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Belgian Nuclear Research Centre



EUROPEAN RADIOECOLOGY ALLIANCE

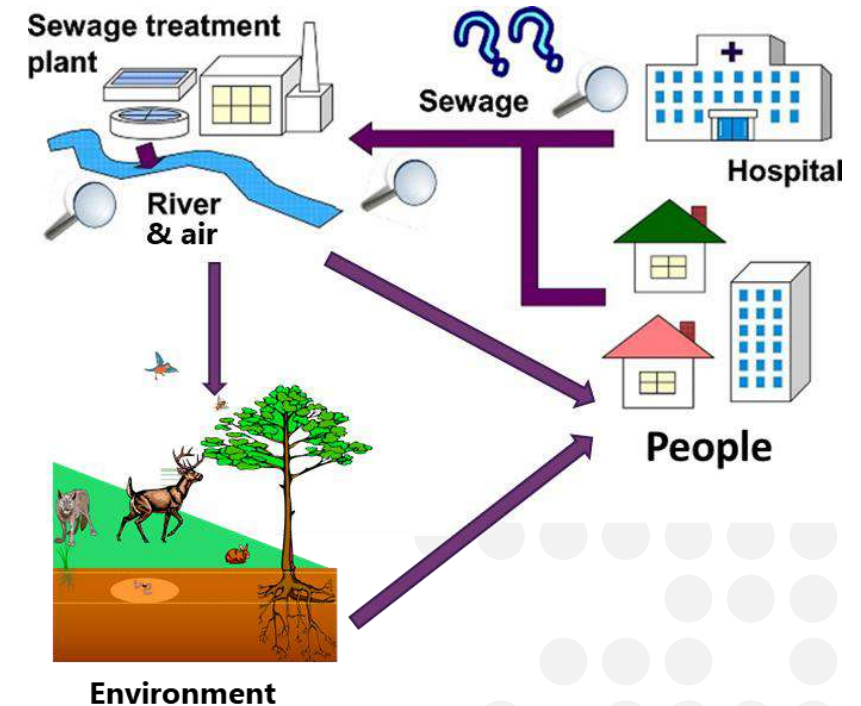
ALLIANCE Webinar - Assessing impact of production, use and disposal of radiopharmaceuticals on members of public and the environment.

Identification of data gaps for medical RNs for the calculation of doses to human and non-human biota.

Jordi Vives i Batlle

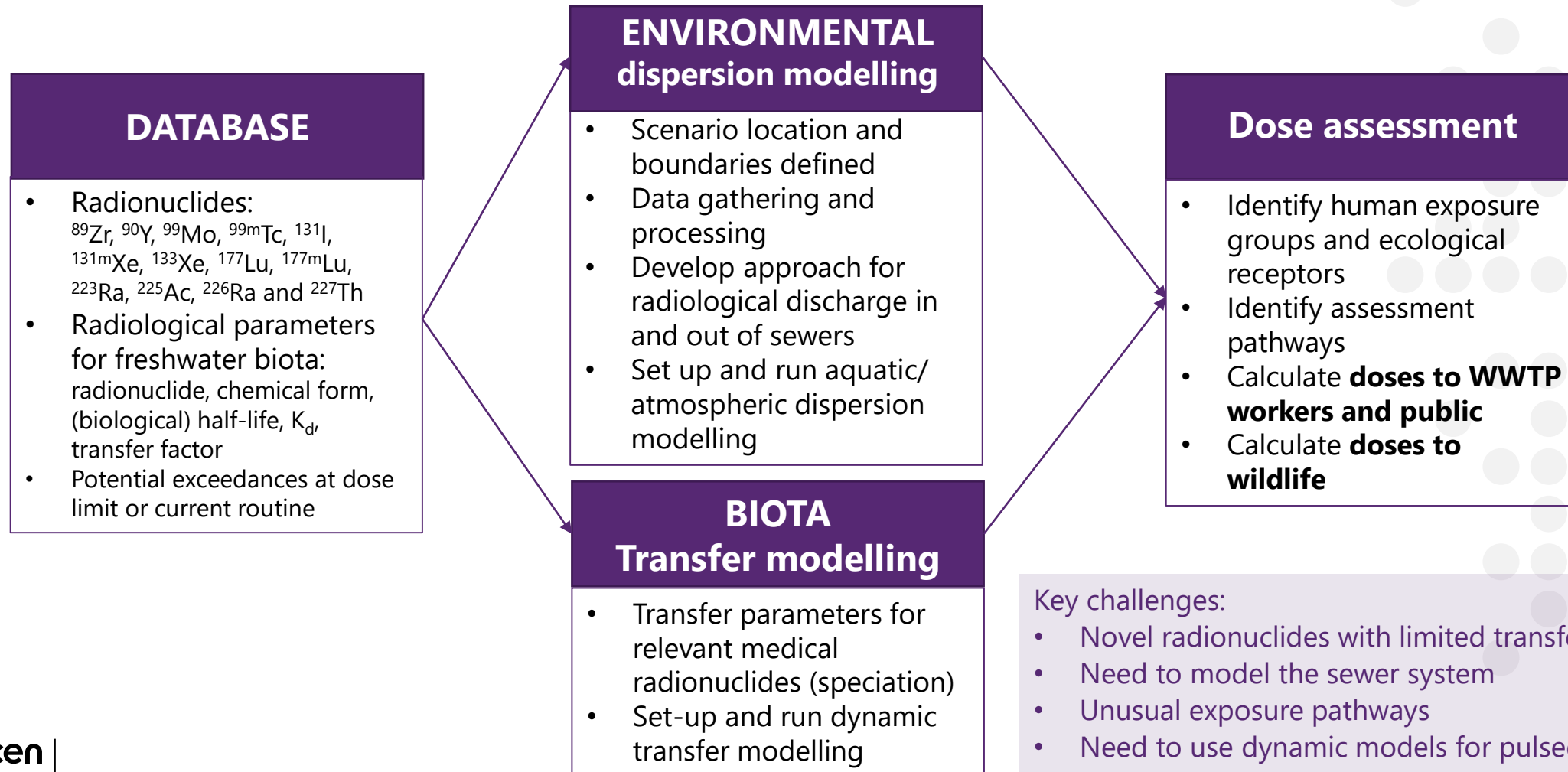
Introduction

- Ongoing improvements in the medical field have resulted in an expansion of the use of radionuclides for diagnostic and therapeutic purposes.
 - Increasing demand for a growing number of new radionuclides (e.g. ^{177}Lu , α -emitting ^{223}Ra and ^{227}Th).
 - Radiopharmaceuticals (RP) production rising to cope with demand.
- This leads to potential releases of new radioactive substances into the environment.
 - Authorised releases from production facilities and hospitals: higher authorization limits than for nuclear reactors.
 - Incidental releases from RP manufacturing plants or hospitals: New production routes (e.g. ^{225}Ac production from ^{226}Ra) may potentially increase exceedances.
- In hospitals, releases occur after RNs leave the patient's body and storage in dedicated decay tanks, plus outpatient treatment.
- Most RNs in nuclear medicine arise from decay of long-lived precursors. Impacts at the level of acquiring or production of such precursors has not been considered (e.g. ^{99}Mo from irradiated HEU).
- Scarcity of assessments for planned & emergency releases in RN production, diagnostic and treatment.



The assessment process

1. Develop **scenarios** with relevant radionuclides and environmental conditions likely to be found after release from RP factories/hospitals
2. Estimate the **activity levels of radiopharmaceuticals in water, sediment AND FOODSTUFFS** at different points of the sewer & surface water systems
3. Calculate the **resulting dose** to humans (sewer workers, members of the public) and biota



What are the key radionuclides?

RN	Relevance	Chemical form administered	Chemical form	Speciation	λ (d ⁻¹)
⁸⁹ Zr	Used in positron emission tomography (PET); hospital releases	Radiolabeled monoclonal antibodies		Soluble	3.3
⁹⁰ Y	Used in radiotherapy to treat cancer	injection of nanoparticulates/colloids labeled with ⁹⁰ YCl ₃	Y ⁺³ (ionic)	Soluble	2.7
⁹⁹ Mo	^{99m} Tc production by decay of ⁹⁹ Mo	Not administered		Highly soluble	2.7
^{99m} Tc	Nuclear medicine diagnostic procedures	^{99m} TcO ₄ ⁻ (VII), other reduced complexes in III or IV state	^{99m} TcO ₄ ⁻ (pertechnetate)	Highly soluble	0.3
¹³¹ I	⁹⁹ Mo production byproduct, unsealed source thyroid radiotherapy or diagnostic cameras; hospital releases	sodium iodide (Na ¹³¹ I) and metaiodobenzylguanidin		Moderately insoluble	8.0
^{131m} Xe	By-product of the ⁹⁹ Mo production process	Noble gas (not administered)	As free element	Gas	12
¹³³ Xe	By-product of the ⁹⁹ Mo production process	Noble gas (not administered)	As free element	Gas	5.2
¹⁷⁷ Lu	Radiopharmaceutical precursor used for radiolabelling medicines; hospital releases	¹⁷⁷ LuCl ₃ , Lutathera lutetium (¹⁷⁷ Lu)-oxodotreotide	Akaline nature, Lu(OH) ₃	Highly soluble	6.6
^{177m} Lu	Radionuclide generator-based production of therapeutic ¹⁷⁷ Lu from ^{177m} Lu	Not administered	Akaline nature, Lu(OH) ₃	Highly soluble	160
²²³ Ra	Xofigo therapy with ²²³ Ra dichloride injections to treat bone tumours	²²³ RaCl ₂		Moderately soluble	11
²²⁵ Ac	Targeted alpha-particle therapeutic applications	Free metal or various chelating and complexing agents		Highly insoluble	10
²²⁶ Ra	²²⁵ Ac production in medical linear accelerator (linac) by bombarding a ²²⁶ Ra target	Not administered	Insoluble	Moderately soluble	584400
²²⁷ Th	Targeted thorium conjugates(TTC)	Attached to targeting proteins such as antibodies for delivery to tumor cells		Highly insoluble	19

Main sources of assessment uncertainty

- Most releases of radionuclides after therapy are limited and their radiological impact will likely be lower than that for RN/RP production
- Environmental levels of short-lived RNs limited due to dilution and radioactive decay during environmental transport
 - There is a regulatory need to be able to demonstrate protection
 - Environmental parameters for short-lived RNs are difficult to obtain, leading to assessment uncertainty.
- Limited environmental monitoring data
 - Hospitals seldom monitor the environment as is done for discharges from the nuclear industry, leading to need to model environmental concentrations, often using generic rather than site specific data.
- Few data available for input in assessment models for many of the medical RNs released.
 - Missing environmental transfer data in current databases for RNs from new treatments, not considered for other uses.
 - Uncertainties in the speciation of RNs used in medical therapy compared to industrial applications.
 - Basic research on transfer parameters (concentration ratios and biological half-lives) not done yet, requiring physico-chemical analogue extrapolations.
- Unusual exposure pathways seldom seen in other assessments need to be considered
 - Release to sewerage network and water treatment plant from inpatient and outpatient treatment
 - Aerial exposure route: sewage sludge incineration, or if the patient dies soon after treatment and the body is cremated
 - Transfer to land: application of sewage sludge to agricultural fields, use of irrigation waters downstream from the treatment plant
- On top of this there is still the issue of conceptual assessment model uncertainty
- Uncertainties in the (mis)perception of human and environmental risks by members of the public

Dealing with transport model uncertainty



- Scenario description



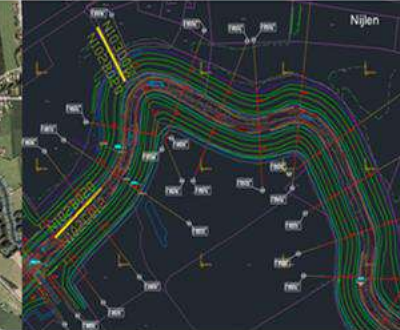
- 2 Hospitals (Geel and Mol)
- Approx. 100 km river network
- Well populated zone - 300-700 Inh/km²
- Land use: Industry and agriculture
- Water use: Irrigation, cattle and recreation

- Topographic data based on real data

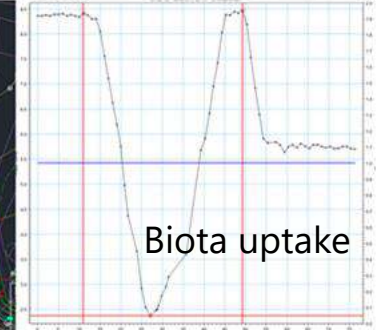
Data identification



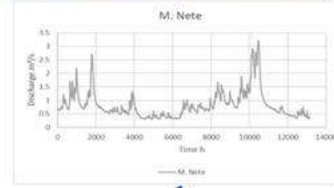
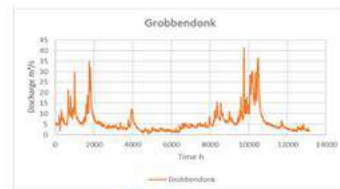
Data Collection



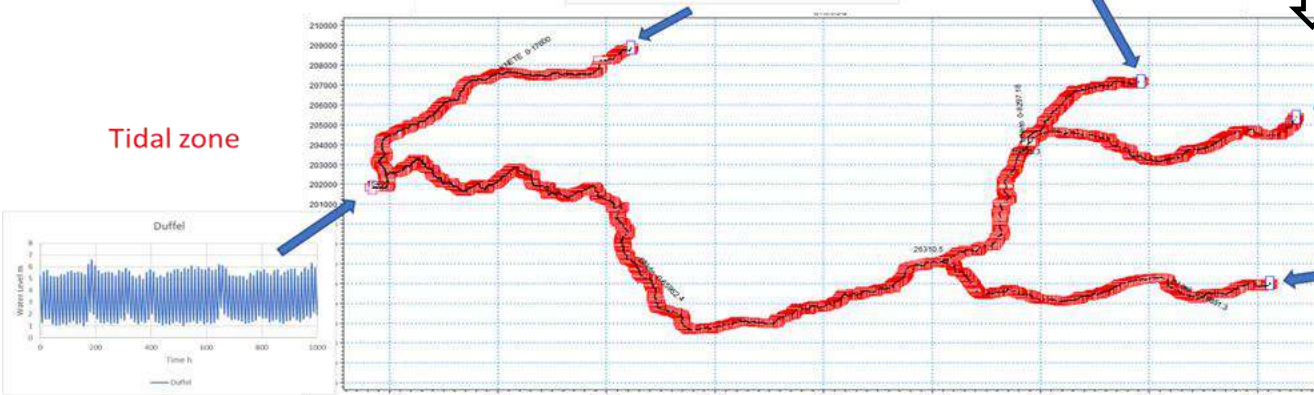
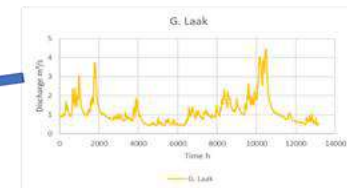
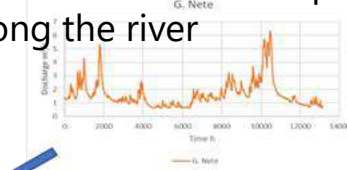
Data Processing – transversal section of river



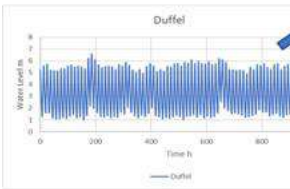
- Hydrological measurements
- Includes tidal effects
- All influences on water system considered



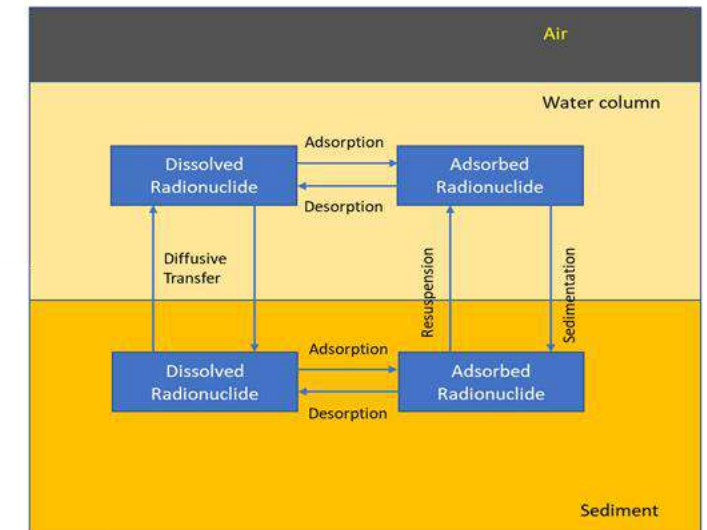
Considers different inputs along the river



Tidal zone



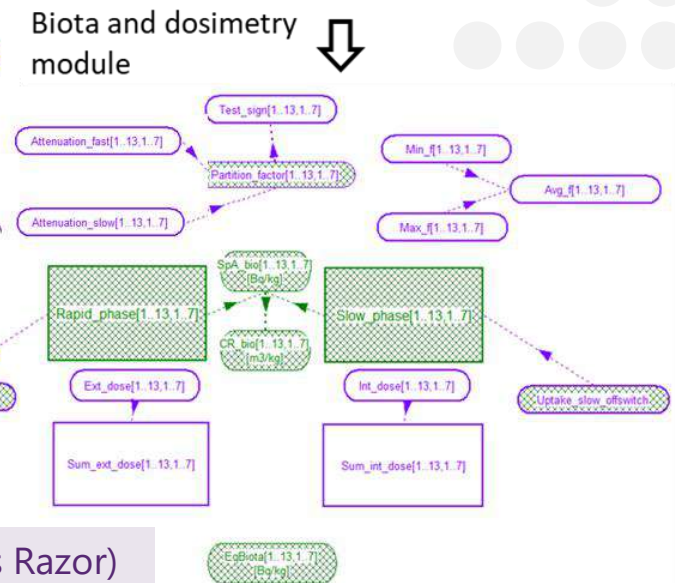
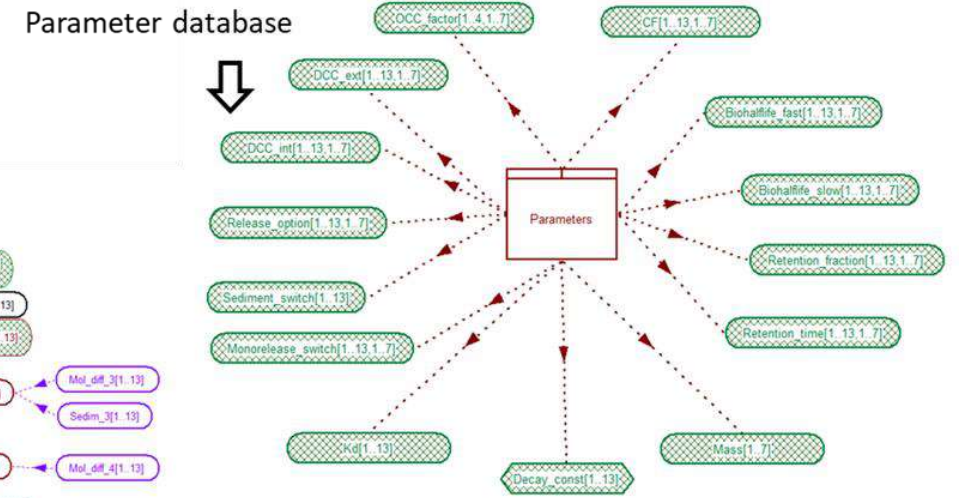
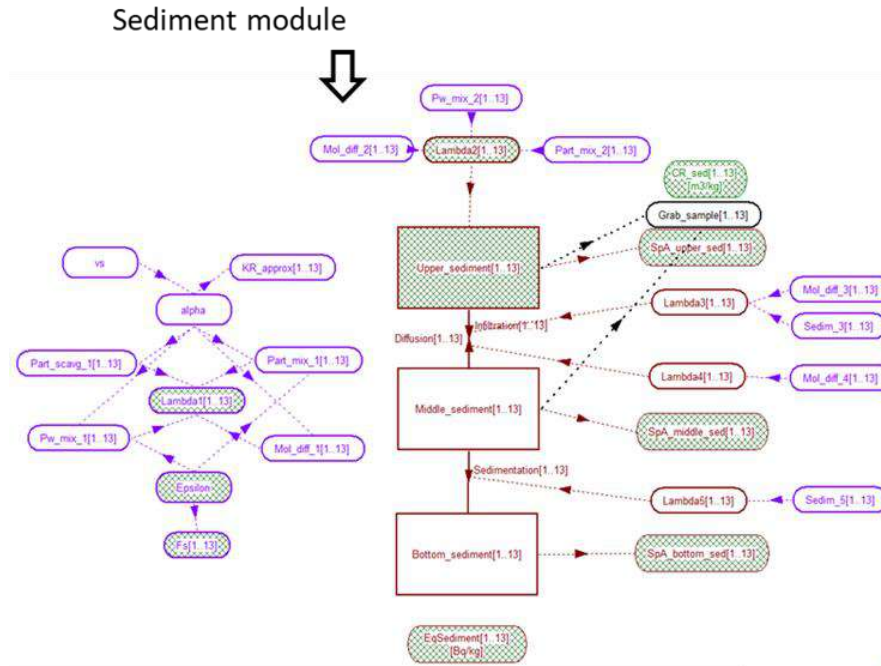
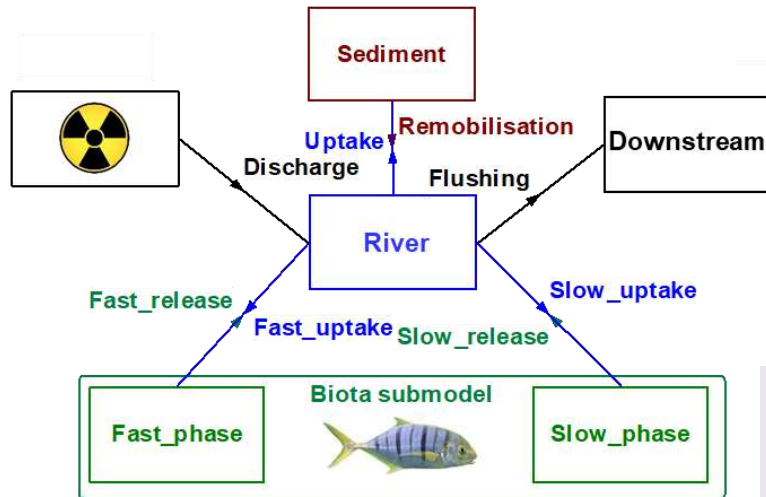
- Interactions in the water column and sediment



- Simplification of the hydrology and bathymetry
- Generic parameters
- Simplification of the Navier-Stokes equation
- Numerical algorithms

Dealing with transfer model uncertainty

- Dynamic biokinetic model
- 3 sub models interacting
- Can calculate internal and external dose rates
- Output: dose rate per unit concentrations ($\mu\text{Gy h}^{-1}$ per Bq kg^{-1})



1...13: Radionuclides

- Zr-89
- Y-90
- Mo-99
- Tc-99m
- I-131
- Xe-131m
- Xe-133
- Lu-177
- Lu-177m
- Ra-223
- Ac-226
- Ra-226
- Th-227

1...7: biota

- Pelagic fish
- Benthic fish
- crustacean
- mollusc
- macroalgae
- phytoplankton
- zooplankton

- Simplification of biokinetic processes (Occam's Razor)
- For biota: simplification of ecosystem/species
- Use as much site specific data as possible
- Search databases/analogs/extrapolation methods
- Do experimental data when possible

Dealing with assessment model uncertainty

4 Disposal Pathway Parameters

Parameter	Value	Units	Comment
Volume of liquid at site outfall blockage	1	m ³	Nominal - please enter realistic value
Flow rate through sewer works	0.011574074	m ³ s ⁻¹	
	1000	m ³ day ⁻¹	Nominal - please enter realistic value
Rate of sludge production to incoming sewage	0.02739726		
Flow rate in river (1, fish and external pathways)	5	m ³ s ⁻¹	Nominal - please enter realistic value
Flow rate in river (2, irrigation)	5	m ³ s ⁻¹	Nominal - please enter realistic value
Flow rate in river (3, public drinking water suppl)	5	m ³ s ⁻¹	Nominal - please enter realistic value
Suspended sediment in river	2.50E-05	tonne m ⁻³	Nominal - please enter realistic value
Average dry weather flow	5	ML day ⁻¹	Nominal - please enter realistic value
Annual Total volume of sludge	10000	m ³	Nominal - please enter realistic value

Colour code

	Data needs to be input
	Data calculated by the tool

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Research and analysis

Investigation of the sources and fate of radioactive discharges to public sewers

This report presents the final findings of research into the sources and fates of radioactive discharges to public sewers.

From: [Environment Agency](#)
 Published 22 June 2005

Documents

Investigation of the Sources and Fate of Radioactive Discharges to Public Sewers
 Ref: UT 2087
 PDF, 19.41MB, 292 pages
 This file may not be suitable for users of assistive technology. [Request an accessible format.](#)

Brexit

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17 Data for assessment of exposure of sewer workers

Parameter	Blocked Sewer Sewage Works	Units	Comment
Breathing Rate	1.2	m ³ h ⁻¹	UK data, needs to be updated with data from biosphere model
Ingestion Rate	5.00E-06	kg h ⁻¹	UK data, needs to be updated with data from biosphere model
Average airborne particle concentration	1.00E-07	kg m ⁻³	UK data, needs to be updated with data from biosphere model
Occupancy	2	h y ⁻¹	UK data, needs to be updated with data from biosphere model
Ingested sewage	1.00E-05	kg y ⁻¹	UK data, needs to be updated with data from biosphere model
Inhaled sewage	2.40E-07	kg y ⁻¹	UK data, needs to be updated with data from biosphere model

26 Data used for terrestrial foodchain calculations

Parameter	Category	Value	Units	Comment
Irrigation by river water (unfiltered)		100	litres/m ² per year	UK data, needs to be updated with data from biosphere model
Application rate of sewage sludge to farmland		8	kg/m ² per year	UK data, needs to be updated with data from biosphere model
Food Consumption rates	Milk	240	L y ⁻¹	UK data, needs to be updated with data from biosphere model
	Beef	45	kg y ⁻¹	UK data, needs to be updated with data from biosphere model
	Sheep meat	25	kg y ⁻¹	UK data, needs to be updated with data from biosphere model
	Green Vegetables	80	kg y ⁻¹	UK data, needs to be updated with data from biosphere model
	Root vegetables	130	kg y ⁻¹	UK data, needs to be updated with data from biosphere model

37 Habit data and other parameters for public exposure

Parameter	Value	Units	Comment
Drinking water consumption	0.6	m ³ y ⁻¹	UK data, needs to be updated with data from biosphere model
Intakes of unfiltered river water	0.001	m ³ y ⁻¹	UK data, needs to be updated with data from biosphere model
Freshwater Fish consumption	20	kg y ⁻¹	UK data, needs to be updated with data from biosphere model
Riverbank Occupancy	1000	h y ⁻¹	UK data, needs to be updated with data from biosphere model

- Source human intake rates, occupancy data workers
- Land (sludge) and air disposal parameters
- Habits surveys for most exposed consumers
- Biota ecosystem characterisation, transfer data
- Dosimetry

2 Source term and fractions appearing in sewage

Radionuclide	Half-Life	Mean Monthly Discharge	Mean Annual Discharge	Average Discharge Rate	Fractions in Sewage Materials		
		Bq	Bq	Bq/s	Reaching Sewage Works	Removal Efficiency for sewage works	In sludge at STP
6 Total alpha		1.65E+03	1.98E+04	6.27E-04	1	0.15	0.15
7 Other beta		1.60E+05	1.92E+06	6.08E-02	1	0.15	0.15
8 Tritium	12.3 y	9.34E+05	1.12E+07	3.55E-01	1	0.15	0.15
9 Sulphur-35	87.5 d	0.00E+00	0.00E+00	0.00E+00	1	0.1	0.1
10 Carbon-14	5730 y	6.69E+05	8.03E+06	2.54E-01	1	0.15	0.15

Note from Jordi: This model does the radionuclides by class (total alpha, beta, etc0 but we want to do this for specific radionuclides: Tc and I

Note from Jordi: In here we can improve the model and put decay factors based on time passed during the sewage processes, and depending on half-life of the radionuclide
 We would do this by modifying the calculation in columns G and H

12 Radionuclide Concentrations

Radionuclide	Activity in blocked drain as % of monthly limit	Average Concentrations (Bq/m ³)					
		Blocked Sewer	Into Sewage works	In sludge at STP	River Fish	River Irrigation	River Drinking
15 Total alpha	1	1.7E+01	5.4E-02	3.0E-01	1.1E-04	1.1E-04	1.1E-04
16 Other beta	1	1.6E+03	5.3E+00	2.9E+01	1.0E-02	1.0E-02	1.0E-02
17 Tritium	1	9.3E+03	3.1E+01	1.7E+02	6.0E-02	6.0E-02	6.0E-02
18 Sulphur-35	1	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
19 Carbon-14	1	6.7E+03	2.2E+01	1.2E+02	4.3E-02	4.3E-02	4.3E-02

In river fish we need to apply a concentration factor, as only the external dose to fish is considered here, this is where Jordi's work will go to improve/replace this calculation with a D-DAT transfer model calculation which will be more realistic

Related EC project 1 - SINFONIA

Assessment approach for people and environment

- Develop hypothetical scenarios with relevant radionuclides and environmental conditions likely to be found downstream from the source point
- Set up method to estimate the activity levels of radiopharmaceuticals in water and sediment at different points of the sewer and surface water systems
- Calculate the transfer and resulting dose to human and biota
- Radionuclide dispersion simulations results for a proof-of-concept case (Geel and Mol hospitals in the Kempen region)
- Scientific publication

Main challenges due to data uncertainty

- Need parameters for the relevant radionuclides/radiopharmaceuticals
- Considering only impact on WTP operators and public/biota downstream the discharge point
- No speciation simulations or process-based modelling in WTP

Deliverables

- Radionuclide dispersion simulations results (D3.4) – 30/09/2022
- Human and biota assessment (D3.5) – 27/02/2023

Project Information

SINFONIA

Grant agreement ID: 945196

DOI

10.3030/945196

Start date

1 September 2020

End date

31 August 2024

Funded under

Euratom

Total cost

€ 5 999 998,75

EU contribution

€ 5 999 997,50



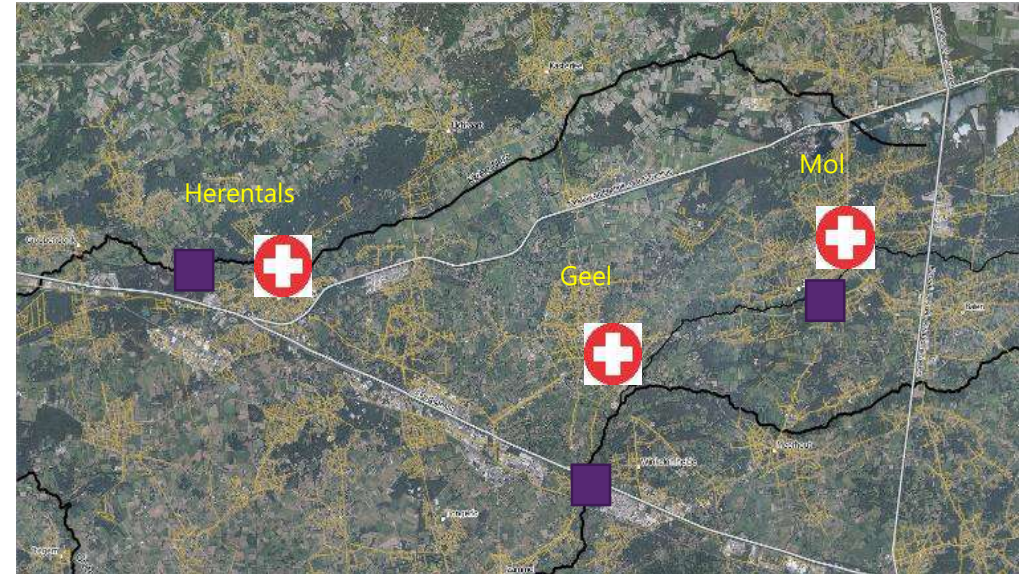
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Project status

- Radionuclides and parameters defined
- Data for releases available from WTP operators and regulator
 - Releases from hospitals (1hr. resolution)
 - Releases after WTPs (1 hr. resolution)
- River flow and level at the outlet of the WTPs modelled
 - Years to be simulated: 1998, 2007 and 2018
- Scenarios designed - currently parameterizing with data
 - Normal operation of the WTP
 - Direct release from hospitals to the river
 - Accidental spill from hospitals
- Next steps: computation of the dose.
 - D-DAT dynamic biota assessment tool implemented for freshwater
 - human Biosphere model parameterisation in progress



It is not the purpose of the project to make an accurate and detailed assessment of a specific case, but to establish the main steps, uncovering the data gaps along the way, leading to recommendations for further research

• Related EC project 2 – EURAMED Rocc-n-roll

- EUROpeAn MEDical application and Radiation prOteCtion Concept: strategic research agenda aNd ROadmap interLinking to healTh and digitisation aspects
- Task 2.4: Identification and prioritisation of ALLIANCE and NERIS SRA topics relevant to medical RP research
 - Consider each stage of radionuclides use in medicine: radionuclides sourcing, radiopharmaceuticals manufacturing, application and environmental fate.
 - Perform a ranking analysis, both within SRA and NERIS appointed panels.
- The aim was not to produce specific project proposals, but to identify (prioritise) research topics that need to be done within the framework of linking ALLIANCE and NERIS with EURAMED.

EURAMED rocc-n-roll
Grant agreement ID: 899995


Start date
1 September 2020

End date
31 August 2023


Funded under
H2020-Euratom
H2020-Euratom-1.

Overall budget
€ 1 959 175

EU contribution
€ 1 959 175



Coordinated by
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DER ERFORSCHUNG DER BIOMEDIZINISCHEN
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What has been achieved

- ALLIANCE/NERIS panels conducted brainstorming and interaction meetings to discuss contribution to EURAMED Rocc-n-Roll
- Additional ALLIANCE meeting with Belgian regulator FANC to discuss the environmental impact of radiopharmaceuticals
- Identification and prioritisation of ALLIANCE SRA topics relevant to medical radiation protection research
- Identification and prioritisation of NERIS SRA topics relevant to medical radiation protection research
- Additional ranking exercise with ALLIANCE board of directors and SRA group, and equivalent effort in NERIS annual meeting.
- Joint writing of deliverable in collaboration with NERIS – deliverable submitted
- European Radiation Protection Week 2021 presentation.



D2.4 ALLIANCE and NERIS SRA topics relevant to medical radiation protection



Project title: EUROPEAN MEDICAL application and Radiation PROTECTION Concept: strategic research agenda and Roadmap interlocking to health and digitisation aspects

Grant Agreement: 899995

Call identifier: NFRP-2019-2020

Topic: NFRP-2019-2020-13 Research roadmap for medical applications of ionising radiation

D2.4 Identification and prioritisation of ALLIANCE and NERIS SRA topics relevant to medical radiation protection research

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Work Package:	WP2
Due date:	Month 18
Actual delivery date:	15/02/2022
Type:	R
Dissemination level:	PU

The project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 899995

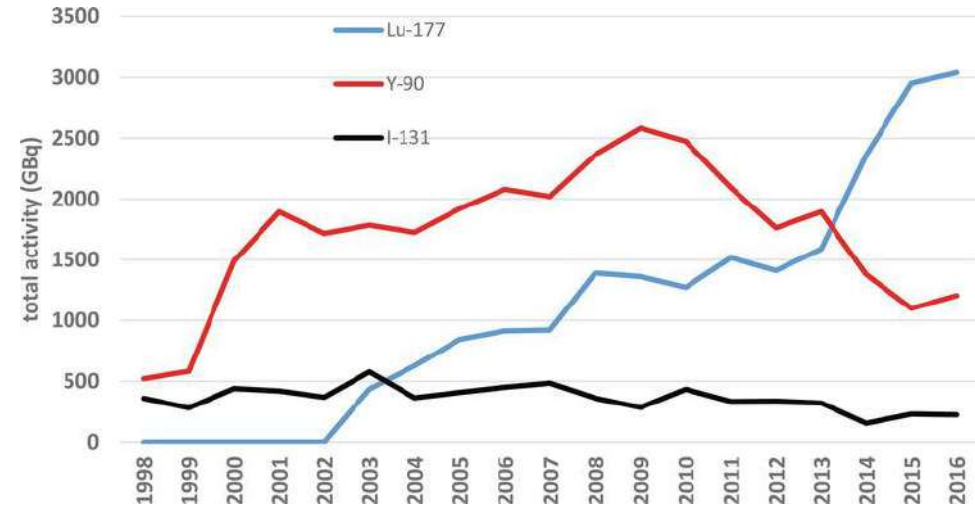


Proposed research topics in order of ranking according to ALLIANCE

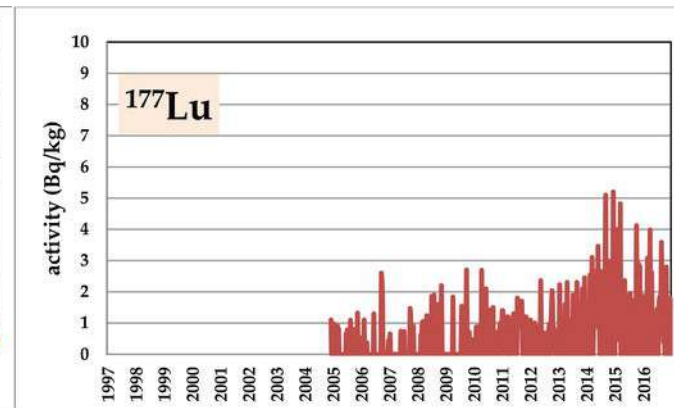
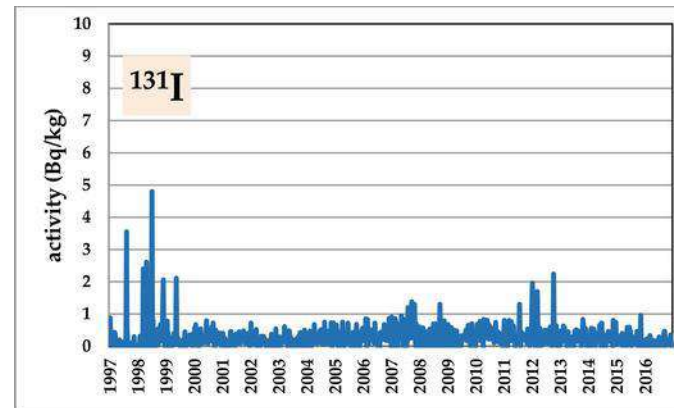
Topic	Ranking
Methodological guide on what radionuclides are relevant and requirements for assessment to people and wildlife.	9.3
European survey on the extent of use of radiopharmaceuticals from production to patient use to waste disposal.	8
Physical and chemical speciation of the most environmentally-relevant, longer-lived medical radionuclides, highlighting the environmental interactions.	7.8
Identification and systematic description of environmental exposure pathways for people (workers and the public) and wildlife.	7.7
Methods to address data gaps in assessment model parameters (mathematical evaluation and communication of uncertainties).	7.5
Compilation of terrestrial and freshwater transfer parameter values (CR , K_d , $T_{B1/2}$, etc.) and identification of data gaps for medical radionuclides.	7.4
Generic assessment software modelling system for release/processing of releases from hospitals and radionuclide production facilities.	7.2
General approach to define scenarios (atmospheric, coastal, river, terrestrial, urban) for transfer to humans and biota in clinical treatments and the radiopharmaceutical industry.	6.8
Estimation of dose to the general public from routine and accidental releases for demonstration of dose assessment procedures involving medical facilities	6.8
Improved radio-ecological dispersion models for use in discharges impact assessment.	6.7
Lifecycle analysis "radionuclide factsheets" from a human and environmental safety perspective.	5.8
Demonstration scenarios for wildlife dose rates arising from routine and accidental releases for medical facilities.	5.7

A reflection on future research

- Main feedback received from the ALLIANCE: ranking should be balanced with dose criteria
 - Consider potential to contribute to dose since dose estimation is the crucial assessment step.
- Additional criteria: need to demonstrate sufficient protection against uncommon exposure pathways
 - E.g. outpatient releases, deceased patient cremation, wastewater treatment
- It seems necessary to implement more organised monitoring programmes.
 - Use of some medical isotopes is growing and levels in WWTPs reflect this.
 - A few violations of the limits for radiopharmaceuticals have been observed.
- Scientific criteria: there are knowledge issues to explore.
 - e.g. unanticipated or altered biodistribution of radiopharmaceuticals.



Used activities of radiopharmaceuticals at Basel hospitals (Zehring, 2017)



Concentrations of some radiopharmaceuticals in WWTPs (Zehring, 2017)

Conclusions

- There are novel sources involved in isotope manufacturing, medical facilities and waste disposal
- For many medical radioisotopes, no information on environmental parameter values
 - Need data on transfer factors, K_d , biological half-lives for biota.
- Physico-chemical form may be very different than for RNs conventionally released from nuclear industry, changing mobility and bioavailability and finally impact
 - Not needed for all RNs/pathways (e.g. fast decaying RNs)
- Need improved transfer and assessment models and methods
- New pathways to workers, public and environment are involved, requiring appropriate modelling approaches to represent these new pathways
 - Patient excretion (outpatient treatment) being routed to sewage treatment plants & patient burial after outpatient treatment
 - Radionuclide emissions into the atmosphere from incinerators
 - Transfer to land
- Abstraction of models to make practical tools for end users,
- There is a need for scientific guidance to regulators in terms of highlighting what information they need to do an assessment,

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