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# Review Radiation Protection

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# Overview

- Expertise for radiation protection review
- Key points for checking submissions:
  - Non-standard patients and situations
  - Standards and Recommendations
  - EANM Dosage Card for paediatric patients
  - ICRP publications for organ doses and whole body dose
- Benefits for the applications

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# Expertise of the Radiation Protection Review

- Internal dosimetry of incorporated radionuclides
- Radiation physics
- Medical physics and imaging
- Radiation biology
- Radiation protection
- International standards and recommendations
- National legislations

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# Key points for checking submissions

Radiation dosimetry of the patient:

- *Organ doses*, most affected organs, whole-body *effective dose*
- Example calculations of resulting radiation doses
- Non-standard patients and situations (see next slide)

Radiation protection:

- Conformity with Swiss legislation
- Staff and patient, shielding, equipment, shipping
- Disposal and waste management, especially for long lived impurities

General aspects:

- All physical data and information is correct and up-to-date
- Use of technical terms, especially «dose»: *effective dose, absorbed dose, (pharmaceutical) dose, dosage*, etc.

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# Non-standard patients and situations

- Paediatric patients: dosage (of drug) and radiation doses
- Pregnancy: contra-indication, radiation dose to the fetus
- Breast-feeding: waiting period
- Children in close contact to mother (as patient)
- Overdosage (of drug), consequences, counter measures
- Disposal of excreta, surplus (radioactive) substances
- Deceased patients

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# Standards and Recommendations

- EANM - *European Association Nuclear Medicine*
- ICRP - *International Commission Radiological Protection*
- ICRU – *International Commission Radiation Units & Measurements*
- *European Union Publications in Radiation Protection*
- Swiss Legislation (StG, StSV, … , BAG Merkblätter)

**Other sources**:

- SmPC (information for professionals) of similar drugs (Swissmedic Homepage)
- SmPC (information for professionals) of the same drug from Germany, France, …
- Scientific literature

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# EANM– European Association Nuclear Medicine Recommendations

Dosage Card for paediatric patients

- Recommendations of administered activities for many RP's
- Based on extensive review of publications by nuclear medicine experts
- www.eanm.org -> Publications -> Dosage Card (latest version of 2016)

Supersedes old procedures of scaling administered activities by weight from adult to child. EANM Dosage Card is based on look-up tables:

## Dosage Card (Version 5.7.2016)

*Multiple of Baseline Activity*

| Weight kg | Class A | Class B | Class C | Weight kg | Class A | Class B | Class C |
|---|---|---|---|---|---|---|---|
| 3 | 1 | 1 | 1 | 32 | 3.77 | 7.29 | 14.00 |
| 4 | 1.12 | 1.14 | 1.33 | 34 | 3.88 | 7.72 | 15.00 |
| 6 | 1.47 | 1.71 | 2.00 | 36 | 4.00 | 8.00 | 16.00 |

*Recommended Amounts in MBq*

| Radiopharmaceutical | Class | Baseline Activity (for calculation purposes only) MBq | Minimum Recommended Activity[1] MBq |
|---|---|---|---|
| $^{123}$I (Thyroid) | C | *0.6* | 3 |
| $^{123}$I Amphetamine (Brain) | B | *13.0* | 18 |
| $^{123}$I HIPPURAN (Abnormal renal function) | B | *5.3* | 10 |
| $^{123}$I HIPPURAN (Normal renal function) | A | *12.8* | 10 |

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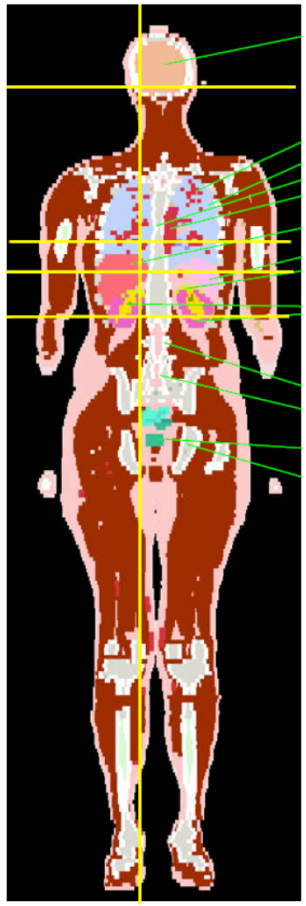
# ICRP- International Commission Radiological Protection

Association of world-leading experts continuously developing universally accepted standards and basis of radiation protection.

**Internal dosimetry of incorporated radionuclides**:

- Modelling of biodistribution in the human body
- Anthropomorphic phantoms, e.g. reference CT-based voxel models
- Radiation energy transport calculation methods

Calculation of ***Organ Doses*** (unit Gray) and whole body ***Effective Dose*** (unit Sievert) per incorporated activity for reference persons.



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# ICRP publication series for common radiopharmaceuticals

- ICRP 128 (2015)
- ICRP 106 (2008)
- ICRP 80 (1998)
- ICRP 53 (1988)

Table C.81. Absorbed doses for $^{99m}$Tc-labelled methoxy-isobutyl-isonitrile.

| | Absorbed dose per unit activity administered (mGy MBq$^{-1}$) | | | | |
|---|---|---|---|---|---|
| Organ | Adult | 15 years | 10 years | 5 years | 1 year |
| **Resting subject** | | | | | |
| Adrenals | 7.5E−03 | 9.9E−03 | 1.5E−02 | 2.2E−02 | 3.8E−02 |
| Bone surfaces | 8.2E−03 | 1.0E−02 | 1.6E−02 | 2.1E−02 | 3.8E−02 |
| Brain | 5.2E−03 | 7.1E−03 | 1.1E−02 | 1.6E−02 | 2.7E−02 |
| Breast | 3.8E−03 | 5.3E−03 | 7.1E−03 | 1.1E−02 | 2.0E−02 |
| Gallbladder wall | 3.9E−02 | 4.5E−02 | 5.8E−02 | 1.0E−01 | 3.2E−01 |
| Gastrointestinal tract | | | | | |
| Stomach wall | 6.5E−03 | 9.0E−03 | 1.5E−02 | 2.1E−02 | 3.5E−02 |
| Small intestine wall | 1.5E−02 | 1.8E−02 | 2.9E−02 | 4.5E−02 | 8.0E−02 |
| Colon wall | 2.4E−02 | 3.1E−02 | 5.0E−02 | 7.9E−02 | 1.5E−02 |
| (Upper large intestine wall | 2.7E−02 | 3.5E−02 | 5.7E−02 | 8.9E−02 | 1.7E−01) |
| (Lower large intestine wall | 1.9E−02 | 2.5E−02 | 4.1E−02 | 6.5E−02 | 1.2E−01) |

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# Benefits for the applications

- Additional scientific expertise
- Text corrections in “Summary of Product Characteristics” (SPC) *{Information Professionnelle / Fachinformation}*
- Contents checking of SPC
- Updates of the application, e.g. newer or missing publications
- Suggestions of improvements (after discussion in the commission)