Nuclear Medicine in Finland – Regulatory Control and Current Challenges

ALLIANCE Webinar on Medical Radionuclides, 2nd June 2022,

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- Status of Nuclear Medicine in Finland
- Regulatory Supervision
- Safety Assessments – focus in the doses to the members of the public
- Current Challenges – Radioactivity in Outpatient Diapers
- Discussion

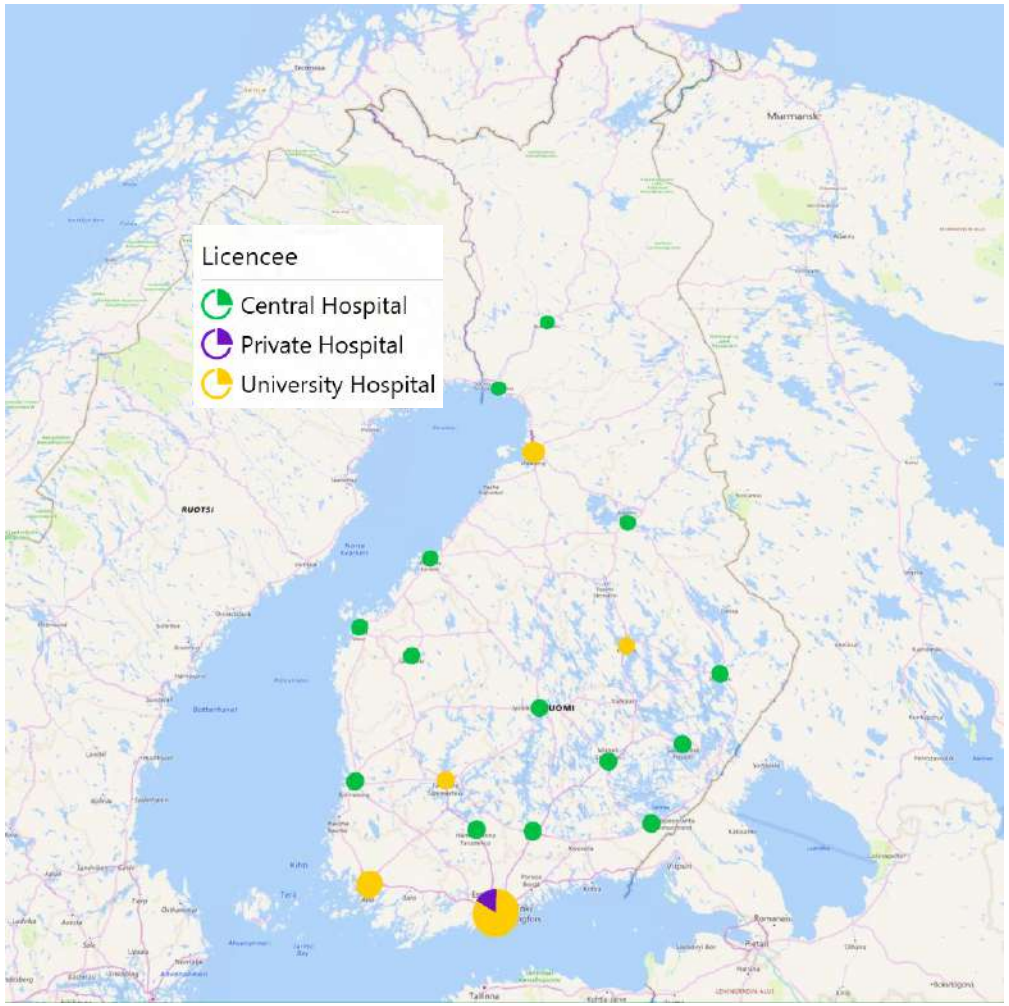
Status of Nuclear Medicine in Finland

Status of Nuclear Medicine in Finland

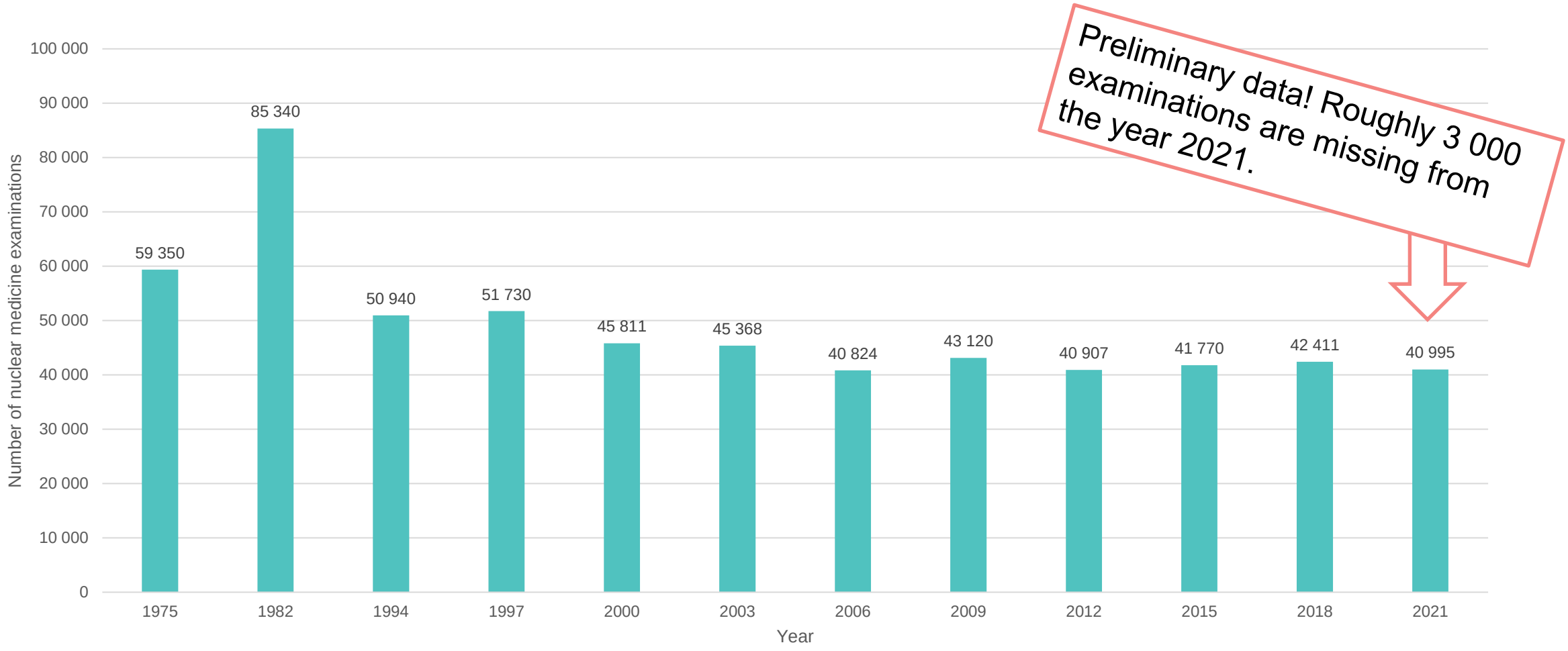
- Population 5 549 599 (31.12.2021)
- 26 safety licensee with the permit to use unsealed sources for medical exposure
  - University hospitals, 11 licensees
  - Central hospitals, 14 licensees
  - Private hospitals, 1 licensee
- Imaging equipment and cyclotrons (spring 2022)

	Number of devices	Per 100 000 people
SPECT and gamma (total)	39	0,70
SPECT and gamma*	2	0,04
SPECT/CT	37	0,67
PET (total)	20	0,36
PET*	0	0,00
PET/MRI*	1	0,02
PET/CT	19	0,34
Cyclotrons for nuclear medicine	~7	0,13

*) Safety licence is not needed for imaging devices that do not emit radiation.

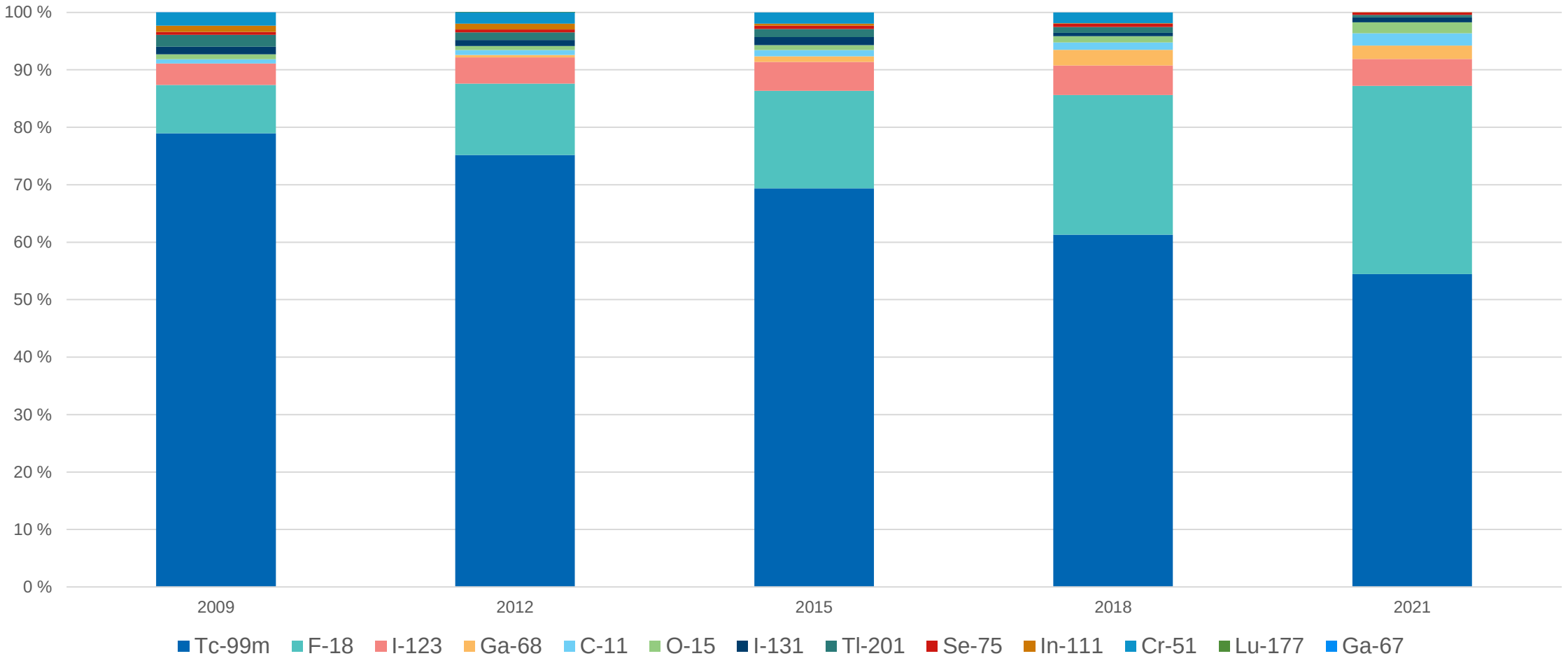


Number of nuclear medicine examinations



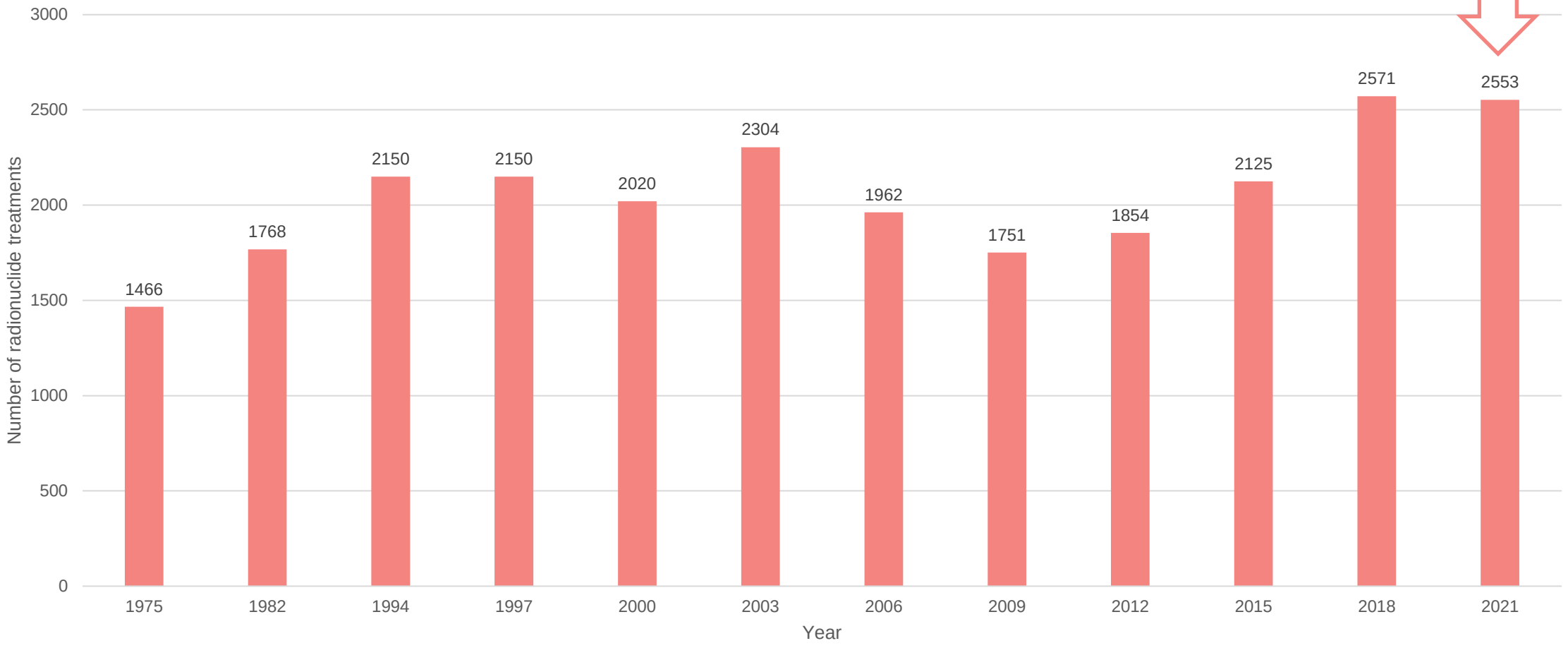
Number of nuclear medicine examinations per 1 000 inhabitants

Relative proportions of radionuclides used in nuclear medicine examinations

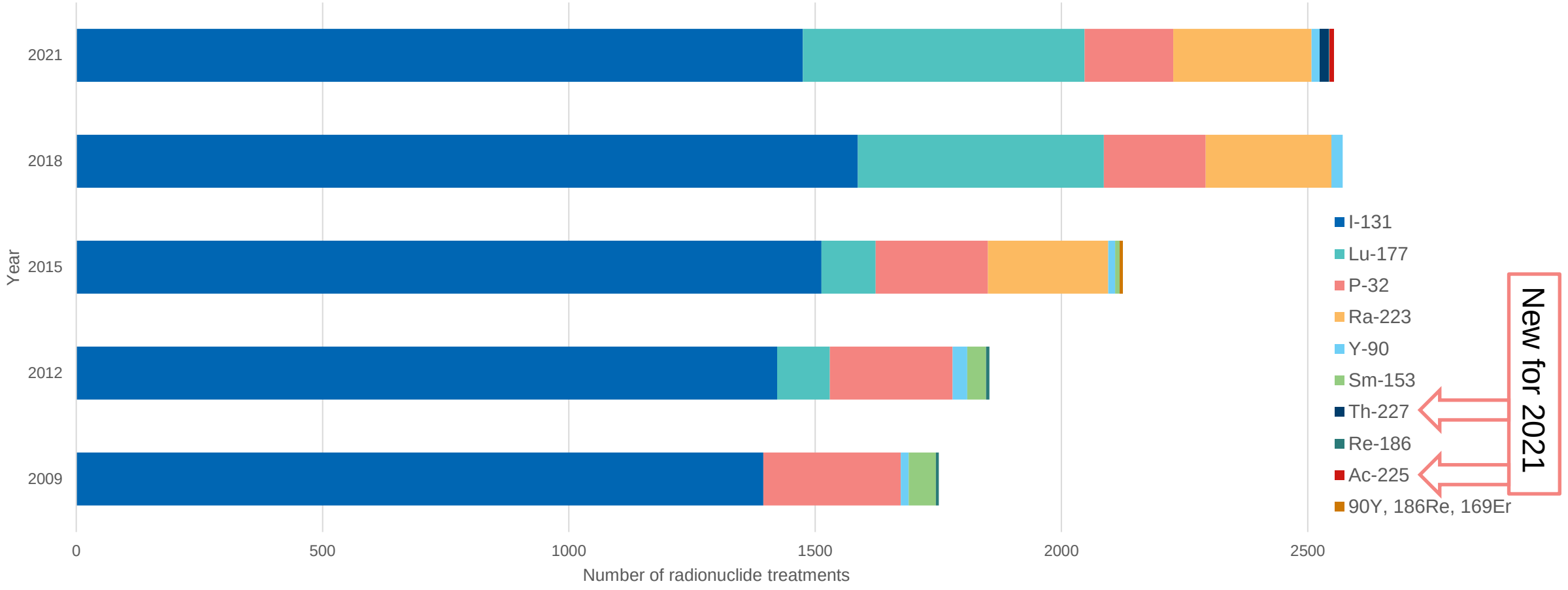


Radionuclide treatments

Preliminary data! Roughly 200 treatments are missing from the year 2021.



Radionuclides used in radionuclide treatments (preliminary data for 2021)

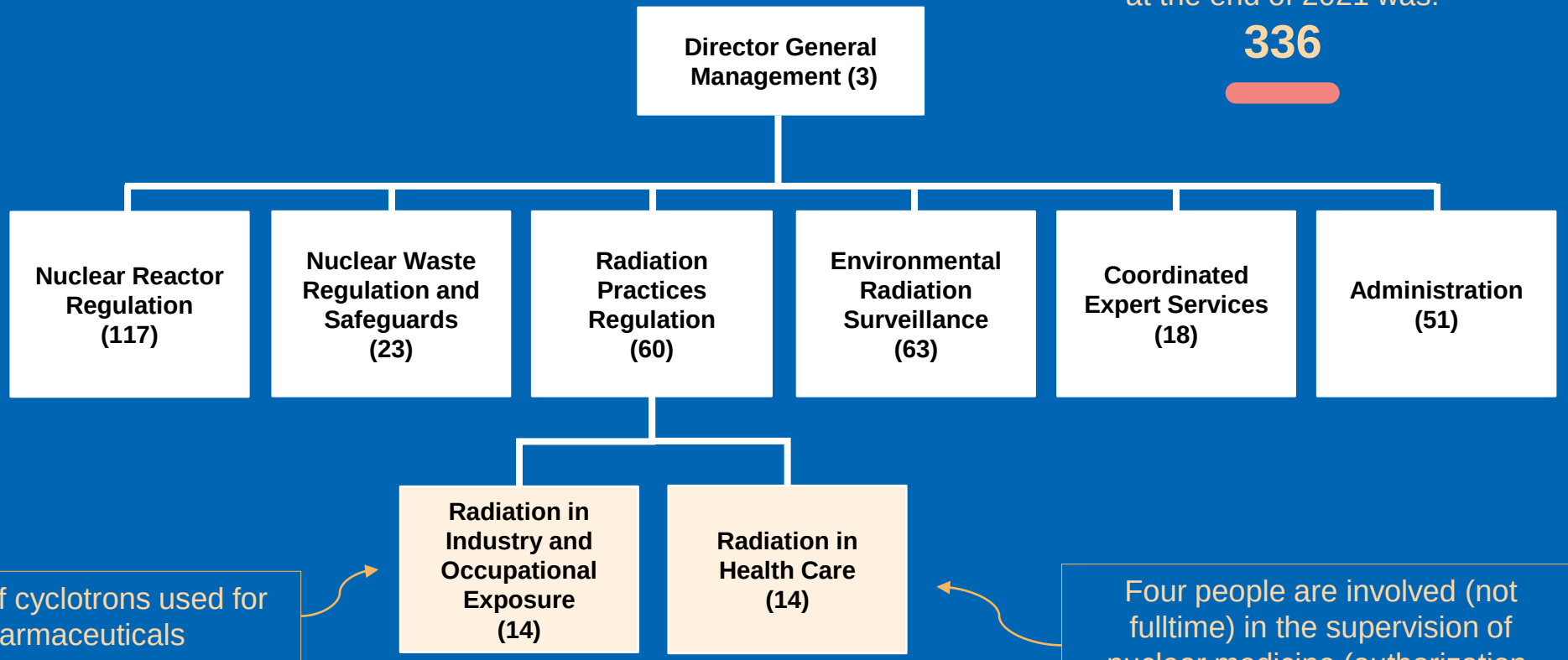


More data in Nuclear Medicine Examinations and Treatments in Finland 2018 (Isotooppitutkimukset ja -hoidot Suomessa vuonna 2018 : Terveydenhuollon valvontaraportti (julkari.fi)) –report. Only available in Finnish.

Regulatory Supervision of Nuclear Medicine

STUK's organization

Number of staff
at the end of 2021 was:
336



Supervision of cyclotrons used for radiopharmaceuticals

Four people are involved (not fulltime) in the supervision of nuclear medicine (authorization, inspection and enforcement).

STUK

Strategy 2018–2022

- The happiest civil servants in the world
- Ability to understand complex entities
- Stable finances secure our operations

- Risk-informed and commensurable supervision
- Flexible and efficient working methods
- Effective national radiation safety research
- Customer-centric digital regulatory services

- Emphasising the responsibility of the operators
- People understand the risks of radiation
- Society is resilient to disturbances

Our values:

expertise

openness

courage

co-operation

Changes in regulatory supervision

- Two main drivers of change:
  - Renewal of Radiation Act (2018) and decrees and regulations under it
    - Requirement for safety assessment
  - STUK's strategy for the 2018-2022
    - Risk informed and commensurable supervision
    - Emphasising of the responsibility of the operators
- Additional drivers
  - Review and assessment of safety assessments took a lot of work (on both sides)
  - COVID-19
    - nearly all nuclear medicine on-site inspections were stopped for over year. Remote inspections
- Previously all nuclear medicine licensees were inspected (on-site) at least every 3 years and commissioning inspections were carried out for all new equipment (SPECT/CT, PET/CT, new facilities, …) within 6 months of the change.
- For now inspections are carried out according to our inspection plan (~yearly risk estimates) and best tool is chosen for the supervision (e.g. on-site inspection, remote inspection, survey, request for clarification, …).
  - No periodical inspections, but the time from last inspection is one parameter that affects our risk estimate and the need to conduct inspection.

Safety assessment

Safety Assessments

- The requirement for safety assessment was on of the major changes in the renewal of the Radiation Act in 2018.
- The renewal also reinforced the importance of dose constraints.
  - *The undertaking shall establish the dose constraints and constraints for potential exposure to be used in the radiation practice in advance, unless STUK has established the constraints to be used.*
  - Default dose constraint for public exposure is 0,1 mSv but it may be greater if it is justified in safety assessment.
  - The dose constraint for public exposure resulting from discharges and waste in radiation practices may not be greater than 0.1 mSv

Radiation Act 859/2018

Section 26 Safety assessment concerning radiation practices

In practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which:

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice.

The safety assessment shall be prepared in writing and kept up to date.

STUK confirms the safety assessment either as part of granting the safety licence or separately.

STUK issues more detailed regulations on the content and preparation of the safety assessment.

Safety Assessments

- On nuclear medicine practices there are the many ways how the public can be exposed.
- Typically, the most exposed member of the public is the minor in patient's home.
  - All minors are by definition members of the public and not carers and comforters, for whom there is no dose limit.
- Dose constraint for the minors at home is typically 0,3 mSv.
- Exposure estimates were often based on scientific articles and the magnitude of exposure was taken as the typical exposure from treatment rather than the maximum exposure.
  - Are the clinic's practices in line with those described in the scientific article?
- Activities should be organized in such a way that the exposure from the planned activities is always below the dose constraint.

Current challeges

Current Challenges – Radioactivity in Outpatient Diapers

- During the review and assessment of medical physicist safety assessment template, it was found that that it didn't address the exposure of member of the public and carers and comforters from the excreta of the released radionuclide treatment patient
  - Excretion of radioactivity after release of the patient from the hospital can be significant.
  - Objects contaminated with radioactive patient excreta (e.g. diapers) might be radioactive waste (e.g. if their activity is above clearance value)
  - There are no limits on discharges of patient excreta to the environment and sewerage systems

Radiation Act (859/2018)

Section 127 Discharges and their limit values

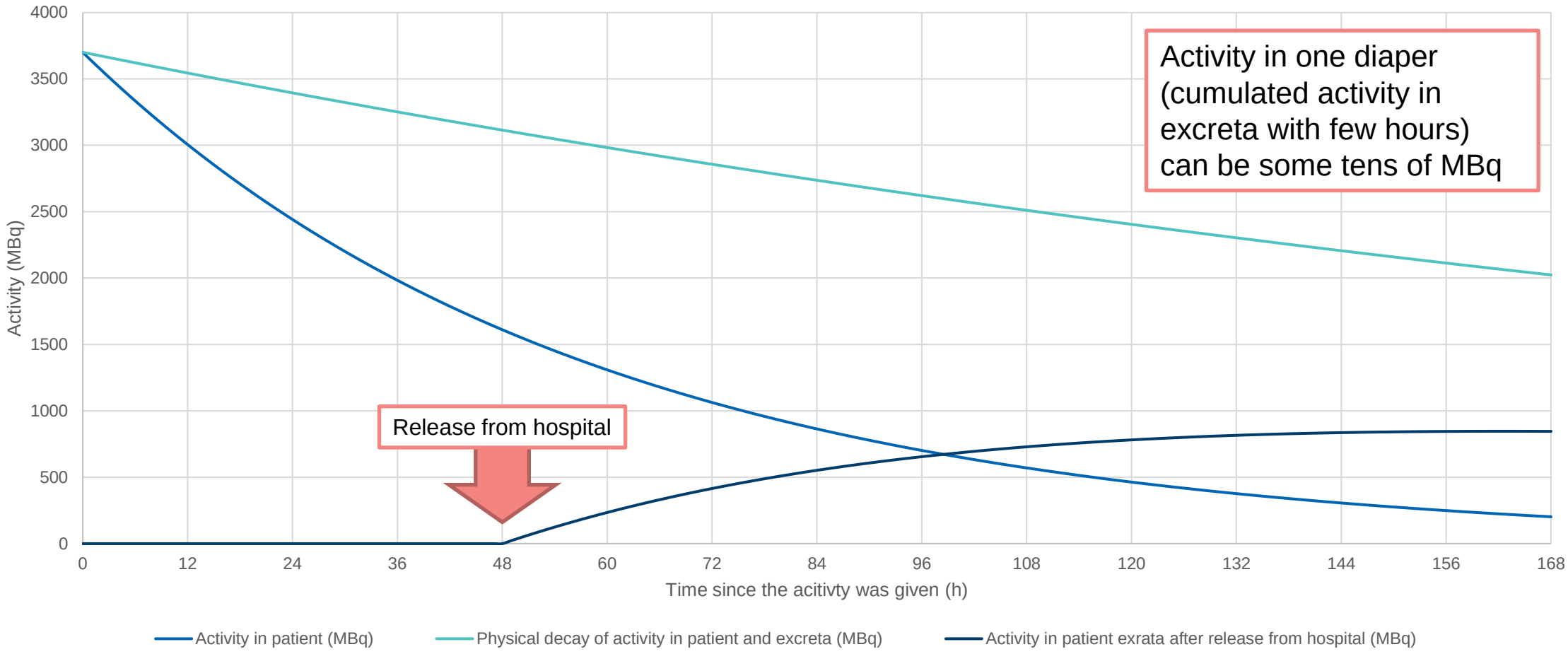
The undertaking must limit the discharges of radioactive substances to the environment and the sewerage system to the absolute minimum. In any event, the amount of the discharge may not exceed the limit value for a minor discharge. A record must be kept of the discharges.

STUK may nevertheless authorize a discharge exceeding the limit value for a minor discharge if there is an absolute need for the discharge despite limiting measures and the undertaking has drawn up a plan for the discharges and assessed the exposure caused by the discharges.

…

The secretions of patients who have received a radioactive substance in medical use of radiation are not subject to subsection 1 and 2.

Thyroid cancer treatment with 3700 MBq of I-131 - Patient and excreta activity, patient released at 48 h



Application for exemption (1/2)

- The disposal of the diapers (and other contaminated objects) of discharged patients with activity above the (current) clearance value with household waste might be the most appropriate overall option.
- Licencee's were instructed to submit an application STUK's decision on exemption.
  - Application was required to be applied for on a radionuclide and safety licence basis.
  - Licensees were instructed to create applications that showed that requirements on the exemption can be fulfilled

Radiation Act (859/2018)

Section 50 Exemption from safety licence under a decision by the Radiation and Nuclear Safety Authority

STUK may exempt radiation practices other than those referred to chapter 13 or 14 from a safety licence, if exemption is the most appropriate alternative and:

1) the radiation exposure and potential exposure caused the practice is insignificant enough not cause a health detriment;

2) the practice has been demonstrated to be justified;

3) the practice is inherently safe.

Government Decree on Ionizing Radiation (1034/2018)

Section 28 Conditions for exemption from a safety licence

The practice is safe in principle as referred to in section 50, subsection 1, paragraph 3 of the Radiation Act if the workers do not need to be categorized as radiation workers and the effective dose of a member of the public is at most, excluding unlikely radiation safety incidents, of the magnitude of:

1) 10 microsieverts a year from artificial radioactive substances;

2) 1 millisieverts a year from nature's radioactive materials.

The effective dose to a member of the public in improbable radiation safety incidents may not exceed 1 millisieverts a year in a practice referred to in subsection 1, paragraph 1.

Application for exemption (2/2)

- 23 licensee sent an application.
- The applications provided estimates of the number of incontinent patient treatment fractions per year in Finland and average activity in excreta.
- Most common treatments with incontinent patients and the range of activity in excreta were
  - I-131 treatment thyroid cancer, n = 58, 50-470 MBq,
  - I-131 treatment of hyperthyroidism, n = 25, 50-430 MBq,
  - Lu-177 PSMA-treatment, n = 100, 230-400 MBq and
  - Lu-177 DOTATE-treatment, n = 20, 1700 MBq

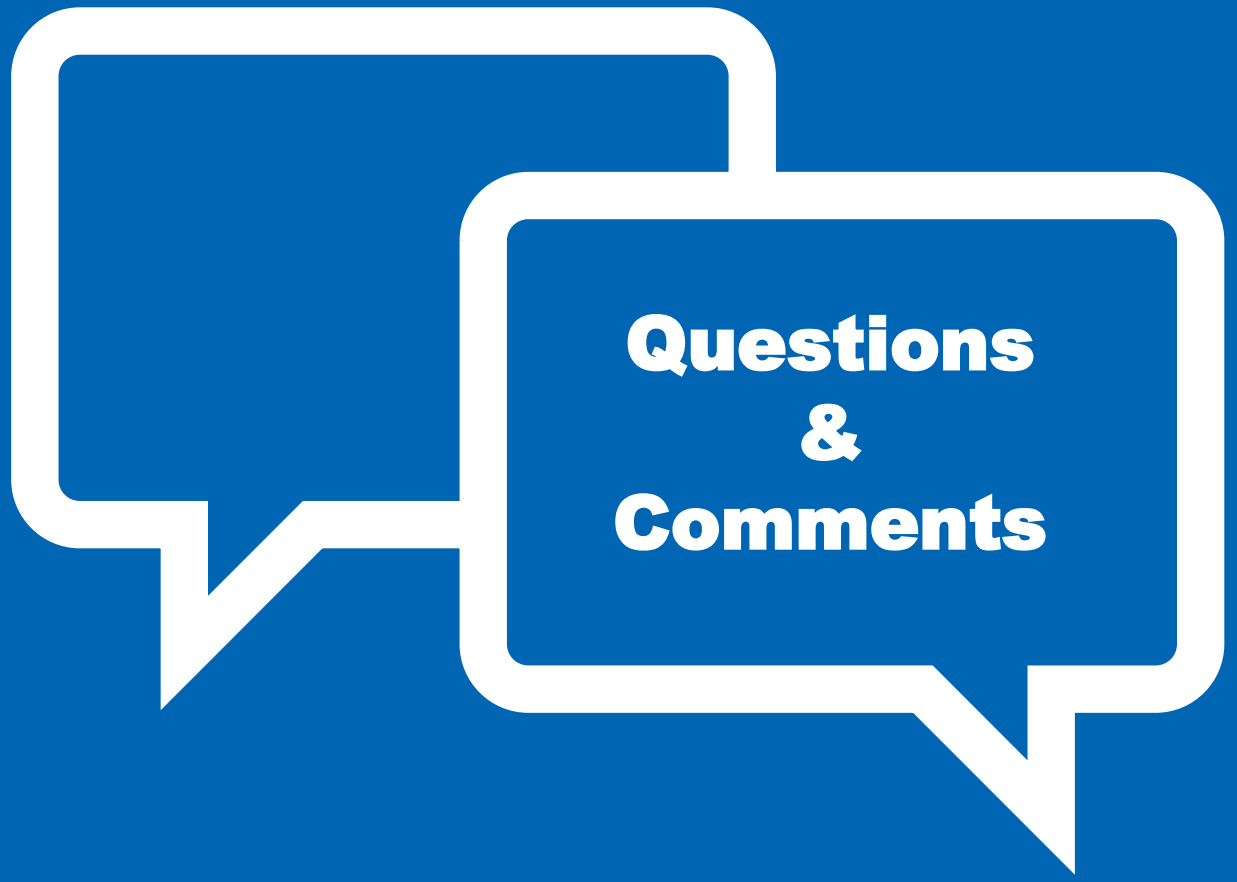
- Difficulties
  - Licensee made rough estimates on the exposure, but the estimates are lacking in many parts
  - Applications lack analysis on why the proposed way is the *is the most appropriate alternative*, when taking account, the resources, exposures (hospital, home, waste management…)
  - If the requirements for exemption are fulfilled when the diaper is processed with local waste management, are they fulfilled if the patient travels to other part of the country where the waste processing is different ?!?

Study on the setting of specific clearance values for radioactive patient excreta disposed in household waste

- STUK in the process of preparing a study on setting specific clearance values for radioactive patient excreta disposed in household waste
- In the preliminary analysis the most significant radionuclides for exposure are the ones with strong gamma component (I-131 and Lu-177)
- The dose to the member of the public
- In the study the exposure is estimated (at least) in the following scenarios
  - Diaper in the waste container of the apartment building
  - Diaper in the waste transit
  - Diaper at the waste processing facility
- Other authorities will also be consulted on the setting of (possible) new specific clearance values

Radioactive municipal waste

- A truck carrying municipal waste caused a radiation alarm when it passed through the radiation measurement gate of a waste-to-energy plant. Further measurements with handheld survey meter showed that one point of the waste container was locally emitting about 100 µSv/h. Survey meter identified the radionuclide to be I-131.
- The origin of the radioactive waste has not been confirmed, but possible sources are I-131 radionuclide treatment patients excreta waste (e.g. diapers), erroneously disposed I-131 capsules and I-131 treated cat litter.
- A preliminary estimate of the I-131 activity is around some tens of MBq.
- The radioactive container has been set aside for further investigation.


Questions
&
Comments