

## Summary

In January 2018, RNT Consulting assessed radiological scenarios at Oncoinvent in document ONC17-03-v2 "*Worst case radiological scenarios at Oncoinvent*". This risk analysis is based on that document with an additional scenario concerning release due to ventilation filter underperformance or failure.

A risk assessment methodology as well as main principles related to NS5814:2021 has also been added.

The document has been revised by Oncoinvent's Radiation Safety Group with support from consultants from Norconsult's Department of Safety.

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## 1. Introduction

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### 1.1 Purpose and scope of risk assessment

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The purpose of this document is to assess risk related to radiation exposure incidents (Th-228, Ra-224 and daughter nuclides) at Oncoinvent AS in Oslo, Norway. It must be regularly reviewed, particularly upon changes to facilities, activity levels, processes and procedures that may impact safety. The estimates regarding radiation exposure are extremely conservative considering the worst scenarios possible, including failure of multiple safety mechanisms.

The potential for accidental release is considered through a number of different scenarios that may occur due to either human error, technical failures or intentional human behaviour

Assumptions, existing barriers and uncertainty are explained for each scenario. Risk reducing measures are identified for further evaluation.

The decay of Th-228 and its progenies will result in the stable isotope Pb-208. Simple calculations show that i.e. a release of 10 MBq Th-228 to the environment will generate 0.3 µg of lead. It is assumed that this amount of lead will be significantly diluted in water, air or soil. Since the limit for lead in drinking water is set to 10 µg/l (source: fhi.no), the amount of lead released to the environment is considered to be negligible and will not be assessed in this report.

### 1.2 Methodology

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This risk assessment is based on the main principles of NS5814:2021. Risk is associated with undesirable events such as accidents, technical faults, intentional or unintentional human behaviour. The assessment of risk is carried out in three steps: (1) Hazard identification and consequence analysis (2) Risk analysis and (3) Risk evaluation. Each scenario is assessed assigned a probability score and consequence score. The risk level is the product of these two scores.

The risks have been found by assuming that all identified risk mitigating actions listed in chapter 4. Conclusions have been successfully implemented.

It is assumed that all the hazard scenarios will be detected without reasonable delay, either due to personnel being present, or due to the monitoring systems of the exhaust air and local monitoring/alarms in facilities. There should be routines and training in place for personnel to act upon alarms.

**Probability**

Score (P)	Probability	Description of impact - one or more factors may be used
P1	Very low	<ul style="list-style-type: none"> <li>Highly unlikely, annual probability less than 1% (once in more than 100 years).</li> </ul>
P2	Low	<ul style="list-style-type: none"> <li>Unlikely, annual probability 1%-2% (once in 50 to 100 years)</li> </ul>
P3	Moderate	<ul style="list-style-type: none"> <li>Occasional, annual probability 2%-20% (once in 5-50 years)</li> </ul>
P4	High	<ul style="list-style-type: none"> <li>Common failure, annual probability 20% - 50% (once in 2-5 years).</li> </ul>
P5	Very High	<ul style="list-style-type: none"> <li>Likely, above 40% (at least once every 2 years)</li> </ul>

**Consequences**

Score (C)	Consequence	Description of impact - staff, the public, facility/economy/reputation
C1	None	No impact
C2	Minor	Insignificant impact (minor facility/economy impact)
C3	Major	Minor impact (minor health impact, staff anxiety, reputation, or facility/economy impact)
C4	Critical	Major impact (significant health impact or major reputation impact)
C5	Catastrophic	Severe health impact or death

**Risk**

Probability (P)	Consequence (C)				
	C1	C2	C3	C4	C5
P5					
P4					
P3					
P2					
P1					

Risk	Level description
High	Risk is unacceptably high. Controls or risk mitigating measures must be implemented.
Medium	Risk may be acceptable. Risk reducing measures shall be implemented as far as it is beneficial.
Low	Risk is acceptable and there is no need to implement risk reducing measures, although risk reducing measures should be considered (ALARA).

## 2. Hazard identification

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### 2.1 Background

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Oncoinvent is a privately held pharmaceutical company established in 2010. Its objective is to develop new cancer treatments. In 2019 Oncoinvent received a GMP certificate from the Norwegian Medical Agency. The company manufactures medicinal products used in clinical trials. Oncoinvent has 39 employees as per 2022.

The production and lab facilities for radiopharmaceuticals are located at Gullhaugveien 7 in Nydalen, Oslo, Norway. The lab area is 581 m<sup>2</sup> with 200 m<sup>2</sup> for GMP production. Surrounding the property are private apartments, homes, offices, and commercial buildings.

The production of radium-224 based radiopharmaceuticals involves hazards that may affect health, facilities/economy, and reputation. Oncoinvent has identified the following hazards:

- External influences (weather, incidents in vicinity etc.)
- Sabotage, theft, terror
- Fire
- Equipment/instrumentation malfunction
- Technical utility failures (incl. ventilation)
- Operating errors
- Integrity failure or loss of containment
- Release of gas (emissions to air)
- Release of fluid (emissions to water)
- Release of particles (emissions to water or air)

The list will be used to identify relevant risk scenarios.

### 2.2 Consequence assessment

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The Norwegian Labour Inspection Authority require all employers to prevent exposure to both ionizing and non-ionizing radiation. The regulations set further requirements for identifying and assessing the risk of health hazards of all radiation.

Th-228 is the parent radionuclide used at Oncoinvent for production of Radspherin®, which is based on Ra-224 (Figure 1).

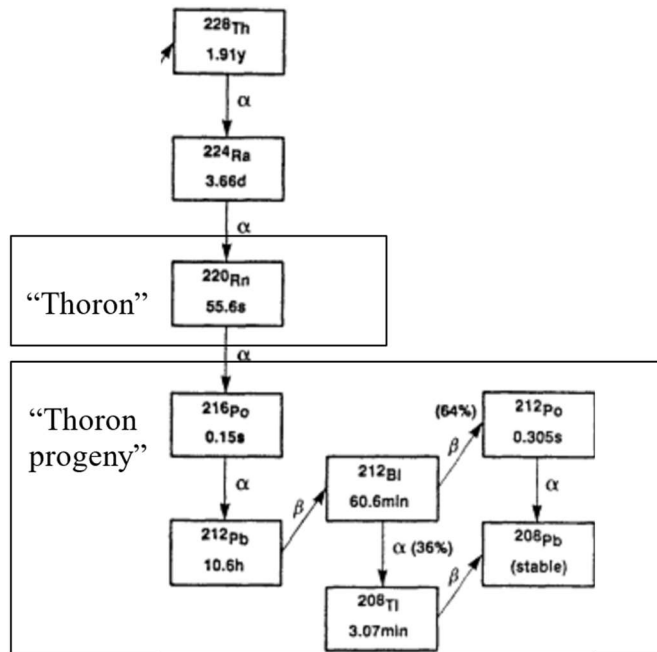


Figure 1 Decay scheme of Th-228 highlighting "thoron" and "thoron progeny"

In order to radiologically assess the effects of Th-228, a number of scenarios are constructed to calculate the radiation exposure, estimate risk or suggest mitigation methods.

The following exposure paths are considered:

- External exposure caused by ionizing radiation
- Internal exposure (Inhalation) after an accidental release and dispersion in the surrounding air.

The national limits for ionising radiation exposure as given in *The Act on Radiation Protection and use of Radiation* for personnel working with ionising radiation is 20 mSv/year (whole body dose rate), 500 mSv/year (extremity dose rate for skin), and 150 mSv/year (rate for eyes).

For the public, the exposure limits are 1 mSv/year (whole body dose rate), 50 mSv/year (extremity dose rate for skin), and 15 mSv/year (rate for eyes).

### 2.2.1 Exposure to radon-220 (thoron)

Radon is a colourless and odourless radioactive noble gas. When inhaled and exhaled it causes no long-term absorption in the body. However, a small fraction of the radon can be absorbed by body fluids to produce a radiation dose. Radon is lipophilic, which causes

accumulation in adipose tissues with a biological half-life of several hours. Radon-220 (also called thoron) has a half-life of 55.6 seconds, which is much shorter than the more common radon isotope, Rn-222 ( $t_{1/2} = 3.8$  days).

The thoron progenies (daughter radionuclides of Rn-220) are solids and positively charged ions of different isotopes. They are easily attached to aerosol particles and can be inhaled. The major dose contribution caused by thoron is to the lungs.

The health risks from exposure to thoron are principally due to the inhalation of the short-lived decay products, and alpha particle irradiation of the bronchial airways. Thoron decay product exposure rates are specified by the measure of Potential Alpha Energy Concentration (PAEC), given in units of  $J/m^3$  or Working Levels (WL), and the equilibrium-equivalent concentration (EEC), given in  $Bq/m^3$ .

The potential alpha energy concentration is derived from a linear combination of the activities of the short-lived decay products in the decay series. For thoron, the EEC (in  $Bq/m^3$ ) can be converted to the PAEC by the relationship:

$$1 \text{ Bq}/m^3 = 7.6 \times 10^{-8} \text{ J } m^{-3} = 3.64 \times 10^{-3} \text{ WL}$$

UNSCEAR (2000) estimate a dose conversion factor for Rn-220 of  $40 \text{ nSv}/(\text{Bq h } m^3)$ , based on an ICRP 50 model, which includes the dose organs other than the lung due to transfer of Pb-212 from the lungs.

A breathing rate of  $1.2 \text{ m}^3/\text{h}$  was assumed. UNSCEAR (2006) published a range of dosimetric assessments to the lungs from thoron decay products that supports the use of their conversion factor.

Thus, the effective dose from inhalation of Rn-220 can be derived as follows:

$$D_{\text{eff}} \text{ (mSv)} = (C_{\text{Rn-220}} * t * DC \text{ Rn-220})/1E6.$$

Where:

Rn-220 = Estimated Rn-220 concentration in air ( $Bq/m^3$ )

t = time of exposure (hours)

DC Rn-220 = Dose coefficient for Rn-220 =  $40 \text{ nSv}/(\text{Bq h } m^3)^{-1}$

For example, spending 8 hours in a room with a Rn-220 concentration of  $270 \text{ Bq}/m^3$  would result in an exposure of  $86.4 \text{ } \mu\text{Sv}$ , which after a month exposure (22 days) will result in inhaled dose of  $1.9 \text{ mSv}$  [WLM UNSCEAR 2000].

### 3. Risk assessment

A number of scenarios are examined below, it should be noted that these are **worst-case** calculations that require simultaneous failure of multiple layers of safety and/or serious operator error.

#### 3.1 Scenario 1: Spillage of a whole vial of 100 MBq Th-228 (room release)

Spillage a whole vial of 100 MBq Th-228 in equilibrium with daughters in one of the chambers of the double glove box and subsequent opening of the glove box.

Assumptions:

- Th-228 activity = 100 MBq (in equilibrium with Ra-224 and Rn-220)
- Liquid volume = 10 mL
- Glove box volume = 0.5 m<sup>3</sup>
- Room volume = 57 m<sup>3</sup>
- Spillage in the box is assumed to be a point source for a conservative approach
- Dose rates taken from Table 10 ONCO-16-02 (RNT Consulting report)
- Distance from worker to spillage is 10 cm air with 10 mm lead (total 11cm)
- The operator's fingers/hands have no shielding during manipulations in the box

**When integrity of glove box is maintained:**

A worker who will clean up the spillage will be exposed to the body when working at the glove box:

- Whole body dose rate = 890 µSv/h (14,8 µSv/minute)

An extremity dose will be received from clearing up the material. Assuming no shielding through the gloves:

- Extremity dose rate = 163000 µSv/h (2717 µSv/minute).

During the initial clean up, around 90% of the radioactive can be quickly collected on absorbent material and placed into a waste container, which is suitably shielded. This will require 1 minute of operator exposure at highest activity.

Duration of initial cleanup	Whole body dose (µSv)	Extremity dose (µSv)
1 minute	14,8	2717

Subsequent clean-up is then performed with lower activity present in the spill, around 10MBq Th-228 remains.

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Duration of second cleanup	Whole body dose (μSv)	Extremity dose (μSv)
1 minute	1,48	271

A final clean-up of the residual activity (1MBq Th-228) is performed. A longer time is needed for the final clean-up and 5 minutes is estimated.

Duration of final clean-up	Whole body dose (μSv)	Extremity dose (μSv)
5 minutes	0,74	136

The total estimated external exposure is 17 μSv for whole body and 3124 μSv to extremities (fingers). The extremity dose to fingers can be greatly reduced by using tongs to place the absorbent material onto the initial spillage to soak up the majority of the activity. The tongs can also be used to place the absorbent material into a shielded waste container.

Assuming equilibrium between Th-228 and Rn-220, the expected initial Rn-220 concentration in the glove box will be 200MBq/m<sup>3</sup>, as the glove box remains sealed. This activity in air will be cleared by the ventilation system while further Rn-220 will be produced from the spillage. As the activity of the spillage is reduced by the clean-up efforts, the concentration of Rn-220 in the glove box will also decrease accordingly. The Rn-220 removed by the ventilation system will be collected on the active carbon filters and the particle-bound progeny collected on the HEPA filter.

**Failure of the ventilation system, the UPS and the glove box is opened.**

Assumptions:

- The main lab power has failed, and the ventilation system is not working
- The UPS that provides back up power to the ventilation system has also failed
- The operator has opened the door to the glove box and released Rn-220 into the lab area.
- Th-228 activity = 100MBq (in equilibrium with Ra-224 and Rn-220)
- Liquid volume = 10mL
- Glove box volume = 0.5m<sup>3</sup>
- Room volume = 57m<sup>3</sup>
- Complete equilibrium between Th-228 and Rn-220
- Complete mixing of the lab air occurs
- A worker is present in the room for 10 minutes before discovering their mistake.

It should be clearly stated that a double failure of safety systems (the power to the ventilation system and the UPS) is a highly unlikely scenario. 100MBq of Rn-220 released into the room of 57 m<sup>3</sup> volume would result in a Rn-220 room concentration of 1.75 MBq/m<sup>3</sup>. Using the calculation of Effective dose for inhalation given in section 2.2, a dose of 11.7 mSv was calculated for a 10-minute exposure.

The assumption that the operator is in the room for 10 minutes before realizing the failure of the ventilation system is highly unlikely. Pressure gauges on the glove boxes, the lack of inflation of the glove box gauntlets, the lack of noise from the ventilation system and any alarms on the ventilation system would indicate a failure. Operators also use air sampling alpha detectors during activities involving radon-emitting radioactive sources. If Rn-220 were to enter the lab, the local radiation monitors in the room and the contamination monitors should immediately alert the user to elevated Rn-220 levels.

If a worker donned a protective mask with a small HEPA and active carbon filter and the mask was correctly fitted, it could be assumed that 99.9% of the Rn-220 would be retained on the carbon filter (the HEPA would filter any particulate bound air contamination). The effective dose for inhalation would then be reduced from 11.7 mSv to 0.0117 mSv.

**Risk evaluation**

	Probability					Consequence					Risk		
Value	1	2	3	4	5	1	2	3	4	5	Low	Medium	High
Public (health, reputation)	x					x					x		
Personnel at Oncoinvent*			x				x						
Personnel at Oncoinvent**	x					x					x		

\*Glove box integrity maintained.

\*\* Failure of safety systems and opening of the glovebox necessary.

The risk assessment takes into account the technical barriers, redundancy in the ventilation system and detection capabilities. If the operator is exposed as described, care must be taken to ensure that the operator does not exceed the total annual limits of exposure at a later stage.

The risk for this scenario is considered to be acceptable.

**3.2 Scenario 2: Spillage of a whole vial of 100 MBq Th-228 (ventilation release)**

Spillage of a whole vial of 100 MBq Th-228 in equilibrium with daughters, in one of the chambers of the double glove box or in the storage cupboard (special ventilation/hot exhaust) failure of all the ventilation filters.

This ventilation air release to the surroundings will be dependent on the emanation rate of Rn-220, the surface area of the spillage and the volume of air removed per second by the ventilation system.

Assumptions:

- Th-228 activity = 100MBq (in equilibrium with Ra-224 and Rn-220)

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- Liquid volume = 10mL
- Th-228 and Ra-224 remain in a solid state and do not escape from the glove box to the ventilation system.
- The only release will be Rn-220 and progeny produced during transportation from the glove box spillage to the surroundings.

#### Estimating the area of spillage:

During spillage of a liquid, the liquid will spread onto the work surfaces. For a small spillage, a droplet of 50  $\mu\text{L}$  spreads into a circular area of  $2\text{cm}^2$  (diameter 16mm). Assuming the surface area is proportional to the volume of the spill, it is assumed that a spillage covers a circular surface with a relative area of  $0.04\text{ cm}^2/\mu\text{L}$ . Therefore, a 10mL spill volume would cover  $400\text{cm}^2$  (diameter around 23 cm).

#### Estimate of Rn-220 emanation rate:

Earlier work with Ra-223 determined Rn-219 emanation rates of around  $0.3\text{kBq}(\text{cm}^2/\text{s})$  per MBq. Since the half-lives of the radon isotopes are relatively similar, this value is considered for these scoping calculations with Ra-224/Rn-220. For a 100 MBq Th-228 source, the Rn-220 emanation rate is estimated to be  $30\text{ kBq}/\text{cm}^2/\text{s}$ , assuming equilibrium.

Estimate of Rn-220 emanation from spillage of 100 MBq Th-228 with a volume of 10 mL can be made by combining the surface area of the spill ( $400\text{ cm}^2$ ) with the estimated emanation rate from a 100 MBq spillage gives an estimate of the Rn-220 produced per second as 12 MBq/s.

If the air capacity of the ventilation system is  $3000\text{ m}^3/\text{h}$ , the volume of air going to the stack per second is then  $0.83\text{ m}^3/\text{s}$ , so the Rn-220 concentration before environmental release is then  $14,5\text{MBq}/\text{m}^3$ .

If a maintenance worker happened to be working with their head placed directly at the exit of the ventilation system, the inhalation dose at the exit from the ventilation system is estimated to be 97 mSv if a 10-minute exposure time is assumed, and only contaminated air is inhaled for the entire 10 minutes (97 times larger than the accepted yearly dose, health impacts are probable).

While an extremely unlikely scenario, it suggests a strict access control is required for the persons who will perform maintenance on the ventilation system and a shutdown procedure should be initiated for all lab workers to avoid release of activity during maintenance. Normal procedure during ventilation maintenance is to shut down the system to allow belts and filters to be replaced. During accidents of this kind, the roof terrace should be evacuated to mitigate risk of exposure to public.

The dose to the surrounding environment will be substantially lower due to the massive dilution effect when the Rn-220 is released to normal air (ref. Assessment of radiation dose arising from Rn-220 discharged from Oncoinvent in Nydalen, 2022)

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This exercise also applies to change of filters in the ventilation system. Due to this, airborne activity in the ventilation channels must be measured before and during exchange of filters, and operator must use gas mask with carbon filter during the whole operation.

*NOTE: Scenario 4 examines the case of a fire in the laboratory and release of all radionuclides to the environment, which should be considered a more significant event than the short environmental release of Rn-220.*

**Risk evaluation**

	Probability					Consequence					Risk		
Value	1	2	3	4	5	1	2	3	4	5	Low	Medium	High
Public (health, reputation)	X								X			X	
Personnel at Oncoinvent	X					X					X		

The risks for this scenario is considered acceptable with the current mitigating actions. The scenario would mean a relevant risk consequence to persons receiving the dose, but this is also considered extremely unlikely.

**3.3 Scenario 3: Accidental release of 10 MBq Th-228 (water release)**

Accidental release of 10 MBq Th-228 in equilibrium with daughters into the sink at the R&D lab and the water tank barrier does not work.

For a worst-case scenario, the following assumptions are made:

- The sewer workers are working within the sewer directly at the point of release from the laboratories at Oncoinvent.
- The volume of activity containing the 10 MBq is assumed to be 10 mL without any further dilution before release to the sewer.
- Once in the sewer system, it behaves as a point source
- The water in the sewer system is constantly moving rather than stagnant
- The flow velocity in the sewer is 1.6 m/s according to DIN 1986-100
- A distance of 0.1 m from the passing volume of contaminated water containing Th-228 and progeny and the sewer worker
- Dose rate from Th-228 and progeny at 10cm from 10MBq = 163 µSv/h (ONCO 16-02).

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**External exposure of the sewer worker:**

The exposure of the sewer worker will be external as the radioactivity passes by them, and potentially from released Rn-220. The released 10mL volume containing Th-228 and daughters will enter into the sewer and pass under the sewer worker at a rate of 1.6 m/s. To simplify the calculations, it is assumed that at 1.6m distance from the radioactive source there is no significant radiation exposure to the sewer worker. Therefore, the total exposure time is over 2 seconds, which covers a distance of 3.2 meters. This would result in an external exposure of <math><0.1\mu\text{Sv/h}</math>

**Internal exposure of the sewer worker:**

Release of Rn-220 into the sewer system air from release of contaminated water is a possible internal exposure pathway for a sewer worker.

As in the assessment of external exposure, it is assumed that the sewer is flowing at 1.6 m/s. The estimation of internal exposure to Rn-220 is made assuming the sewer has a diameter of 2 meters and that in 2 seconds, the contaminated material will travel 3,2 metres. The volume of this section of sewer is therefore 10m<sup>3</sup>.

A worst-case air concentration is derived by assuming 10 MBq of Rn-220 in mixed 10m<sup>3</sup> of air, which equals 1 MBq/m<sup>3</sup>. The exposure to the sewer worker is estimated by calculating the exposure during the passing of Rn-220 contaminated air over 2 seconds. The estimated internal exposure is therefore 0.02 mSv.

**Public and environmental exposure**

The large degree of dilution within the wastewater treatment system of a large urban and industrial area will ensure that the concentrations after the initial point of entry do not present any significant exposure to workers at the sewage treatment plant or if sewage sludge is applied to crops after treatment. For example, the Bekkelaget wastewater facility in Oslo can handle up to 50 million m<sup>3</sup> of wastewater per year or around 136000m<sup>3</sup> per day ([www.bvas.no](http://www.bvas.no)). Therefore, the exposures at the point of entry into the sewer systems represent the worst-case scenario.

**Risk evaluation**

Value	Probability					Consequence					Risk		
	1	2	3	4	5	1	2	3	4	5	Low	Medium	High
<i>The public</i>		X				X					X		
<i>Personnel at Oncoinvent</i>		X				X					X		

Internal and external exposure is significantly lower than the annual exposure limits for both personnel and public.

The risks associated with this scenario is considered acceptable.

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**3.4 Scenario 4: Fire in the laboratory**

A fire in the laboratory at Oncoinvent could have very significant consequences when taking the “Worst-case scenario” into account. A fire could lead to Th-228 being released to the air with significant exposure from inhalation to those *in the vicinity* of the labs and to the surroundings, where remediation costs and compensation costs to businesses may be needed. In order to assess the radiation dose rate to the surroundings, a calculation was performed to assess the inhalation dose at 200 metres from the source of Th-228. A worst case is where the total inventory of Th-228 is released (assuming 10 generators at 100MBq per generator). A Gaussian plume model used by NRPB produced the time-integrated air concentrations per unit release (Cooper et al., 1989).

Major assumptions in the release:

Inventory released:	1000MBq Th-228
Fraction of inventory discharged:	1.0
Height of the release:	10m
Release duration:	1 hour
Inhalation dose calculated at:	200m
Meteorological conditions:	Pasquill E, wind speed 3 m/s

The following equation can be used:

$$E_{inh} = C_A \cdot C_F \cdot I_A \cdot R \cdot D_I \quad \text{where:}$$

- $E_{inh}$  = Dose from inhalation (Sv)
- $C_A$  = Time integrated air concentration per unit release =  $3.5E-04$  (Bq s/m<sup>3</sup> per Bq)
- $C_F$  = Correction factor for a 1 hour release (0.78)
- $I_A$  = breathing rate =  $2.67E-04$  m<sup>3</sup>/s (adult)
- $R$  = <sup>228</sup>Th released =  $1E+09$  Bq
- $D_I$  = Dose equivalent (Th-228) per unit activity inhaled (EURATOM)  $2.9E-05$  Sv/Bq Adult

Thus  $E_{inh} = 2.1$  mSv effective dose to an adult (annual limit for general public is 1 mSv per year) - hence 2.1 times annual limit. No significant public health impact is expected, but there will most likely be consequences for economy, operation and anxiety to employees and neighbours.

**Risk evaluation**

Value	Probability					Consequence					Risk		
	1	2	3	4	5	1	2	3	4	5	Low	Medium	High
The public (economy)		X						X				X	
Th Public (health)		X				X					X		
Oncoinvent* (financial)		X						X				X	

\* Evacuation of employees building prior to release. Staff has significant risk knowledge and will act accordingly.

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The risks associated with this scenario are acceptable, as the medium risks are mostly related to financial issues.

**3.5 Scenario 5: Theft/break-ins and vandalism**

The loss of radioactivity by theft or vandalism has a very low probability. The access to the labs requires passage through several locked doors and then the intruder would need to find the radioactive storage areas in the lab. In general, items such as laptops in the offices would be much easier targets for thieves and vandals.

The amount of radioactive substance a person can steal, may cause health issues for that person or accomplice. The staff may be impacted with anxiety or possible exposure to radiation during clean up if items are broken during vandalism.

**Risk evaluation**

Value	Probability					Consequence					Risk		
	1	2	3	4	5	1	2	3	4	5	Low	Medium	High
<i>The public (thief, vandal)</i>	X							X			X		
<i>Personnel at Oncoinvent</i>	X							X			X		

The risks associate with this scenario are acceptable.

**3.6 Scenario 6: Terrorism/Sabotage**

The radioactive materials stored at Oncoinvent could be used by terrorists to create a Radiological Dispersal Device (RDD) or sabotaged by competing companies who wish to damage Oncoinvent’s public image. It is unlikely that any conventional security measures could stop a group of determined terrorists or industrial saboteurs. This risk is a low probability/high consequence risk.

The amount of radioactive substance a person can obtain, may cause health issues if the substance is handled without care or as a threat (similar to "white powder" incidents).

**Risk evaluation**

Value	Probability					Consequence					Risk		
	1	2	3	4	5	1	2	3	4	5	Low	Medium	High
<i>The public (fear/reputation)</i>	X								X			X	
<i>Personnel at Oncoinvent</i>	X							X			X		

The risks associated with this scenario are acceptable.

### 3.7 Scenario 7: Release of radon exceeding the permit from DSA

This scenario is related to release of radioactive material due to ventilation, filter or equipment under-performance or failure during normal operating conditions.

During production Th-228 is in equilibrium with daughters, in the chambers of the double glove box, biosafety cabinet or in the storage cupboard. These units are connected to the dedicated ventilation system with ducts leading to an outdoor exhaust on the roof of the building. Filters are located inside the ventilation system. These filters are affected by air humidity, which during summer, makes them less efficient. Hence, a release exceeding the permit may be caused by underperformance or failure of the filters.

This release to the surroundings will be dependent of on-going activities in the lab, the emanation rate of Rn-220, and the volume of air removed per second by the ventilation system.

The ventilation of the facility is monitored for Rn-220 both with permanently mounted detectors and detectors which can be connected at other specific monitoring sites.

#### Risk evaluation

Value	Probability					Consequence					Risk		
	1	2	3	4	5	1	2	3	4	5	Low	Medium	High
<i>The public (fear/reputation)</i>		X*						X				X	
<i>The public (health impact)</i>		X*					X				X		
<i>Personnel at Oncoinvent (health impact)</i>		X*				X					X		
<i>Oncoinvent (reputation/financial)</i>		X*						X			X		

\*Probability score assumes mitigating actions listed in Chapter 4, Conclusions, are successfully implemented.

The risks associated with this scenario are considered acceptable.



## 4. Conclusions

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The scenarios created in this report are conservative in their approach and caution is advised in their interpretation.

An Emergency Response Plan has been developed addressing these scenarios.

The following risk reducing measures have been identified;

### Radiation safety measures:

- The use of tongs instead of hands to clean up spills should be available in the lab (scenario 1)
- Consider relocating or changing work operations for operator who are largely exposed to radioactivity, to avoid future exposure that exceeds the total yearly limit (scenario 1).
- Strict access control for the persons who will perform maintenance on the ventilation system and a shutdown procedure should be initiated for all lab workers to avoid release of activity during maintenance (scenario 2).
- Routine for evacuation of the roof terrace if accidental release of radon-220 to air (scenario 2 and 7).
- Measurement of radon-220 in air and use of protective masks during exchange of ventilation filters (scenario 2).
- Continuous monitoring of exhaust air for detection of radon-220. (Scenario 7)
- Redundancy of filters in ventilation system. (Scenario 7)
- Routines for service and maintenance of critical equipment and support systems. (Scenario 2 and 7)
- Cleaning routines (Scenario 1,2 and 7)
- Training of personnel in handling of spills and accidents (Scenario 1, 2 and 7)
- Drying of inlet air to stabilize filter performance (Scenario 7)

Fire protection measures (scenario 4):

- Minimise chemical storage in the laboratory areas
- Keep flammable reagents in fire proof cabinet
- Minimise any high risk work where the potential for explosion or flammable materials is high
- Ensure that radioactive sources are stored appropriately contained and shielded in their designated storage areas.
- Training in basic fire fighting for staff
- Ensure that all fire extinguishing apparatus is inspected according to regulations.

Measures regarding secure area management (scenario 5 and 6):

- Automatic locking of main door to building and to the laboratory
- Access to the lab areas requires an electronic key

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- A 24-hour security response service
- Motion sensors should cover the potential entry points into the labs (windows and doors) and in the Level B labs and storage areas
- All radiation source storages areas are locked with requirement for additional access key(also defined in the radiation protection regulations)
- The inventory of radioactive materials and its location within the building should be confidential information
- Adequate security measures must be in place to protect radioactive sources.

## 5. References

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Norsk Standard 5814. *Krav til risikovurderinger*. NS5814. 2021 (Standard Norge)

ONCO 16-02: RNT Consulting report. Lab activities and shielding considerations. July 2016.

Level for lead in drinking water: <https://www.fhi.no/ml/miljo/miljogifter/fakta/bly-i-mat-og-miljo---faktaark/#grenseverdier> last edited 14.09.20.

ICRP 65: Protection against radon at home and at work. ICRP Publication 65. Annals of the ICRP, 23(4). 1993

UNSCEAR 2000 (United Nations Scientific Committee on the Effects of Atomic Radiation) Sources, Effects, and Risks of Ionizing Radiation (New York: United Nations)

UNSCEAR 2006 (United Nations Scientific Committee on the Effects of Atomic Radiation). Effects of ionizing radiation, Annex E (New York: United Nations)

DIN 1986-100: Entwässerungsanlagen für Gebäude und Grundstücke - Teil 100: Bestimmungen in Verbindung mit DIN EN 752 und DIN EN 12056

Cooper J.R., Walmsley, A and Charles, D. Individual and collective doses from the release of Sr-89 into the environment following medical administration. NRPB-M193 (1989).

Report: Assessment of radiation dose arising from 220Rn discharged from Oncoinvent in Nydalen, written by Simon Jerome, researcher at NMBU, 2022.