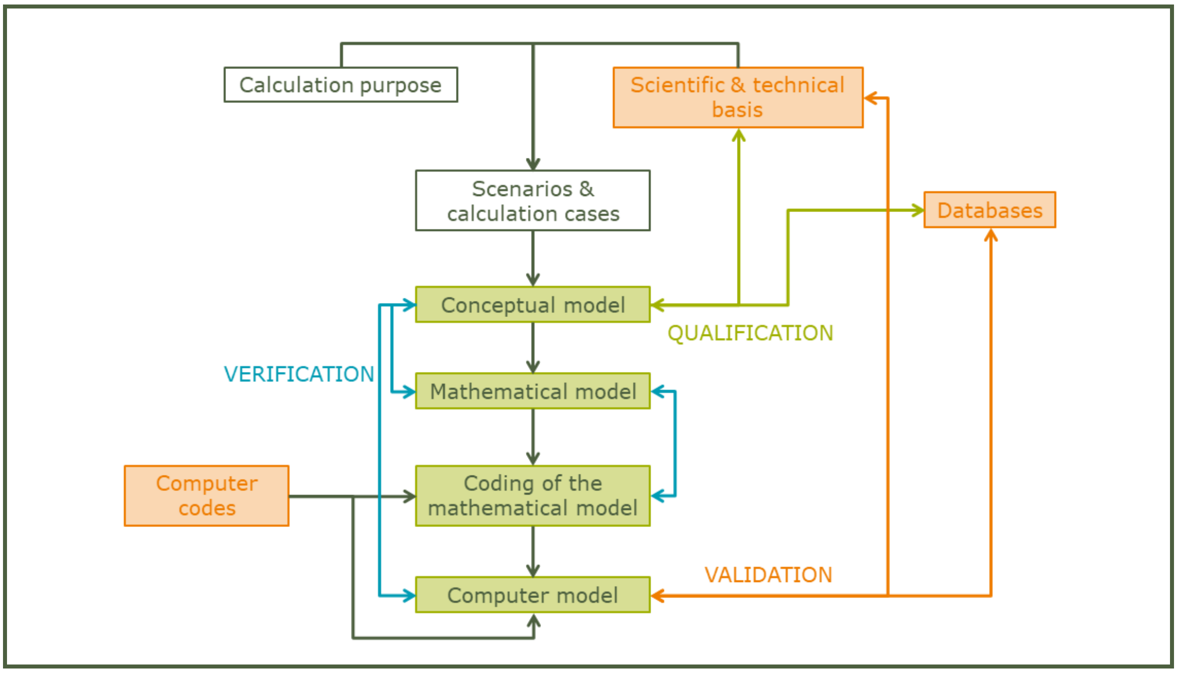

Figure 1 – Model formulation and implementation (green boxes) and the concepts of qualification, verification and validation.

- **Scientific and technical basis & databases (assessment basis)** – referring to the real system, its features, and how one thinks it will evolve and behave. This documentation on the one hand assembles all the available experimental data and data obtained from characterisation efforts, and on the other hand describes all the pertinent phenomena occurring in the disposal system domain and its interfaces.
- **Conceptual model** – a stylised representation of reality, covering assumptions on the geometry and dimensionality of the system, initial and boundary conditions, time dependence, and the nature of the relevant physical, chemical and biological processes and phenomena.

  The complexity of a conceptual model should be commensurate with the amount and quality of available knowledge and data, but it also depends on the purpose of the calculation to be undertaken.
- **Mathematical model** – a representation of the phenomena and processes considered in the conceptual model, using mathematical equations.
- **Coding of the mathematical model** – implementation of the mathematical equations in algorithmic form, into a computer code that is fit for purpose.

- **Computer model** – the hypotheses concerning geometry, spatial domain, and initial and boundary conditions are implemented in the code.

In summary, the *computer model* is the numerical representation of the *conceptual model*.

The key consideration in the selection and development of models, datasets (input parameters) and computer codes is that they should be *fit for purpose* – which involves considerations of qualification, verification and validation. The overall goal of the model qualification, verification and validation (QVV) process is

- to reduce, or reasonably bound, conceptual model uncertainties; and
- to establish confidence in the fact that a real system is represented by a particular computer model in an appropriate manner, given the model's intended use.

Qualification of a conceptual model (green arrows in Figure 1) is the process of ensuring that it is consistent with scientific understanding within the assessment basis and adequately represents the considered phenomena and processes and their interactions, given its objective(s) and intended use. Model qualification thus deals with the link between the scientific and technical basis for the assessment, including databases, and the conceptual model.

Verification (blue arrows in Figure 1) is the process of determining whether a computer model correctly implements the intended conceptual model; for the practical application of the QVV process, verification is taken to consist of three distinct stages, as indicated in Figure 1:

1) Verification of the **mathematical model** – aimed at exploring the accuracy with which the phenomena and processes considered in the conceptual model are represented by the mathematical equations. In general, when simplifications are introduced, they should have low impact on calculated results, or be conservative.
2) Verification of the **coding** – aimed at ensuring that the code is free of programming errors and able to solve the mathematical equations that define a case accurately and without error.

   This can be achieved by showing that the results generated by the code for simpler problems are consistent with available analytical solutions, or are the same, or similar, as results generated by other codes (benchmarking).
3) Verification of the **computer model** – aimed at exploring the accuracy with which the model hypotheses, initial and boundary conditions, and input data are implemented in the computer code.

Validation (orange arrows in Figure 1) consists of comparing the predictions of computer simulations with observations on a real system over the timeframes and spatial scales of interest. Over the timeframes relevant for long-term safety, only partial validation is possible.

In practice, confidence in the computer models and results is assured by:

- Documentation of qualification files or relevant scientific peer reviewed references on the use of the code;
- Verification by means of benchmarking techniques (comparison with alternative codes) and through comparing the results with the results of analytical models;
- Trained and qualified staff to conduct the simulations;
- Appropriate QA procedures, including back-ups of input and output files for external audits and traceability;
- External independent checks.

1.3 Report structure

This report is structured as follows:

- Chapter 2 sets out the objectives and foreseen use of the ERICA model.
- Chapter 3 gives an overview of the model and its key features.
- Chapter 4 sets out the QVV efforts applied.
- Chapter 5 concludes on the ERICA model adequacy.

Chapter 6 lists the references used in this report.

A number of annexes complete the report:

- A glossary of terms is included in annex 1.
- A list of acronyms is contained in annex 2.

2 Objectives and foreseen use of the ERICA Tool

2.1 The ERICA integrated approach

The goal of the ERICA radiological impact model for fauna and flora is to determine whether the calculated doses to wildlife species are below a given *screening value*, which is set to protect ecosystems. The ERICA Tool is a user-friendly software programme that implements an Integrated Approach to assessing radiological risk to non-human biota. This approach combines elements of environmental management, risk characterisation and impact assessment built on the foundations developed during the EU EURATOM projects FASSET [5], EPIC [6] and ERICA itself [7, 8].

The ERICA software guides the user through the assessment process, keeps records and performs the necessary calculations to estimate dose rates to selected biota. A detailed help is provided to assist the user in making appropriate choices and inputs, as well as interpreting the outputs. The Tool interacts with a number of databases and other functions that help the assessor to estimate the radionuclide concentrations in environmental media, radionuclide concentrations in biota, and dose rates to a number of reference organisms in terrestrial and freshwater ecosystems (marine ecosystems need not be considered for the Category A assessment). To enable the dose calculations, information on environmental concentrations is needed as well as information on reference organism characteristics (dimensions and occupancy factors), environmental parameter values (e.g. concentration ratios and solid-liquid distribution coefficients). This information is partly available in the supporting databases and can be amended or supplemented by the user.

A multi-tiered approach is used, as described by Beresford *et al.* [9]:

- Tier 1 assessments are media-concentration-based and use pre-calculated environmental media concentration limits (EMCLs) to estimate risk quotients; hence, Tier 1 does not allow modifications by the user.
- Tier 2 calculates dose rates, allowing the user to examine and edit most of the parameters used in the calculation including concentration ratios, distribution coefficients, percentage dry weight soil or sediment, dose coefficients, radiation weighting factors and occupancy factors. At this level, the user can also add or remove radionuclides and reference organisms during the calculation process.
- Tier 3 offers the same flexibility as Tier 2 but allows the user to run the assessment probabilistically if the underlying parameter probability distribution functions are defined.

The ERA for the Dessel repository [4] is performed at the Tier 2 level.

2.2 Key indicators and outputs

The key indicators/outputs in the ERICA model are the *dose rates* to biota and the associated *risk quotients* (*RQ*), defined in Tier 2 as the ratios of the predicted environmental dose rates (PEDR) to the predicted environmental no effect dose rate (PNEDR). The PNEDR of 10 µGy/h proposed by ERICA [9] and PROTECT [10], based on a joint statistical analysis, is considered as a screening dose rate, aimed at screening out sites of no (regulatory) concern. This proposed screening value is assumed to protect ecosystems. The 10 µGy/h value proposed by ERICA for the PNEDR is selected as the *dose rate reference level* for the ERA in the category A disposal programme.

Beyond ERICA there is some general consensus on dose rate levels that are unlikely to cause effects to flora and fauna [4]. Brown *et al.* [11] concluded that there are only minor effects for dose rates < 100 µGy/h. UNSCEAR [12] concludes that dose rate to the most highly exposed individual unlikely to have significant effects on communities is 100 µGy/h for terrestrial species and 400 µGy/h for aquatic communities. The ICRP's [13] 'derived consideration reference level' (DCRL) is 4-40 µGy/h for the most sensitive Reference Animals and Plants[1] (RAPs), whereby the lower boundary of this range serves as the reference point in planned exposure situations [14]. A screening value of 10 µGy/h seems therefore to be reasonably robust, on the basis of current knowledge.

Conservative assessments are performed as far as possible, based on available knowledge and information. The required precision, given the current level of knowledge, can be expressed quantitatively as a factor of ~ 10 for the dose rate.

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1 higher vertebrates (ICRP deer, rat, duck) and pine trees

3 Overview of the model and its mode of calculation

3.1 General considerations

The ERICA calculation chain operates as shown in Figure 2. Starting from input data relating radionuclide concentrations in biota to the reference media (water, soil, sediment or air), the Tool calculates external and internal dose rates based on its suite of parameter values and equations to a collection of reference organisms [5], each with its own specified geometry and habits. The reference organism approach is compatible with that used by the ICRP [13].

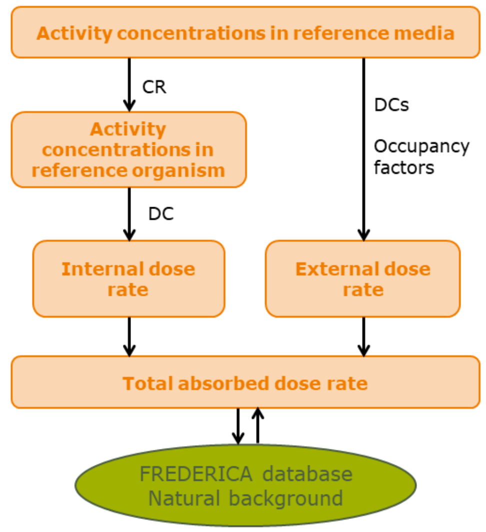

Figure 2 – Schematic of the calculation chain in the ERICA assessment tool (CR: concentration ratio; DC: Dose Coefficient).

The Tool includes default information for a suite of radionuclides chosen to cover a wide range of exposure situations, including potential releases from repositories for radioactive waste, as required by this project [8]. The Tool allows for inclusion of additional radionuclides – covering the majority of the radionuclides included in ICRP Publication 107 [15] – and associated parameter values as required in the category A project.

Presently, ERICA can assess doses for three ecosystem types: terrestrial, freshwater and marine. Assessments can be performed for organisms at eleven habitats, as shown in Figure 3. These include: in or on soil or in air (not shown in Figure 3) for terrestrial and, for both marine and freshwater, on and in water and on and in sediment. Although ten (eleven when considering birds and flying insects in air for the terrestrial ecosystem) ERICA habitats are possible, just six (seven) habitats are evaluated since a marine ecosystem is not relevant for the Dessel site's reference biosphere [16]. Identified Reference Organisms in the Dessel region are categorised within one or two of these six (seven) habitat categories and appropriate occupancy factors are assigned for the relevant biota in these six (seven) habitats.

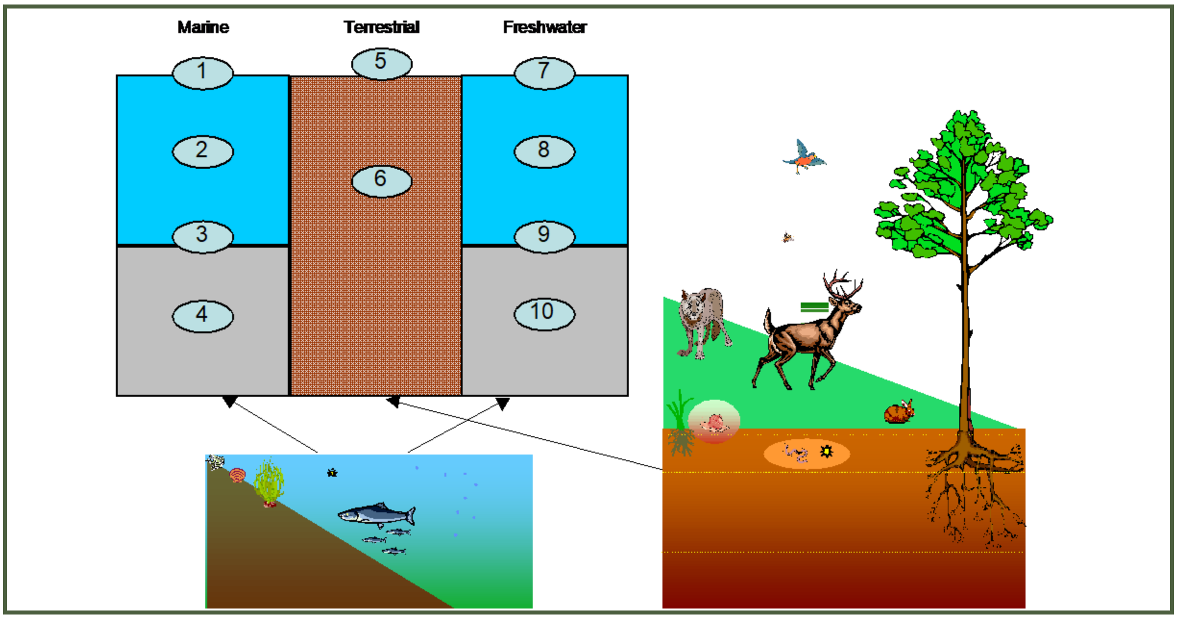

Figure 3 – The ten main ERICA habitats, representing most of the logical habitats in different ecosystems; ERICA can however not assess doses from air contamination for all radionuclides.

The software tool is not designed to assess radionuclides whose concentration is referenced to air, with the exception of ^{3}H, ^{14}C, ^{32}P and ^{35}S. In its version 2.0, as an advanced user option, the tool has also been expanded with the possibility to perform assessments for *noble gases*, including radon and its internal dosimetry (see section 3.2.4).

Dose rates arising from external or internally deposited distributions of radionuclides to biota in these habitats are calculated by means of occupancy factors (OF) or activity concentration ratios (CR), respectively. The main hypotheses of the calculation are:

- whole body doses (uniform distribution);
- homogeneous distribution of activity in medium;
- transfer of radionuclides from the environmental medium (soil, air, water, sediment) to the organisms at equilibrium; and
- simplified dosimetry for basic organism shapes (ellipsoids).

All these assumptions may engender an important uncertainty.

The final step in the calculation chain is the determination of total dose rates, whereupon the Tool establishes the significance of the dose rates the organisms are exposed to, by calculating a risk quotient (in Tier 1 and 2) defined as the ratio of the PEDR and the PNEDR (selected as 10 µGy/h). Databases are provided that allow comparison the predicted dose rates with the radiation effects database (FREDERICA).

The tiered approach implemented in the ERICA Tool allows users to add different layers of complexity in the assessment, triggered by the results of the previous tier. At Tier 1, the Tool uses Environmental Media Concentration Limits (EMCLS), defined as the radionuclide concentrations in the relevant media depending on the ecosystem considered. Passing Tier 1 (i.e. *RQ* <1) results in exiting the assessment whilst being confident that the effects on biota are low or negligible and that the situation requires no further action, whilst failing Tier 1 results in the user entering Tier 2, where satisfying criteria (doses lower than a PNEDR) also allows to exit the assessment process. Where the effects are not shown to be negligible, it is recommended that further assessment be conducted. This does not necessarily mean progressing to Tier 3, by making full use of all relevant information available through the

Integrated Approach – it may, for instance, be possible also to refine the input parameters if justifiable and rerun the assessment at Tier 2. As mentioned, the ERA for the category A disposal programme was done at the Tier 2 level [4].

3.2 Key assessment steps (modelling stages)

From the foregoing, it is clear that the key modelling stages of the ERICA Tool are the transfer of radionuclides from environment to biota, dosimetry calculations and radiation dose calculations, as summarised in Table 1.

Table 1 – Key modelling stages in ERICA.

Modelling stage	Description
Transfer of radionuclides	Biota concentration ratios and solid/liquid distribution coefficients (Excel databases with optional user input via the ERICA interface)
Dosimetry	Interpolation of internal and external DCs based on radionuclide characteristics, reference organisms' geometry and occupancy factors (Excel databases)
Dose rates	Internal, external and total dose rates are calculated for selected reference organisms

Dose rates obtained for selected reference organisms using the environmental media concentrations as the starting point can be compared with *dose-effects tables* provided by the Tool [8]. When related to the PNEDR, the Tool calculates the risk quotient.

3.2.1 Transfer parameters

Freshwater distribution coefficients $K_{df,i}$ [L/kg] are used to describe the partitioning of radionuclides between water and sediments:

$$K_{df,i} = \frac{\text{concentration of radionuclide } i \text{ on solid phase (sediment) [Bq/kg}_{\text{dw}}]}{\text{concentration of radionuclide } i \text{ in water [Bq/L]}}$$ **Equation 1**

For the ERA in the category A disposal programme we select the $K_{df,i}$ values used in the biosphere model for human exposure assessment [16, 17].

Concentration Ratios (CR) are used as input parameters to represent the radionuclide transfer from the environmental medium to the non-human biota in the model and thus depend on the radionuclide and biota under consideration. The CR value directly links reference environmental media concentrations (soil, water, air) with biota concentrations, thereby encompassing the whole food chain for a given organism:

$$CR_{o,i} = \frac{\text{concentration of radionuclide } i \text{ in biota } o \text{ whole body [Bq/kg}_{\text{fw}}]}{\text{concentration of radionuclide } i \text{ in medium (water [Bq/L], soil [Bq/kg}_{\text{dw}}], \text{air [Bq/m}^3])}$$ **Equation 2**

In the original ERICA Tool, CR values were based on extensive literature review [18, 19]. In the latest version (2.0) of the Tool, these sources of CR values were expanded into the Wildlife Transfer Parameter Database (WTD) (https://www.wildlifetransferdatabase.org/) that was developed as part of the IAEA MODARIA programme on Modelling and Data for Radiological Impact Assessments (http://www-ns.iaea.org/projects/modaria/).

For several radionuclide-biota combinations, however, empirical CR values are not available and are derived following a homologous approach based on similarities in taxonomy, reference organism, bio(geo)chemical analogues and/or allometry, and, in some cases, specific activity models or simply the highest available value.

It is generally accepted that uncertainties associated with the CR parameter values contributes most to the uncertainty in the model outcome [20, 21]. For these reasons, in the Category A project, the available state-of-the-art CR values benefit greatly from the aforesaid WTD now incorporated in ERICA. Where there are still data gaps, selected CR values are tabulated and commented upon where required.

3.2.2 Dosimetry

Derivation of Dose Coefficients (DCs) in ERICA is based on radiation transport simulated for mono-energetic photons by means of Monte Carlo techniques. Due to the complexity of the processes and the variability of life forms, it is impossible to cover all possible exposure conditions. Therefore, generalised, representative cases as defined by energy, contaminated media and organism sizes are selected for detailed consideration. It is important to note that assumptions of environmental contamination (e.g. soil/sediment contaminated over 50 cm depth) and organism location (e.g. in centre of contaminated soil/sediment/water) have a strong influence on DCs, and the combinations.

A key step for estimating dose rates is an absorbed fraction, which is defined as the fraction of energy emitted by a radiation source that is absorbed within the target tissue, organ or organism. In ERICA, absorbed fractions for photon and electron sources assume uniform distribution of the radionuclide within soft-tissue spheres and ellipsoids immersed in an infinite medium of the same density as water. Such absorbed fractions have been systematically calculated by Monte Carlo simulations. The calculations cover an energy range of 10 keV to 5 MeV and shapes from spheres to ellipsoids with varying degree of non-sphericity. From the computed absorbed fractions, a set of rescaling factors has been derived, which allow to evaluate dose coefficients for ellipsoidal shape organisms from the data for spheres, using mass and proportions of the organism. An analytical approximation has been found relating the derived re-scaling factors and the non-sphericity parameter of the organism's body. With the use of the absorbed fractions for spheres and an appropriate rescaling technique, internal dose coefficients can be calculated for all reference organisms within predefined mass ranges: 1.7×10^{-3} to 5.5×10^{2} kg for animals above ground, 1.7×10^{-3} to 6.6 kg for animals in soil, 3.5×10^{-2} to 2 kg for birds and 10^{-6} to 10^{3} kg for aquatic organisms. Radioactive progeny nuclides were included in the calculation of the DCs whenever their half-lives are shorter than 10 days. The method, which is fully described in references [22, 23], has been further refined as part of the ICRP Biota DC software tool, ver. 1.5.1 reported in ICRP Publication 136 [24]. Hereby, an assessment-specific consideration of the contribution of radioactive progeny to the dose coefficients of parent radionuclides, was implemented. By incorporation of the 'Biota DC' module within ERICA, it is now fully ICRP-compatible in terms of the dosimetry in its current version 2.0.

There is a degree of uncertainty associated with the heterogeneous distribution of some radionuclides and this is discussed in full in the ERICA Tool help. Overall, it can be concluded that for photons, the uncertainty due to a possible non-homogeneous radionuclide distribution is lower than 20-25 per cent in the considered cases. For electrons, uncertainty is negligible below a threshold energy, which is dependent on the size of the organisms.

3.2.3 Radiation effects and risk characterisation

The ERICA ecological risk assessment approach requires risk assessment benchmark values for risk characterisation within Tiers 1 and 2 to assess incremental doses. The object of protection within the ERICA Integrated Approach is that generic ecosystems (freshwater, marine and terrestrial) should be protected from effects on structure and function under chronic exposure to radionuclides. As stated previously, the proposed 10 µGy/h incremental screening dose rate has been derived from examination of data on effects of ionising radiation in non-human biota collated in the FREDERICA effects database. This database includes data from the original FASSET Radiation Effects Database (FRED), covering the period 1945-2001, plus data from newer references up to the end of the ERICA project (early 2007). FREDERICA also contains the output from experiments conducted within the ERICA project and field data from the former Soviet Union. In the framework of the IAEA EMRAS-II Biota transfer and effects working groups, input of data published since 2006 in the open literature, some data which UNSCEAR thought to be missing and inputs from Japanese, Russian and Ukrainian literature were added in an update of the database [25].

The 10 µGy/h incremental screening dose rate is the result of an analysis following QA/QC of a selection of the chronic exposure data from more than 26 000 data entries in the FREDERICA database. The analyses conducted to derive the Predicted No-Effect Dose Rates follows the EC recommendations for the estimation of Predicted No-Effect Concentrations (PNEC) for chemicals [26].

3.2.4 Recent updates to the ERICA tool

The ERICA Assessment Tool has been updated to version 2.0, released in November 2021. The update from the previous ERICA version 1.3 to version 2.0 comprises the following new features, changes, and fixes. The changes that are relevant to the present study are as follows:

- New *dosimetry*: The ERICA Tool now integrates the ICRP Biota DC software tool, ver. 1.5.1 (implementing ICRP Publication 136 [24]) for the calculation of dose coefficients (DCs) for user-defined organisms. A new approach for the calculation of the dose contribution from short-lived progeny in a decay chain has been implemented, for a chosen integration period of 1 year. Short-lived progeny are now modelled explicitly, with a correction to allow for radioactive decay of the unsupported progeny during the integration period. Further information is available in the help file (see "Calculation of media activity concentrations in decay chains").
- Updated *transfer* parameters (*CR* values and K_ds):
  - *CR* values updated for consistency with the Wildlife Transfer Database (WTD). A new method has been implemented to derive an ERICA default CR value when no empirical data are available for the nuclide/organism combination. References to the WTD have been added. New equilibrium correction factors for short-lived radionuclides have been implemented to allow for lower steady state activity concentrations than would be predicted for stable or longer-lived nuclides. Lastly, CR values for Phosphorus and Sulphur in the terrestrial ecosystem now relate to radionuclide activity concentrations in soil and not in air as in previous versions of the tool.
  - Updated (default) K_ds for freshwater have also been made, so that they are now consistent with the IAEA MODARIA working groups' efforts to extend the freshwater K_d data [27]. It is to be noted, however, that in the Category A assessment, freshwater K_d data from the biosphere model were used for consistency with human impact assessment.

  Although the assessment was performed at the Tier 2 level, it is also worth mentioning that EMCLs (used in Tier 1) are evidently updated to take account changes to parameter values.
- Noble gases: at Tier 2, a suite of *noble gases* (Ar, Kr, Xe, Rn) is now included as default, whereby concentration ratios and distribution coefficients are set to zero in the underlying system of equations. Immersion dose coefficients from Biota DC are used, assuming that the organism is 100% of the time present in contaminated air.

  For radon (^{222}Rn) and thoron (^{220}Rn), the contribution of these radionuclides, and their progeny, to dose rates arising from inhalation and deposition in the lung is taken into account, according to the methodology of Vives i Batlle *et al.* [28].

Lastly, there are various functional enhancements, including: (a) added option to import several organisms (see Database > Organisms), (b) added new screen to display the WTD references (see Database/WTD references), (c) the Help documentation has been updated and (d) a number of fixes and enhancements have been made to the tool's interface.

These changes are summarised in slides from the fifth International Conference on Radioecology & Environmental Radioactivity Online event, held in July 2021, which are still available for download[2].

With substantial updates having been made to ERICA since the release of the previous version (1.3) in 2019, differences in output were to be expected and a rigorous series of quality assurance checks have been undertaken to ascertain the basis for any observed differences in output between versions 1.3 and 2.0 and to ensure that consistency between assessment tiers had been maintained (e.g., tier 1 output is at least as conservative as tier 2 output). Therefore, a new report describing the main features of the update, the implication of changes on ERICA Tool results (as compared with version 1.3) and an overview of the underlying reasons behind the key changes has been prepared and is also available in a comparison report [29] that has been released online so, in the interests of brevity, details (already summarised above) are not duplicated here.

[2] https://erica-tool.com/wp-content/uploads/2021/11/ERICA_2.0_presentation_for_ICRER_Online_release.pdf (page accessed on 21 June 2022)

4 Qualification, Verification, Validation

4.1 General overview of argumentation of appropriateness of models

The ERICA Tool was selected for the assessment because it is a comprehensive, yet user-friendly and flexible software programme with supporting databases, which, together with its associated help, is designed to guide users through the assessment process. More than 60 European scientists contributed to the ERICA Integrated Approach. In addition, a large number of experts, policy makers, and decision-makers in different areas have contributed views on the ERICA Integrated Approach and its associated Tool from the user's perspective, through participation in the End-Users Group set up for this purpose under the ERICA project. Therefore, ERICA represents a wide international consensus in the field of environmental radiological protection. Additionally, the Tool has already been used successfully in numerous international case studies reflected in an extensive publication record. The Tool is freely available from the dedicated website www.erica-tool.com and, as a result of being continuously maintained, it is still at the forefront of developments in the field.

In deciding what model to use other alternatives were considered, such as (see [4] for some further details) the RESRAD-Biota code developed by U.S. DOE. Although this tool contains allometric models enabling the user to create simple food chains (transfer factor approach rather than relying on an assumed equilibrium approach), it is a less flexible tool than ERICA where one cannot easily add radionuclides and reference organisms. Moreover, it does not yet incorporate the most recent dosimetric developments; hence, it is not fit for the purposes of this study. In addition, there are several 'national' codes, which have been evaluated alongside ERICA in international intercomparison studies, but generally those are only in use by the developers themselves [21, 30]. Most of these codes have databases that are not as up-to-date as that of ERICA or do not take advantage of the latest IAEA and ICRP data and approaches. Therefore, in its current version 2.0, the ERICA Tool is most fit for purpose for assessments of the Category A near surface repository in Dessel.

It is felt that enough confidence in the results of the ERICA model has been generated through appropriate use of input data (based on the current scientific understanding and the assessment context), various model intercomparison exercises and real case studies as discussed in detail in the following sections.

4.2 Argumentation of level of detail of the QVV process

Regarding the level of detail invested in the three aspects of "qualification", "verification" and "validation", most of the QA/QC effort in ERICA focussed on the reliability of the input parameter values. The model developers carried out verification. Validation was partially achieved by the developers by performing assessments for contaminated sites and comparing the predicted biota concentrations and where possible external dose rates with measured values.

Extensive comparison exercises have been conducted, involving model developers and tool users with ERICA and other models for specific case studies, resulting in a full ERICA deliverable report [31]. Two further noteworthy examples are the Chernobyl Scenario comparison [32] and the Perch Lake scenario comparison [33]. Several other exercises took place within the IAEA EMRAS II (https://www.iaea.org/topics/environment/environmental-modelling-for-radiation-safety-emras) and MODARIA projects (http://www-ns.iaea.org/projects/modaria/) in which SCK CEN participates. An additional ERICA report containing the additional documentation submitted upon release of version 2 of the software [29] is also available.

4.3 Qualification

The ERICA model approach is a simplified reflection of the reality given the complexity of the environment; hence, important assumptions/hypotheses have to be made also for the ERA of the category A waste repository:

- Selection of a limited number of *reference organisms* to represent the ecosystem.
- Reference organisms represented by an *ellipsoid* for the DC calculations.
- Limited number of exposure conditions (habitats) for which homogeneous constant contamination situations are assumed.
- Concentration ratios (CR) are not species specific, not age-class specific, do not consider food webs, and assume equilibrium. They can be considered as lump-sum parameters, unable to provide a mechanistic interpretation of transfer, but they still represent the best information available in most cases.
- Distribution coefficients for soil ($K_{d,i}$) or sediment ($K_{df,i}$) to water are likewise equilibrium parameters.
- There is no direct relation between parameter values (CR and $K_{df,i}$) and environmental characteristics, though the latter will influence the former.

All these assumptions have an impact on the accuracy of the estimated dose rate to biota. Model developers and its users at SCK CEN (Annex 5 of reference [4]) performed QA/QC on all input data, including concentration ratios and solid-liquid distribution coefficients. Further efforts to represent the state-of-the-art of the current research on non-human biota were greatly simplified by the release of ERICA version 2.0.

Though the reality is only to some extent adequately represented, the ERICA approach assembles state-of-the-art information for generic environmental risk assessment in a scenario where environmental concentrations do not fluctuate too rapidly in comparison with biological retention times. This approach has been adopted as the standard ecosystem assessment tool in many European states and beyond (Annex 6 of reference [4]).

4.3.1 Procedures followed to ensure an adequate representation of reality

For the Category A work, we have endeavoured to ensure that the model provides an adequate representation of reality by taking on specific steps. Reference organisms are selected such that they adequately represent the Dessel ecosystems, i.e. they are selected such that they represent the major components of a relevant food web and locally protected or endangered species [4]. As a basis for the selection of reference organisms, an ecological survey in the vicinity of the disposal site, conducted in the framework of the environmental impact assessment report was consulted. However, it is necessary to acknowledge that any selection is to some extent arbitrary.

Special precaution is taken to ensure that CR values and the distribution coefficients $K_{df,i}$ are appropriate according to best knowledge. Since ERICA contains the latest international wisdom generated by the IAEA EMRAS and its successor MODARIA programmes, particularly the Wildlife Transfer Database (WTD), the task in relation to CR values has become simplified. For the $K_{df,i}$ however, we have departed from the ERICA tool defaults in favour of choosing the same values used in the biosphere model for human impact assessment in the local area [16, 17].

It must be re-emphasised that the conceptual model embedded in the ERICA Tool does *not* address time-evolution. ERICA incorporates a steady-state representation of transfer and considers immediate equilibrium, which generally results in a conservative assessment. This is within frame of the current regulatory framework, which requires analysing consequences of chronic, long-term releases, which tend to be essentially at equilibrium in biota.

4.3.2 QA/QC of the input parameters

The environmental input data for the different scenarios are taken from the data generated under Category A for the human impact assessment. Environmental concentrations (concentrations in groundwater, surface water, sediment, soil, air for the different exposure scenarios) calculated for and available from the impact assessment to humans have to be independently entered in the ERICA Tool (no link with e.g. excel or access-file possible) and this activity is hence prone to copying and typing errors. All environmental concentration input files were therefore reviewed by double entry and separate duplicate checking.

In general, since the beginning of the ERICA Tool development, all available 'default' input data (i.e. concentration ratios, solid-liquid distribution coefficients) have been subjected to an extensive QA/QC control in order to select appropriate and reliable input parameters taking into account the assessment context and assumptions herein. New parameters are only included within the Tool after the required QA/QC. For the category A assessment, the following choices were made regarding ERICA default input data:

- Freshwater distribution coefficient $K_{df,i}$ used within the SCK CEN Biosphere model [16, 17] are preferred over ERICA default entries and are therefore replaced, subject to a QA/QC. $K_{df,i}$ inputs are reviewed by at least one colleague.
- CR values were selected from the ERICA database and, where unavailable, the Wildlife Transfer Database was brought to bear or, failing this, the logical process involving selection rules available in the Tool were used. The data selections are explained in the assessment report [4].

Further, QA/QC was also performed to evaluate if the entry of reference organisms' characteristics (mass and dimensions) in ERICA was done appropriately. Occupancy factors (*OF*s) were selected such that they lead to conservative dose assessments. *OF* entries are also QA/QC checked.

When the data files are finalised, the input database is barred from further alteration, i.e. "frozen", to protect its integrity.

4.4 Verification of the mathematical model

The most sophisticated part of the model is the mathematical approach to calculated DCs [34] Absorbed fractions for monoenergetic α, β and γ rays are calculated using the well-known and tested MCNP code [35] or point kernel dosimetry calculations [36]. These methods involve an assumption of homogeneity of the distribution of radionuclides in the biota, and the uncertainties incurred with this assumption have been evaluated and found to be acceptable for a conservative dose assessment [37]. The interpolation method for radionuclide DCs with size and shape has been independently verified and published in the scientific literature [22, 23, 38]. Dosimetry and transfer calculations have been tested in two successive intercomparisons, the latest involving over 70 radionuclides and 5 exposure scenarios with 11 international biota dosimetry models [18, 21, 30]. Verification is also partly achieved through case studies [31]. The method is further refined in the aforesaid ICRP Publication 136 [24], which is the final form of the approach in ERICA version 2.0.

For the prediction of environmental concentrations one must rely on the environmental concentrations predicted in the context of human impact assessment [4]. All parameter values and contamination conditions (environment and biota) are equilibrium values, so no time-dependent mathematical equations are applicable. The dose rates are calculated via simple and commonly used physical equations set out in the assessment report [4]. The approach is fully described and justified elsewhere [8, 9].

4.5 Verification of code

The ERICA Tool is maintained by a consortium comprising the Norwegian Radiation Protection Authority, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), the Environment Agency (England and Wales), the Centre for Ecology & Hydrology (UK), IRSN (France) the Swedish Radiation Safety Authority and CIEMAT (Spain). Facilia AG (Sweden) is responsible to continue the ERICA Tool development.

During the initial development of the Tool, and whenever it has been updated, Facilia has carried out substantial QA testing. Intensive debugging of the software was undertaken in the period leading up to the release, and the facility exists to report online any occasional problems that may still arise. Additionally, the code includes, for each module involved in the deterministic calculation, unit test functions to verify that the equations have been implemented correctly. Information about the changes, improvements and corrections applied to the Tool since its inception can be found at release notes under the Help menu of an installed ERICA Tool (Help -> Release Notes).

Predictions of activity concentrations in biota and media made by the Tool as part of the above study were generally adequately in agreement with observed data. Where this was not the case, reasonable arguments could be presented to explain difference. The case studies did not provide any definitive validation of the radiation effects prediction provided by the Tool beyond the observation that, for one particular case where a cursory comparison was practicable, the predictions made were not in contradiction to the observed effects in the field. It is concluded that the mathematical equations implemented in the software have been adequately implemented.

The fact that the ERICA Tool has been rigorously tested by both the developers and independent users in inter-comparison exercises of the IAEA's EMRAS programmes [20, 21, 30, 32, 33] prove that ERICA gives sensible results as such and in comparison with other tools.

4.6 Verification of computer model

All hypotheses related to organism geometry, initial conditions of the assessment (biota and/or media concentrations), transfer and occupancy parameters, etc. have to be manually entered and extracted from the ERICA Tool unless default values are used. Consequently, all input/output files and data are reviewed independently by suitably qualified personnel.

4.7 Validation

The most important validation document, containing information on the testing carried out in ERICA, is the Deliverable D10 of ERICA [31]. This document presents the application of outputs of the ERICA project to five different case study sites: Drigg Coast Sand Dunes, UK (terrestrial ecosystem); Loire River, France (freshwater ecosystem); Sellafield, UK (marine ecosystem), Komi Republic, Russia (terrestrial ecosystems) and the Chernobyl exclusion zone, Ukraine (terrestrial ecosystems), to assess the applicability of the methodology. The exercises involved comparison of predicted and observed activity concentrations in biota (and water/sediments for aquatic ecosystems) and, where possible, to compare measured doses and observed radiation induced effects with estimated doses and predicted effects, for a broad suite of engineered radionuclides.

The ERICA Tool has also been validated partly through some real scenario exercises for the Chernobyl area, Perch Lake scenario, legacy & NORM sites and other specific scenarios, which have already been published. These exercises are effectively comparisons with experiments and field data.

The referred publications from the relevant IAEA EMRAS and MODARIA programmes include a detailed assessment of robustness of the radiological risk assessment for wildlife used by the Tool [39], model comparison exercises for a waste disposal site in Australia [40], a uranium mining and milling site in Canada [41] and an assessment study for wetland ecosystems [42], as well as additional dosimetry [43, 44] and model comparison studies [21, 33], all attesting to the full scientific validation of the ERICA tool as such and/or by comparison with other models.

5 Conclusions

5.1 Authorised domain of application

The ERICA Tool is an internationally accepted approach for performing assessments of radiological impact to non-human biota. It is backed by a solid record of scientific publication and comparison with other models available to different IAEA member states. The methodology is publicly available; it is continuously maintained by a dedicated team and represents a wide and well-documented scientific consensus at European level. Some European countries, such as England & Wales, have largely replaced their own national approach in favour of the ERICA methodology. For these reasons, we believe that ERICA is the appropriate tool to use within the framework of the long-term safety assessment for near-surface disposal of Category A waste disposal at Dessel.

The main FEPS in the conceptual model are dose rate levels that cause effects on non-human biota, migration and transfer of radionuclides in the ecosystem (CR, $K_{df,i}$), as well as the selected reference organisms. The ERICA model is readily applicable once all input parameters and the reference organisms are selected such as to represent the terrestrial and freshwater ecosystems of the environs of the Dessel site. After this has been achieved, the input database and files are brought to a frozen state. In this 'frozen state' the model is applicable to a given ecosystem (terrestrial and/or aquatic) for the various scenarios selected for the ERA of the category A disposal programme.

The model results apply within the spatial and temporal domain of the 'here and now' of the specific assessment. This is because the ERICA approach is not dynamic in respect of transfer, assuming constant partitioning of radionuclides between the medium and the biota, i.e. only equilibrium parameters are considered. Furthermore, contamination has to be considered as homogeneous within the medium. Within these restrictions, ERICA will provide a suitable assessment in line with the current regulatory framework for non-human biota, which requires analysing consequences of chronic, long-term releases, which tend to be essentially at equilibrium.

5.2 Precision and uncertainties

The main uncertainty in the conceptual model lies with *transfer,* assumed to be at equilibrium via a concentration ratio, which has a high degree of variability [18, 20]. This variability is due to two main factors:

1) the CR value is an average representing a reference organism rather than a value for a specific species. Hence, for example, the actual CR value for bird-duck is unlikely to be the same as for bird-falcon;
2) the CR value is growth-stage independent, homogeneous for species and the fact that there may be different CR values for different organs (e.g. if an organ has a specific retention capacity for a particular radionuclide, e.g. iodine in thyroid) is not included.

Moreover, the CR value is independent from (potentially changing) environmental conditions.

Another potential area of uncertainty in the model is that reference organisms (ROs) are *hypothetical* entities. They are a simplified representation of ecosystems and RO geometry and their habits are also simplified. As stated previously, the distribution of internally incorporated radionuclides within the RO is assumed to be uniform. However, the error committed by this approximation has been proven to be relatively small [38].

For radiological assessment in non-human biota, several features, events and processes (FEPS) are uncertain and require more research, e.g. dose rate levels that cause effects on population (limited knowledge for limited species), contaminant migration factors in natural ecosystems, effect of environmental change on cycling of radionuclides, physic-chemical factors (speciation) and dynamics of radionuclide transfer to biota. These are open and widely debated areas of research. Additionally, certain boundary and initial conditions of the assessment have a level of uncertainty, such as the assumption of contamination being homogeneously distributed, CR values (likely the main source of uncertainty as explained above), limitations of the equilibrium K_d approach, etc.

Whilst it has to be accepted that there are no definite answers to some of the above uncertainties, the ERICA Tool still represents the best consensus available on the quantification of the effects of radiation in non-human biota. Moreover, where simplifying assumptions have been made, the ERICA Tool factorises a degree of conservatism in the assessment so that radiological effects are unlikely to be underestimated.

5.3 Recommendations for future work

The ERICA Tool version 2.0 represents the current state of the art in assessment of radiological impact to non-human biota. The tool's databases have been fully updated in order to cover some of the existing data gaps. The Tool continues to evolve, and we advise updating an assessment if a major version change occurs in the future.

If assessment results indicate a potential problem area, more thorough data gathering for the specific condition may be required, and perhaps more detailed modelling (outside the ERICA Tool) may need to be performed, eventually complemented with experimentation. For the assessment documented in [4], there is, however, no need for such developments.

Throughout the process, we continuously follow-up scientific developments in the domain, capitalising on our current involvement in international working groups and networks of expertise within IAEA, ICRP and UNSCEAR.

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Annexes

1 Annex 1: Glossary of terms

A **conceptual model** is a stylised representation of reality, covering assumptions with respect to the geometry and dimensionality of the system, initial and boundary conditions, time dependence, and the nature of the relevant physical, chemical and biological processes and phenomena.

To have **confidence** is to have reached a positive judgement that a given set of conclusions are well supported.

Disposal is the emplacement of radioactive waste in an appropriate facility without the intention of retrieval.

A **FEP** is a feature, event, process or other factor that may be necessary to consider in a repository safety assessment. This includes physical features, events and processes that could directly or indirectly influence the release and transport of radionuclides from the repository or subsequent radiation exposures to humans, plus other factors, e.g. regulatory requirements or modelling issues that constrain or focus the analysis.

Qualification of a conceptual model is the process of ensuring that it is consistent with scientific understanding within the assessment basis and adequately represents the considered phenomena and processes and their interactions, given its objective(s) and intended use.

Validation is the process of comparing model predictions to observations on a real system, taking into account the involved temporary and spatial scales.

Verification is the process of determining whether a computer model correctly implements the intended conceptual model.

2 Annex 2: List of acronyms

CR	Concentration Ratio
DC	Dose Coefficient
DCRL	Derived Consideration Reference Level
DOE	Department of Energy
EMCL	Environmental Media Concentration Limits
EMRAS	Environmental Modelling for RAdiation Safety
EPIC	Environmental Protection from Ionising Contaminants in the Arctic
ERA	Environmental Risk Assessment
ERICA	Environmental Risk from Ionising Contaminants: Assessment and Management
FANC	Federal Agency for Nuclear Control
FASSET	Framework for Assessment of Environmental Impact
FEPS	Features, Events and Processes
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
MCNP	Monte Carlo N-Particle
MODARIA	MOdelling and DAta for Radiological Impact Assessments
OF	Occupancy Factor
ONDRAF/NIRAS	Belgian Agency for Radioactive Waste and Enriched Fissile Materials [*Organisme National des Déchets Radioactifs et des matières Fissiles enrichies/Nationale Instelling voor Radioactief Afval en verrijkte Splijtstoffen*]
PEDR	Predicted Environmental Dose Rate
PNEDR	Predicted No-Effect Dose Rate
QA/QC	Quality Assurance/Quality Control
QVV	Qualification, Verification and Validation
RAPS	Reference Animals and Plants
ROS	Reference Organisms
RQ	Risk Quotient
SCK CEN	Belgian Nuclear Research Centre [*StudieCentrum voor Kernenergie/Centre d'étude de l'Énergie Nucléaire*]
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiaton
WTD	Wildlife Transfer Database

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