ALLIANCE Webinar / 2nd June 2022 – 9:30-16:30

**Assessing impact of production, use and disposal of radiopharmaceuticals on members of public and the environment.**

EUROPEAN RADIOECOLOGY ALLIANCE

# *Regulatory Control and Current Challenges of use of medical radioisotopes in Italy*

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# legislative decree 101/2020, July 31st

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II *Non-legislative acts*

DIRECTIVES

★ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom ..... 1

CHAPTER X

**FINAL PROVISIONS**

*Article 106*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by **6 February 2018**.

*Supplemento ordinario alla "Gazzetta Ufficiale„ n. 201 del 12 agosto 2020 - Serie generale*

*Spediz. abb. post. - art. 1, comma 1*
*Legge 27-02-2004, n. 46 - Filiale di Roma*

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N. 29/L

DECRETO LEGISLATIVO 31 luglio 2020, n. **101.**

**Attuazione della direttiva 2013/59/Euratom, che stabilisce norme fondamentali di sicurezza relative alla protezione contro i pericoli derivanti dall'esposizione alle radiazioni ionizzanti, e che abroga le direttive 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom e 2003/122/Euratom e riordino della normativa di settore in attuazione dell'articolo 20, comma 1, lettera *a)*, della legge 4 ottobre 2019, n. 117.**

| | Directive 2013/59 Euratom | D. Lgs. 101/2020 |
|---|---|---|
| # of articles | 109 | 245 |
| # of annexes | 19 | 37 |
| # of tables | 3 | 17 |
| # of pages | 73 | 348 |

# Title VII
# Licensing regime and provisions for radioactive waste

| Article and title | Referring article in EU Directive |
|---|---|
| Art. 46: Notification | Art. 25 |
| Art. 47: exemption from notification | Art. 26 |
| Art. 48: ionizing sources registry | Art. 85 – Art. 88 |
| Art. 49: recognised sources registry | Art. 27 |
| Art. 50: licensing and practice authorization | Art. 24 - Art. 28 – Art. 29 |
| Art. 51: licensing cat. A | Art. 24 - Art. 28 – Art. 29 |
| Art. 52: licensing cat. B | Art. 24 - Art. 28 – Art. 29 |
| Art. 53: cessation of practice | |
| Art. 54: release from regulatory control | Art. 30 – Art. 65 – Annex VII |
| Art. 55: Waste with other hazardous characteristics | |
| Art. 56: radioactive waste collection and transport activities | |
| Art. 57: shipments, imports and exports of radioactive waste and exhausted nuclear fuel | |
| Art. 58: specific provisions on shipments of exhausted fuel and radioactive waste for disposal | |
| Art. 59: licensing of temporary storage facilities or radioactive waste management facilities | |
| Art. 60: data reporting requirements | |
| Art. 61: suspension and revocation of authorization measures | |

# Graded approach to regulatory control

Notification: For radioimmunoassay laboratories (RIA): $^{125}I$, $^{3}H$

Licensing: Category A, Category B } Mandatory for patient's administration with radiopharmaceuticals

⇩

Nuclear Medicine Practice are always Cat A or Cat B

# Radioisotopes for medical use

| Radioisotope | Activity concentration (KBq/Kg) | Activity (Bq) | Use |
|---|---|---|---|
| $^{99m}Tc$ | $10^2$ | $10^7$ | nucl. medicine/diagn. |
| $^{123}I$ | $10^2$ | $10^7$ | nucl. medicine/diagn. |
| $^{131}I$ | $10^2$ | $10^6$ | nucl. medicine/diagn&therapy |
| $^{67}Ga$ | 1 | $10^4$ | nucl. medicine/diagn. |
| $^{111}In$ | $10^2$ | $10^6$ | nucl. medicine/diagn. |
| $^{18}F$ | 10 | $10^6$ | PET |
| $^{11}C$ | 1 | $10^4$ | PET |
| $^{13}N$ | 1 | $10^4$ | PET |
| $^{64}Cu$ | $10^2$ | $10^6$ | PET |
| $^{68}Ga$ | 1 | $10^4$ | PET |
| $^{90}Y$ | $10^3$ | $10^5$ | nucl. medicine/therapy |
| $^{177}Lu$ | $10^3$ | $10^7$ | nucl. medicine/therapy |
| $^{223}Ra$ | 1 | $10^5$ | nucl. medicine/therapy |

Notification: activity values > this table

Licensing cat A: times
- instant activity values > $10^6$ this table;
- annual activity values > $50 \times 10^6$ times this values
- National authorization

Licensing cat B: times
- instant activity values > $10^3$ this table;
- annual activity values > $50 \times 10^3$ times this values
- Local authorization

# Art. 54 – Clereance from regulatory control

With the old radiation protection law, there was a limit of **< 1Bq/g** for the clearence in exemption for radioactive waste (solid, liquid and gases) of radionuclides with a half life < 75 days.

Legislative Decree 101/2020 introduced permitted clearance levels for solid waste and demonstration of radiological non-relevance for liquid and aeriform waste.

**Solid waste** →

Licencing with permitted levels.
- If required levels are below values of table I-1B => no additional statements
- If required levels are higher than values of table I-1B => the hospital must demonstrate the radiological non-relevance of the discharge.

**Liquid and aeriform waste** →

The hospital must demonstrate the radiological non-relevance of discharges to the environment by proposing an appropriate discharge formula

Hospitals have time until next August (2 years from the decree) to ask the conversion of authorization under the new decree.

# Art. 54 – Clereance from regulatory control of solide waste

*Table I-1B extract*

| Radioisotope | Activity concentration (KBq/Kg) |
|---|---|
| $^{99m}Tc$ | 1 |
| $^{123}I$ | 1 |
| $^{131}I$ | 1 |
| $^{67}Ga$ | 1 |
| $^{111}In$ | 1 |
| $^{18}F$ | 1 |
| $^{11}C$ | 1 |
| $^{13}N$ | 1 |
| $^{64}Cu$ | 1 |
| $^{68}Ga$ | 1 |
| $^{90}Y$ | 1 |
| $^{177}Lu$ | 1 |
| $^{223}Ra$ | 1 |

Solid waste →

Licencing with permitted levels.

- If required levels are below values of table I-1B => **no additional statements**
- If required levels are higher than values of table I-1B => the hospital must demonstrate the radiological non-relevance of the discharge.

*Radiometric control of solid waste bins*

- Each bin produced in nuclear Medicine is controlled
- Measures below background levels guarantee the absence of activity and the respect of table I-1B values.

However, some bins from inpatient wards may escape radiometric control and arrive at the incinerator!

# Art. 54 – Clereance from regulatory control of solide waste

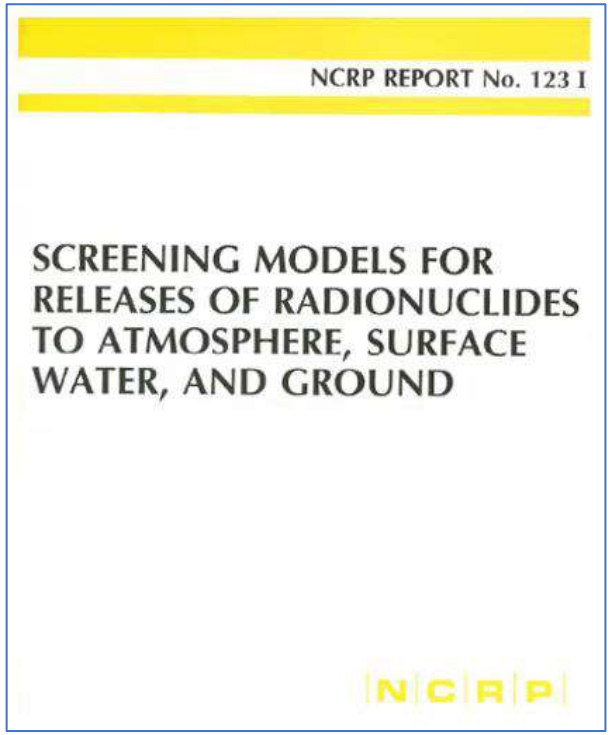
It is reasonable to assume that a fraction of $10^{-4}$ and $10^{-6}$ of the total activity received in a year for diagnostic and therapy radionuclides, respectively, escapes radiometric control and is sent to the incinerator.

Activity released into the environment generates dose to the population.
The hospital must demonstrate the radiological non-relevance of the release, that means a dose to representative person ≤ 10 µSv.

$$\sum_{i}^{n} E_i < 10\mu Sv \rightarrow \sum_{i}^{n} (C_{ia} \times SF_{ia}) \times 10^6 \leq 10\mu Sv$$

$$C_{ia} = \frac{f \times Q \times P}{u}$$

Where:
$E_i$ = effective dose from the i-th radionuclide
$C_{ia}$ = Average concentration of the i-th radionuclide at the point of release to the environment (Bq/m$^3$)
$SF_{ia}$ = screening factor of the i-th radionuclide in air Sv Bq$^{-1}$ m$^3$
f = fraction of time the wind is blowing toward the receptor (standard value = 0,25)
Q = activity emission rate (Bq/s)
P = gaussian diffusion coefficient (m$^{-2}$), st. value at 100 m = $10^{-5}$ m$^{-2}$
u = wind speed (m/s) (standard value = 2 m/s)



# Art. 54 – Clereance from regulatory control of solide waste

Effective dose due to activity that escapes the radiometric controls from the hospital.

| Isotope | licensed/injected activity | disposed activity ($x\ 10^{-4}$ D ; $x\ 10^{-6}$ T) | Q = disposed activity rate | $C_{ia}$ = activity conc. at receptor point | Screening Factor | Effective dose |
|---|---|---|---|---|---|---|
| | Bq/year | Bq/year | Bq/sec | $Bq/m^3$ | $Sv/Bq/m^3$ | µSv/year |
| $^{99m}Tc$ | 7,4E+12 | 7,4E+08 | 2,3E+01 | 2,9E-05 | 1,6E-06 | 4,7E-05 |
| $^{18}F$ | 1,1E+14 | 1,1E+10 | 3,5E+02 | 4,4E-04 | 4,1E-06 | 1,8E-03 |
| $^{123}I$ | 7,7E+10 | 7,7E+06 | 2,4E-01 | 3,1E-07 | 7,6E-06 | 2,3E-06 |
| $^{131}I$ | 6,4E+10 | 6,4E+04 | 2,0E-03 | 2,5E-09 | 2,8E-02 | 7,1E-05 |
| $^{177}Lu$ | 1,5E+12 | 1,5E+06 | 4,8E-02 | 5,9E-08 | 1,5E-04 | 8,9E-06 |
| $^{90}Y$ | 3,0E+11 | 3,0E+05 | 9,5E-03 | 1,2E-08 | 2,8E-04 | 3,3E-06 |
| | | | | | | |
| **Total effective dose (µSv/year)** | | | | | | **1,9E-03** |

$$C_{ia} = \frac{f \times Q \times P}{u}$$

*f = 0,25*
*$P = 10^{-5}\ m^{-2}$*
*u = 2 m/s*

<< 10 µSV

# Art. 54 – Clereance from regulatory control of liquid effluents

**Liquid and aeriform waste** → The hospital must demonstrate the radiological non-relevance of discharges to the environment by proposing an appropriate discharge formula

Sources of radioactive liquid effluent:

1) outpatients who perform examinations in nuclear medicine and then go back to their homes (fraction of activity in the NM diagnostic tanks);

2) inpatients who perform examinations in nuclear medicine and then return to the ward (fraction of activity in the NM diagnostic tanks and a fraction directly into the hospital sewer);

3) inpatients who receive nuclear medicine treatments in shielded rooms with dedicated tanks.

4) outpatients who receive treatments in nuclear medicine and after some hours go back to their homes (fraction of activity in the NM diagnostic tanks)

There are two possible scenarios:

1) release into surface water (river, lake, sea, etc)

2) release to a sewage treatment plant

# Art. 54 – Clereance from regulatory control of liquid effluents

The effective dose to the representative person due to the discharge of radioactive effluents in the environment must be < 10 µSv/year.

$$H = \sum_{i}^{n} Q_i \times SF_i \leq 10\ \mu Sv$$

Where:

$Q_i$ = concentration in fresh water of i-th isotope activity discharged (source term) ($Bq/m^3$)

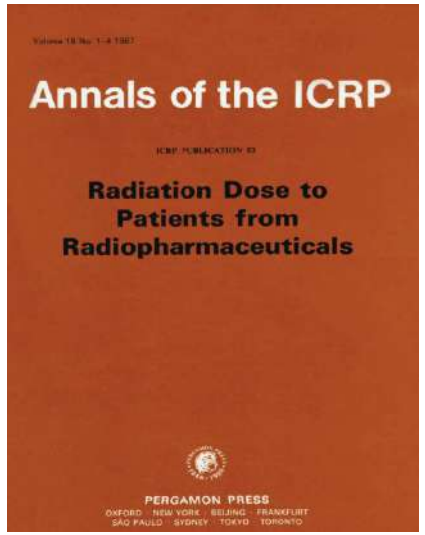
$SF_i$ = dose screening factor (depend on the discharge pathway) ($Sv/Bq/m^3$)

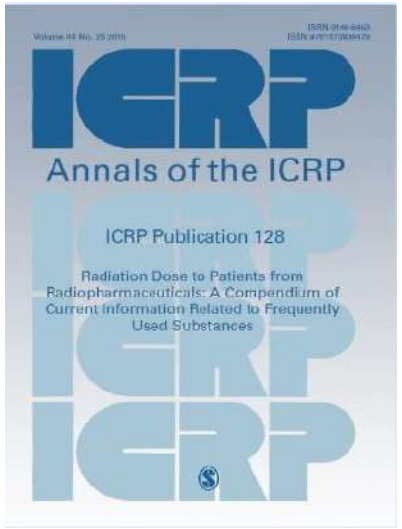
There are two possible scenarios:

1) discharge into surface water (river, lake, sea, etc)

2) discharge to a sewage treatment plant

# Art. 54 – Clereance from regulatory control of liquid effluents




Activity released in the environment depends on:

- Total activity injected to patients
- Fraction of activity excreted with urine
- Fraction of activity intercepted by tanks
- Fraction of activity discharged directly into hospital sewer (fraction of inpatients)

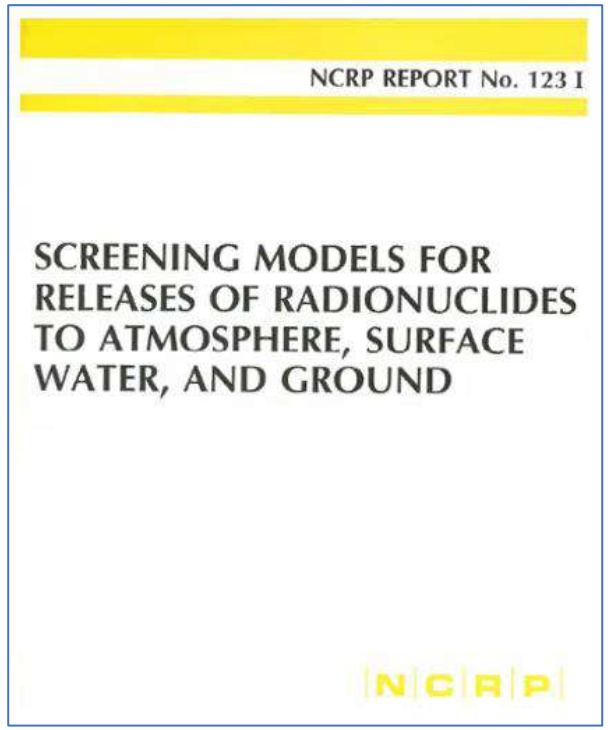
| | | | | A | B | C | D = B x C | E = A x C | F = D - E | G = F x f | H = F - G | I = E x DF | L = G + L | f |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Radionuclide | tracer | half life (h) | time in NM division (h | fraction f of activity released in NM | total excreted fraction of activity f(∞) | Total injected activity (Bq/year) | Total excreted activity (Bq/year) | Total activity released in NM tanks (Bq/year) | Total activity not interceped by NM tanks (Bq/year) | Activity released in sewer by inpatients in ordinary wards (Bq/year) | Activity released in sewer outside the hospital (Bq/year) | Activity released in sewer after decay in NM tanks (7 days) (Bq/year) | Total activity released in sewer by hospital (Bq/year) | fraction of inpatients |
| $^{99m}$Tc | DTPA | 6,02 | 2,00 | 51% | 78% | 7,4E+12 | 5,8E+12 | 3,8E+12 | 2,0E+12 | 4,0E+11 | 1,6E+12 | 1,5E+04 | 4,0E+11 | 0,20 |
| $^{18}$F | FDG | 1,83 | 2,00 | 13% | 15% | 1,1E+14 | 1,7E+13 | 1,4E+13 | 2,2E+12 | 4,4E+11 | 1,8E+12 | 3,3E-15 | 4,4E+11 | 0,20 |
| $^{123}$I | DATSCAN | 13,20 | 4,00 | 11% | 33% | 7,7E+10 | 2,5E+10 | 8,5E+09 | 1,7E+10 | 3,4E+09 | 1,4E+10 | 1,2E+06 | 3,4E+09 | 0,20 |
| $^{131}$I | iodide | 192,00 | 3,00 | 9% | 54% | 6,4E+10 | 3,5E+10 | 5,8E+09 | 2,9E+10 | 2,9E+08 | 2,9E+10 | 3,1E+09 | 3,4E+09 | 0,01 |
| $^{177}$Lu | PSMA | 160,80 | 6,00 | 67% | 96% | 1,5E+12 | 1,4E+12 | 1,0E+12 | 4,2E+11 | 4,2E+09 | 4,2E+11 | 4,9E+11 | 4,9E+11 | 0,01 |
| $^{90}$Y | microspheres | 64,00 | 0,00 | 0% | 0% | 3,0E+11 | 6,0E+06 | 0,0E+00 | 6,0E+06 | 6,0E+06 | 0,0E+00 | 0,0E+00 | 6,0E+06 | 1,00 |

$Q_i$

# Art. 54 – Clereance from regulatory control of liquid effluents

Scenario 1) release of activity into surface water

| Radionuclide | Total activity released in sewer by hospital (Bq/year) | Total activity released in sewer by hospital (Bq/s) | Activity conc. under conditions of complete mixing and river flow = 20 $m^3/s$ ($Bq/m^3$) | Fresh water screening factors ($Sv/Bq/m^3$) | Effective dose (µSv/year) |
|---|---|---|---|---|---|
| $^{99m}Tc$ | 4,0E+11 | 1,3E+04 | 6,3E+02 | 3,3E-11 | 2,1E-02 |
| $^{18}F$ | 4,4E+11 | 1,4E+04 | 7,0E+02 | 1,4E-10 | 9,8E-02 |
| $^{123}I$ | 3,4E+09 | 1,1E+02 | 5,4E+00 | 2,2E-10 | 1,2E-03 |
| $^{131}I$ | 3,4E+09 | 1,1E+02 | 5,4E+00 | 8,6E-08 | 4,7E-01 |
| $^{177}Lu$ | 4,9E+11 | 1,6E+04 | 7,8E+02 | 1,3E-09 | 1,0E+00 |
| $^{90}Y$ | 6,0E+06 | 1,9E-01 | 9,5E-03 | 3,8E-09 | 3,6E-05 |
| | | | | | |
| **Total effective dose (µSv/year)** | | | | | **1,61** |




→ < 10 µSV

# Art. 54 – Clereance from regulatory control of liquid effluents

Scenario 2) release to a sewage treatment plant: evaluation of the effective dose to workers as representative individuals in the population

$$C_i = \frac{Q_i * D_i}{S} \Longrightarrow$$ Activity conc. in wet sludge (Bq/Kg); sludge density 1600 Kg/m$^3$

$$D_i = \frac{1 - e^{-\lambda_i * 20}}{\lambda_i * 20} \Longrightarrow$$ Decay factor for 20 days of sludge manipulation

$$S = \frac{B * P}{0.05} \Longrightarrow$$ Kg of producted sludge: P = kg of sludge/person, B = n. of people

$$E_i = C_i * DF_i * O_f$$

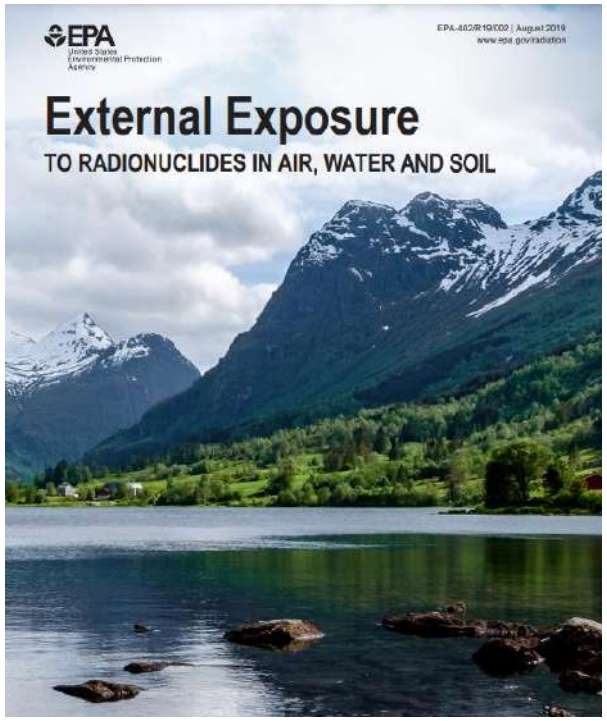
$DF_i$ = dosimetric coefficient ((Sv/y)/(Bq/kg))

$O_f$ = occupational factor = 2000 h / (365x24)h = 0,228

# Art. 54 – Clereance from regulatory control of liquid effluents

release to a sewage treatment plant

| Radionuclide | λ ($d^{-1}$) | D | Total activity released in sewer by hospital (Bq/year) | Total activity released in sewer by hospital (Bq/s) | Ci (Bq/kg) | DFi (Sv/y/(Bq/kg) | µSv/y |
|---|---|---|---|---|---|---|---|
| $^{99m}Tc$ | 2,8 | 0,02 | 4,0E+11 | 1,3E+04 | 1,8E+01 | 1,4E-07 | 5,7E-01 |
| $^{18}F$ | 9,1 | 0,01 | 4,4E+11 | 1,4E+04 | 6,1E+00 | 1,5E-06 | 2,0E+00 |
| $^{123}I$ | 1,3 | 0,04 | 3,4E+09 | 1,1E+02 | 3,4E-01 | 1,8E-07 | 1,4E-02 |
| $^{131}I$ | 0,1 | 0,48 | 3,4E+09 | 1,1E+02 | 4,1E+00 | 5,5E-07 | 5,1E-01 |
| $^{177}Lu$ | 0,1 | 0,42 | 4,9E+11 | 0,0E+00 | 5,2E+02 | 4,7E-08 | 5,6E+00 |
| $^{90}Y$ | 0,3 | 0,19 | 3,0E+08 | 9,5E+00 | 1,4E-01 | 1,1E-07 | 3,7E-03 |
| | | | | | | | |
| **Total effective dose (µSv/year)** | | | | | | | **8,70** |




< 10 µSV

# Clereance from regulatory control of liquid effluents: release formula

Based on the considerations made and the scenario considered, it is possible to calculate for each radionuclide the value of $A_{max}$ (Bq) that implies a committed effective dose of 10 µSv for the representative individual in the population.

This value is provided by the following release formula:

$$\sum_i \frac{A_i}{A_{i,10\mu Sv}} < 1$$

Where:

$A_i$ = annual activity of the i-th radionuclide released into the environment directly from the hospital (Bq/year)

$A_{i,10\mu Sv}$= activity of the i-th radionuclide that can result in an annual effective dose to the representative population individual of 10 µSv.

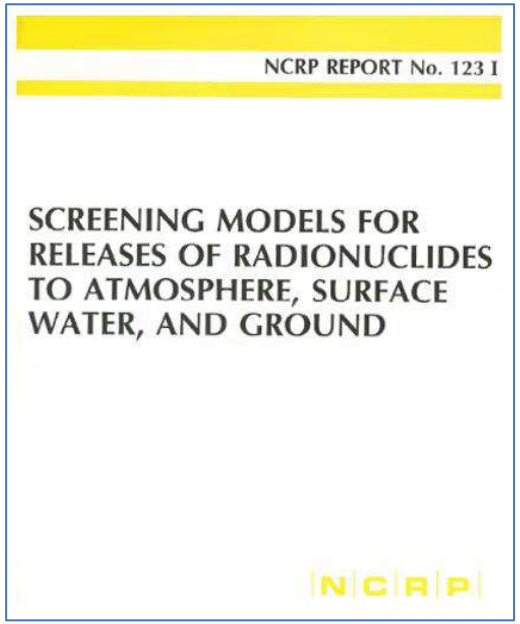
| Radionuclide | Ai,10µSv (Bq/y) |
|---|---|
| $^{99m}$Tc | 6,99E+12 |
| $^{18}$F | 2,17E+12 |
| $^{123}$I | 2,48E+12 |
| $^{131}$I | 6,71E+10 |
| $^{177}$Lu | 8,79E+11 |
| $^{90}$Y | 8,04E+11 |

# Art. 54 – Clereance from regulatory control of gaseous effluents

Release of radioactive gases in the atmosphere from Hospitals is not negligible only if there is an onsite cyclotron for the radioisotopes production fro PET applications.

If there is the cyclotron is convinient to have an air extraction system that pushes air from the hot cells, cyclotron vault and radiopharmacy rooms into the air compressing system, for storage and decay.

| | A | SFin | SFp+g | C<100 | D<100 |
|---|---|---|---|---|---|
| **Radioisotope** | **activity released in the environment (Bq/y)** | **SFinal (µSv/(Bq/m3))** | **SFplume+ground (µSv/(Bq/m3))** | **activity conc. at d < 100 m (Bq/m3)** | **Effective dose [µSv]** |
| $^{41}Ar$ | 8,3E+09 | | 1,5E+00 | 1,4E+00 | 2,1E+00 |
| $^{18}F$ | 7,0E+08 | 1,8E-01 | 3,9E+00 | 1,2E-01 | 4,8E-01 |
| | | | | | |
| **Total effective dose (µSv/year)** | | | | | **2,6E+00** |



*… please…*
*I just know what I've already said… don't ask me difficult questions…*

GRAZIE!!!!

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