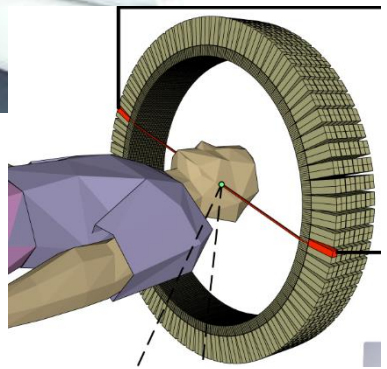
10. Case Study 7: Use of radiopharmaceuticals in nuclear medicine services for PET examination with Fluor-18: Optimisation for external and internal exposure

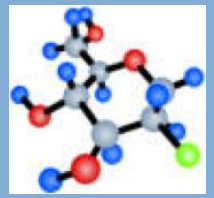
Why and how to make use of fluorine 18 for diagnosis (1)

Positron emission tomography, also called *PET* imaging, measures important body functions, such as blood flow, oxygen use, and sugar (glucose) metabolism, to help evaluating organs and tissues functioning



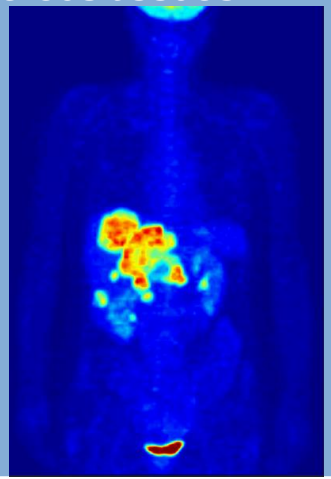
Why and how to make use of fluorine 18 for diagnosis (2)

Diagnostic in nuclear medicine makes use of small quantities of radiopharmaceuticals by injection into the patient.
The radiotracer generally used with PET is Fluorine 18, beta emitter, producing 511 keV photons due to the annihilation of the old positrons, which makes it one of the most irradiating radionuclide's in nuclear medicine. It is primarily incorporated into a glucose molecule as fluorodeoxyglucose (FDG); that tracer being similar to glucose, is going to be fixed on tissues consuming a lot of glucose like cancerous tissues.

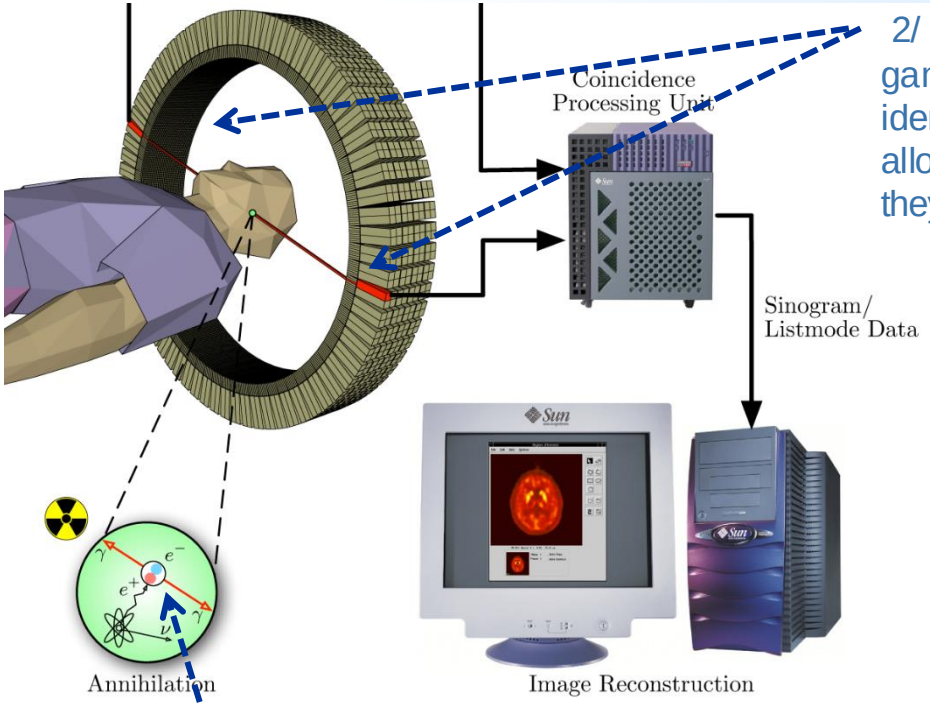


The average activity used is 400 MBq.

Use of PET after Fluorine 18 injection allows to draw a map of glucose - or looking like - consumption within the body and then to point out where are the locations of tumours.



Why and how to make use of fluorine 18 for diagnosis (3)



2/ The sensors detect the two gamma photons and then identify their "line", which allows to know exactly where they come from in the body

1/ The positron issued by the disintegration of the FDG atom, is very quickly annihilated by an electron encountered on its way, this produces two 511 keV gamma photons going on the "same line", but with two opposite directions

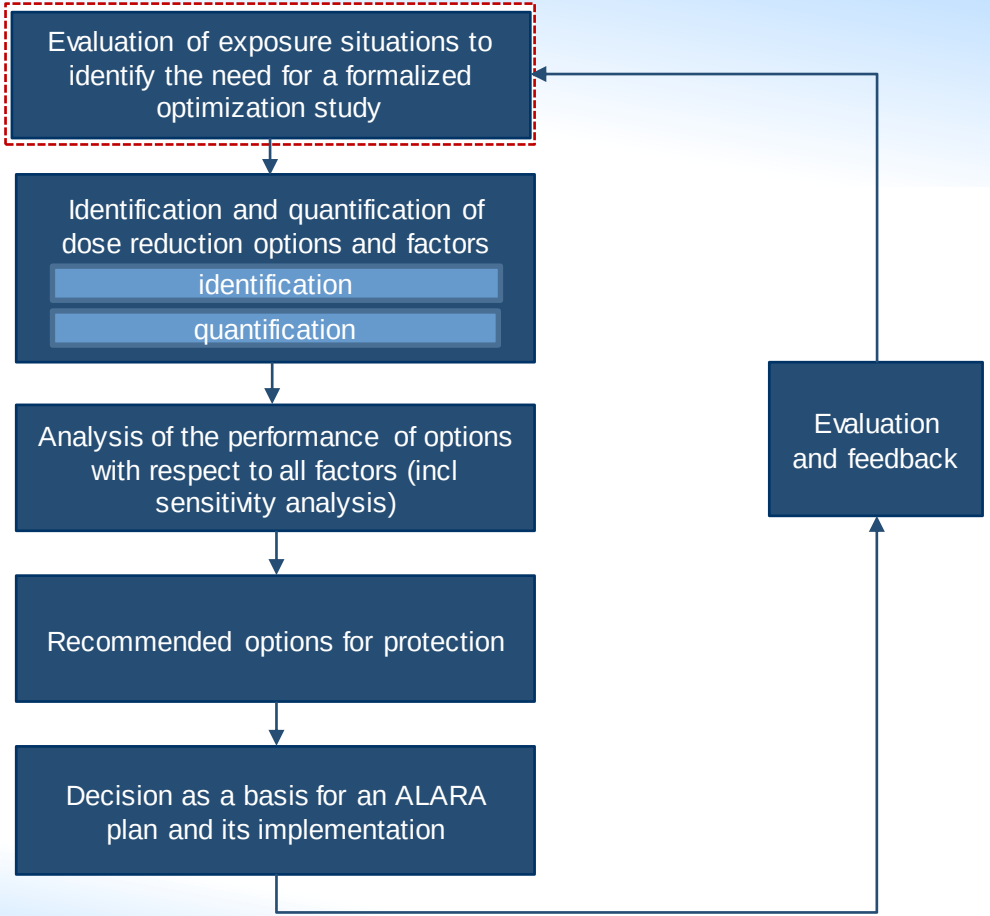
What are the occupational stakes?

Fluorine 18 being one of the most irradiating radio nuclides used in nuclear medicine,

Is there a potential for high occupational doses ?

If yes, when and where?

What is the system to be optimized?



What are the occupational stakes? What is the system to be optimized?

Major Steps	Institution concerned	Workers concerned
1. FDG production with a cyclotron	Radiopharmaceutical company	technicians and radio chemists
2. FDG transport to the medical department	Transport company	drivers
3. FDG storage in the medical department	Medical department	Nucl. Med technicians, (or radio pharmacists)
4. Preparation of the FDG syringe	Medical department	Nucl. Med technicians, (or radio pharmacists)
5. FDG Injection	Medical department	Nucl. Med technicians,
6. PET CT examination	Medical department	Nucl. Med technicians, or radiographers
7. Waste management	Medical department	Nucl. Med technicians,

In some cases nurses participate too in different steps

What are the occupational stakes? What is the system to be optimized?

The workers of the first 2 steps belong to totally different firms and institutions with regards to the next steps;

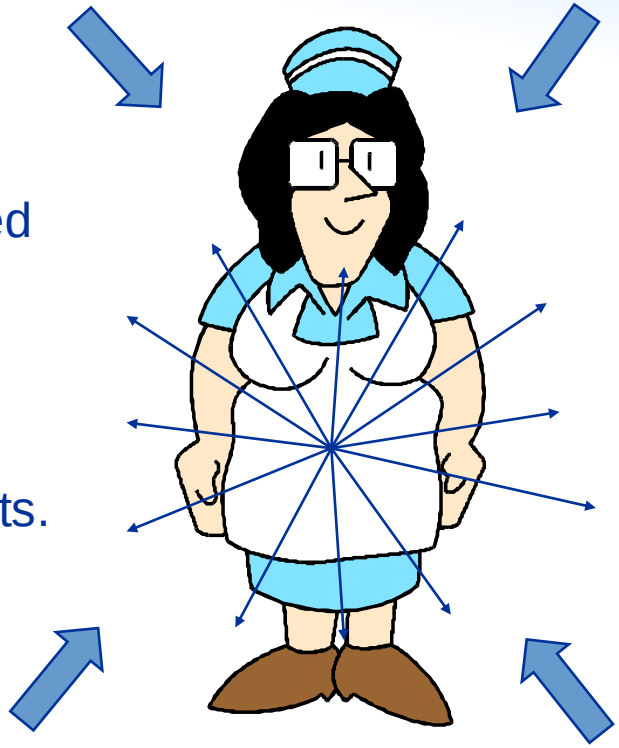
The optimization of their doses will have no direct impact on the optimization of occupational exposures within the medical department

In the case study, *the optimization will be limited to that of the occupational exposure in the medical department* : however it will include FDG manipulation and PET CT imaging

Exposures in Nuclear Medicine

Internal
Ingested and/or inhaled radionuclides

External
Vials, syringes, patients.



What are the occupational stakes?

What are “a priori” the concerned exposures types?

Major Steps	External exposure to fingers and hands	External effective dose	Contamination (inhalation and external contact)
3. Storage	+++	+	+
4. Preparation of the syringe in a depressurised hood	+++	+	0
5. Injection	+++	+	++
6. PET CT examination	0	++	+
7. Waste management	++	+	+

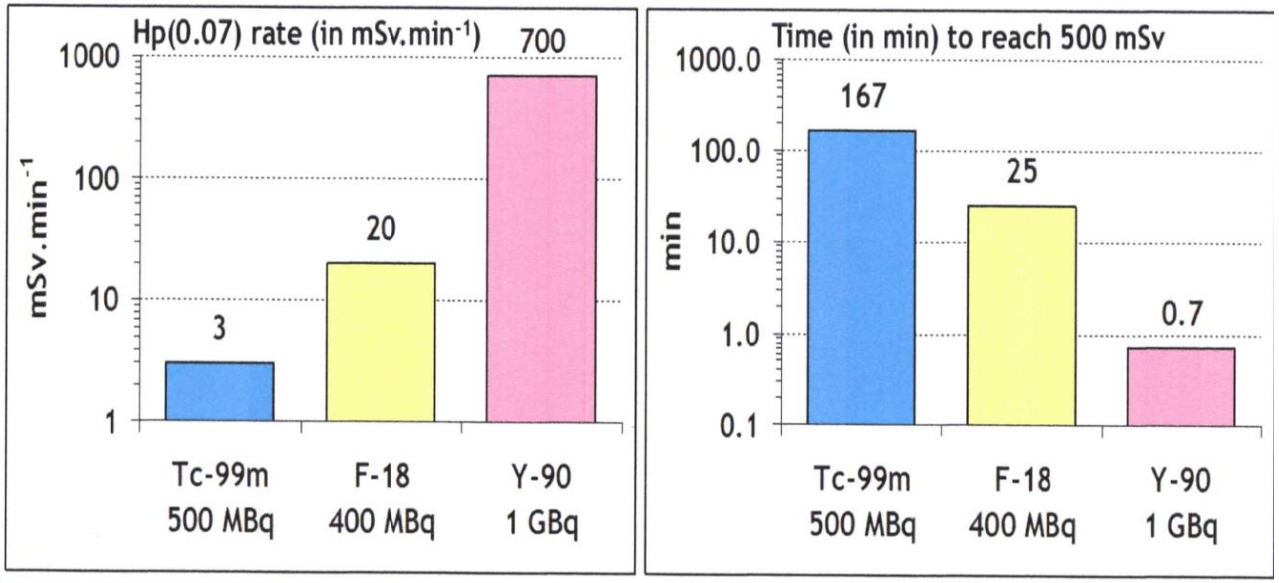
It is clear that while manipulating the FDG the main type of exposure concerns external exposure to fingers and hands

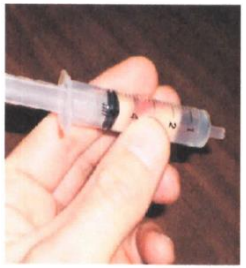
While after the injection and during the PET examination, the patient has become himself a source and effective dose is the most important exposure type for those working at a short distance from the patient.

What are the occupational stakes:

Some ORAMED dose rates extrapolations

In contact of an unshielded (5 ml) syringe

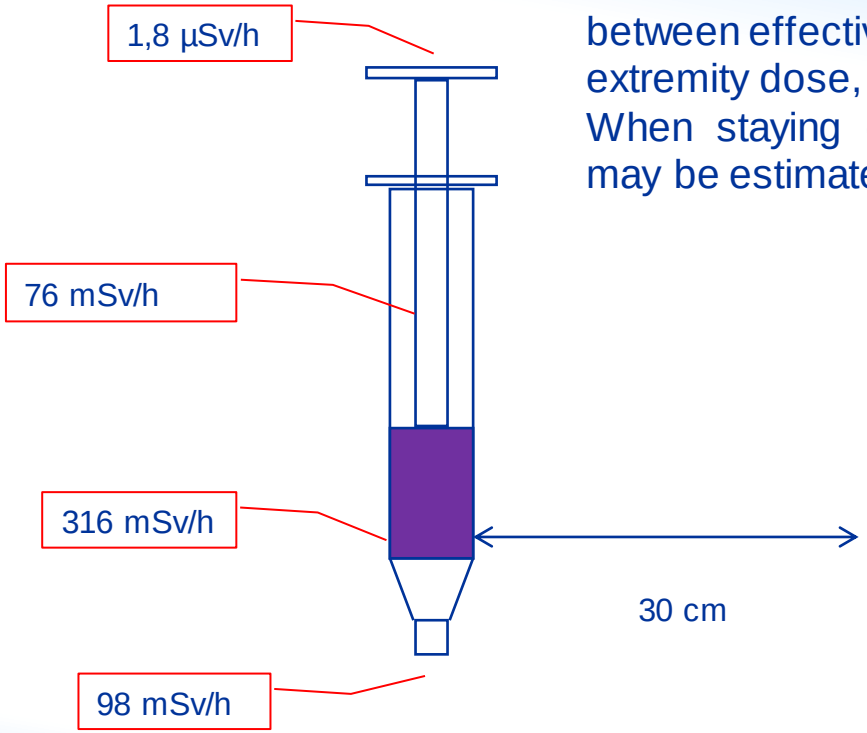




As can be seen on the figure, after 25 mm the extremity dose limit should be reached without any protection. In that case it should be reached within a day (with less than 10 procedures).

Contact dose rates and H(10) at 30 cm

No shield



These measures show that the ratio between effective dose and extremity dose, due to the F18
When staying close to the patient may be estimated to around 0,5 %

400 MBq F-18 2 ml

Measures from Sebastien Balduyck

What are the occupational stakes: patient as source
Some ORAMED dose rates extrapolations

Fluorine 18
FDG, A= 370 MBq, N=21

Distance (m)	Dose rate Immediately after application µSv/h	Dose rate 2 hours after application µSv/h
0	590	190
0,5	81	30
1	29	11
2	8,6	3,4
3	4,1	2,1
5	1,5	1,0
7	0,6	0,4

One nuclear medicine technician staying one hour at 25 cm from the patient should work in average under a dose rate of 220 µSv per hour *(=(81x4+30x4)/2)*

He should stay 100 hours at the contact of several patients for reaching 20 mSv

This should never occur, however…

What are the occupational stakes: Effective dose observations

PET with Fluorine 18 started to be used mid 90's and became common with CT at beginning of 21st century

The first data provided around 2004(*) showed occupational effective dose per PET examination (syringe preparation+ injection+ installation of the patient in the PET) around 10 μSv (± 5 μSv)

Under the hypothesis of a worker performing 10 examinations per day 200 days/year ; his annual effective dose should have been comprised between 10 and 30 mSv (average 20). One may consider that at that time only few protection actions were implemented

More recent studies (**) point out annual individual doses ranging between 2 and 5 mSv. This is obviously the result of recent spreading of radiological protection culture among the concerned technicians.

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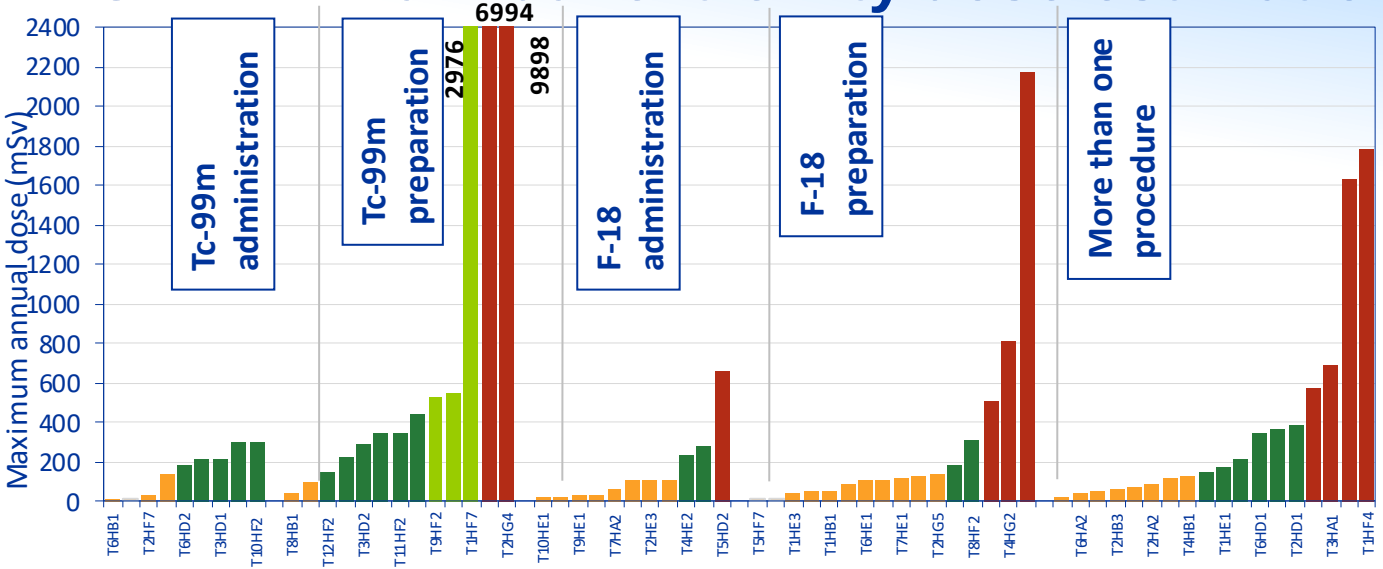
What are the occupational stakes: ORAMED annual extremity dose estimation



D < 150 mSv → 49%

D > 500 mSv → 19%

D > 500 mSv → 19%

- Some workers were monitored for only one type of procedure for the ORAMED project when actually they performed more. In these cases, the estimation of the annual dose has been calculated only considering the monitored procedures, from which real measured values were available.
- Even considering this hypothesis, it is found that the extrapolated doses reach the annual limit for 19% of the workers.

What are the occupational stakes? the contamination risks

The effective dose coming from internal exposure.

The quantity that should be inhaled or ingested through one drop of F18 corresponds to 20 to 50 µl (± 4 MBq) which is around 100 times less than the quantity to be injected, as a maximum the effective dose to the worker in case of contamination would not exceed 0,05 to 0,1 mSv during the preparation phase.

And decades or even hundred (of) time less when diluted into the patient blood, if the worker is contaminated by a drop of blood.
patient doses measured range between 5 and 10 mSv procedure as
if that occurs one or two times a month per worker due to manipulation errors ; this will lead to a maximum of dose due to contamination never exceeding 1 mSv per individual in a year, which is very small in comparison with effective external exposure

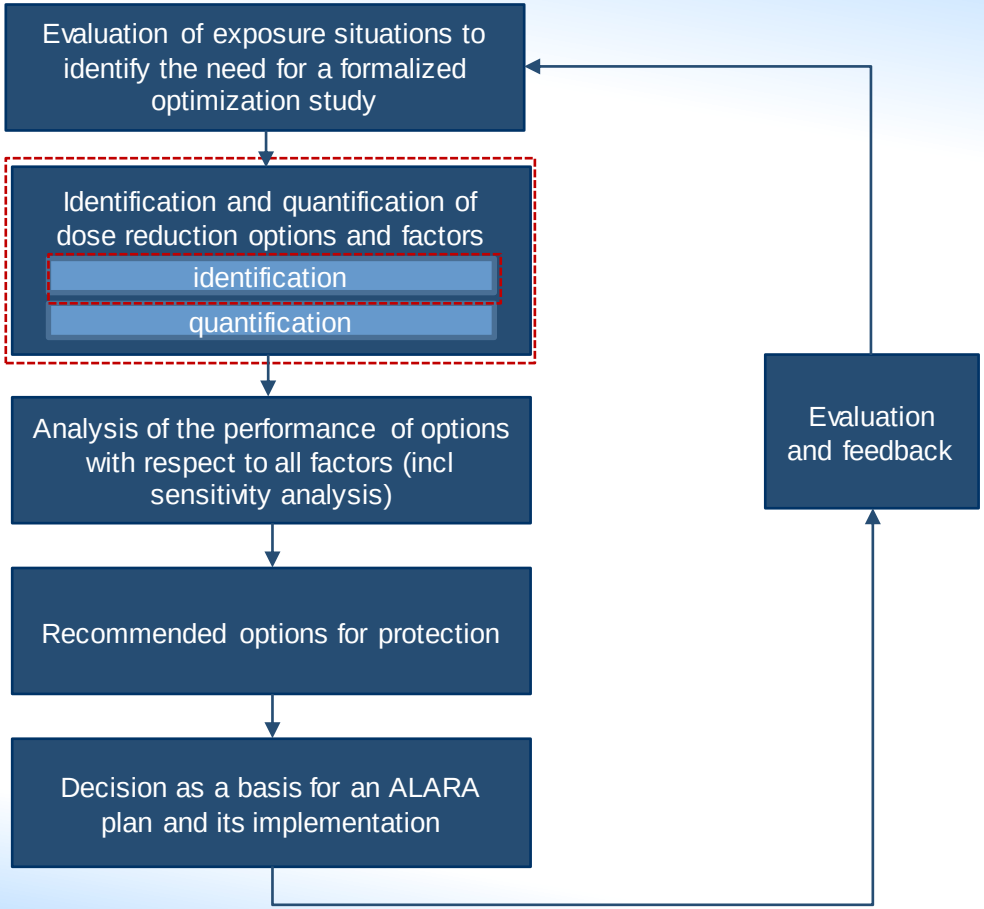
Conclusion about stakes:

Theoretical estimations have shown that without radiological protection actions the occupational dose limits could easily be reached quite quickly both for the effective dose and the extremity dose, mainly through external exposure, with a normal workload in PET CT.

The practical observations from the ORAMED study show that in reality skin dose limits are reached in Europe for at least one fifth of the workers, while effective dose should still be, even if less often, a crucial topic.

Therefore the need for a formal optimization procedure remains important in particular in countries where the radiological protection culture is not widely spread.

Of course this will have to take into account the impact on profitability if any.



What are from your point of view the possible protection actions that can be envisaged for the different steps, from unpacking to waste management, including the PET examination itself?

What are the steps?: an analytical approach (1)

Time Schedule

start

15 min

+ 90 min

+ 45 to 60 min

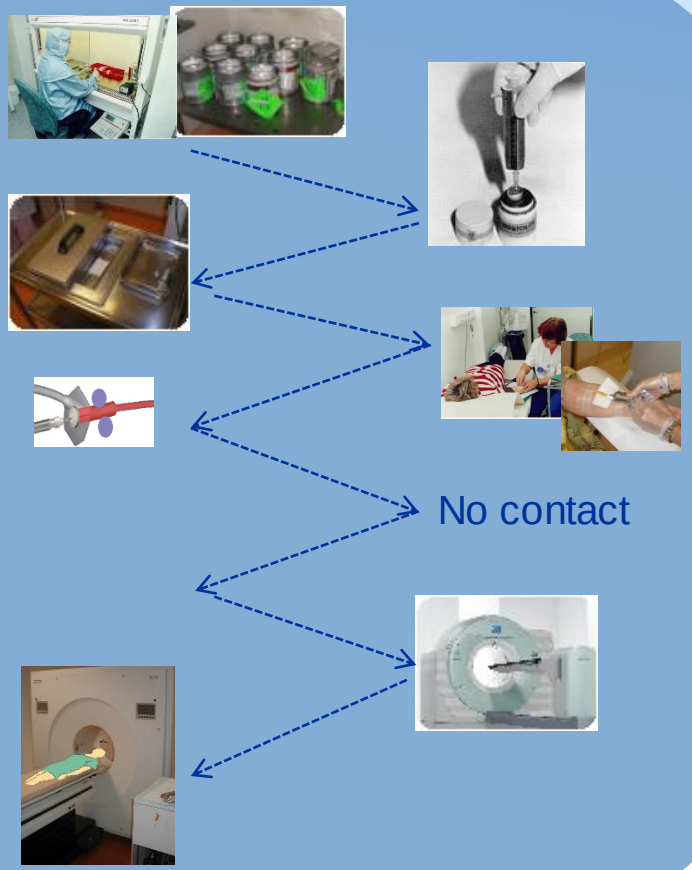
Total Duration 2h30 to 3h

1. Unpacking and manipulating the radioactive material
2. Preparing the syringe
3. Transporting the syringe to the injection “box”
4. Injecting F18
5. Removal of the syringe
6. The patient rests
7. Accompanying the patient to PET
8. Installing the patient in PET
9. Performing PET examination
10. Withdraw and release of the patient

What are the steps? : an analytical approach (2)

One can mention here that the analytical approach can be more or less detailed depending on the stakes for each step, if one step is more costly in terms of doses, then it can be subdivided into sub steps, while on the contrary if several steps are not “interesting” in terms of doses they can be merged.

Of course for the follow up, electronic dosimetry (coupled with video eventually at least during a study phase) will be an important facilitator of any analytical approach



Possible radiological protection options for each

Options	Dose rate and contamination reduction		EWL reduction	EWL and DR reduction
	Collective External exposure	PPE Internal exposure		
Storage and unpacking	Vial shield Room shield	Gloves		Totally automated shielded tool for preparation and injection
preparation	Vial shield Forceps Syringe shield Shielded hot cell with glove box	Gloves Use of absorbing blot Shielded hot cell with glove box	Training for good use of shielding and good manipulation gesture	
transport	Syringe shield Shielded carriage or Shielded wallet	Gloves		
injection	Syringe shield Shielded mobile screen	Gloves and mask	Use of catheter Training for good shielding use and good gesture	
withdrawal of syringe	Shielded screen	Gloves and mask Use of catheter	Training for adequate sequence	
Patient resting			Audio Video system	
Going to PET			*Arrows on the floor (old installations)* Audi video system	
Installation and PET exam	Distance	Gloves	Audio video system	

How to implement the Optimization procedure?

The optimization procedure will now be fully implemented in two sequences:

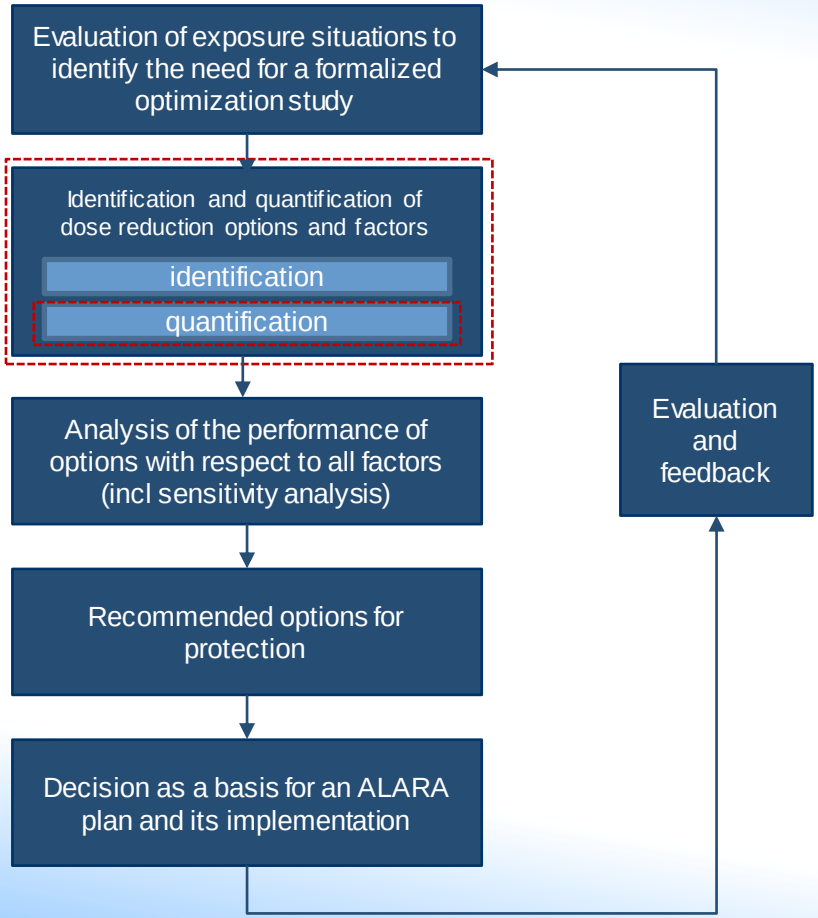
1. Firstly, for the classical radiological protection options (shielding, training…) corresponding to most situations all over the world. In that case the reference will be an “all manual operation” with no protection actions

2. Secondly as a possible further step, is it still (or when is it?) reasonable to go further to the fully remote preparation and injection? in that case the reference will be the “optimal classical situation”

For simplification reasons of the case study the waste management will be excluded from the case study as well as the initial storage.

This case shows that implementing an optimization *procedure is not strictly bounded. One has to be flexible and to adapt its implementation to the context of the study and to its potential evolution.*

First radiation protection optimization sequence



1. The *classical* actions are all feasible
2. They can be considered as all complementary (they can be implemented all together)
3. They do not have any impact on the patient dose (or it is aimed at)
4. Neither (or few) on the non radiological working conditions
5. Therefore the quantification phase will mainly focus on the efficiency and costs of each option or combination of options

Time of exposure with totally manual procedures

step	Time of exposure to the F18	Time of presence near the patient
preparation	3 minutes with only 1,5 at contact	
transport	0,5 minute at contact	
injection	1 minute at contact	
Patient resting		From 0 to 1 minute at contact or a little bit more far
withdrawal		< 1 minute at contact
Installation in PET and examination		From 1 to 5 at one meter (or even closer)

Reference doses per procedure without any protection

Step	Time of exposure to the F18	Time of presence near the patient	Extremity doses	Effective dose
preparation	3 minutes with only 1,5 at contact		20 x 1,5 = 30 mSv + *1,5 x 20/200 = 0,15*	0,005 x 30 > 0,15 mSv + ε
transport	0,5 minute at contact		0,5 minute at contact = 10 mSv	0,005 x10< 0,05 mSv + ε
injection	1 minute at contact		20 mSv	0,005 x 20 = 0,1 mSv + ε
Patient resting		From 0 to 1 at contact		From 0 to 4 µSv (220/60) 2 µSv in average
withdrawal		1 minute at contact		≤ 4 µSv
Installation in PET and examination		From 1 to 5 at one meter (or even closer)		From 0,3 µSv To 20 µSv
TOTAL			>60 mSv	≥ 0,3 mSv

Reference doses per procedure without any protection

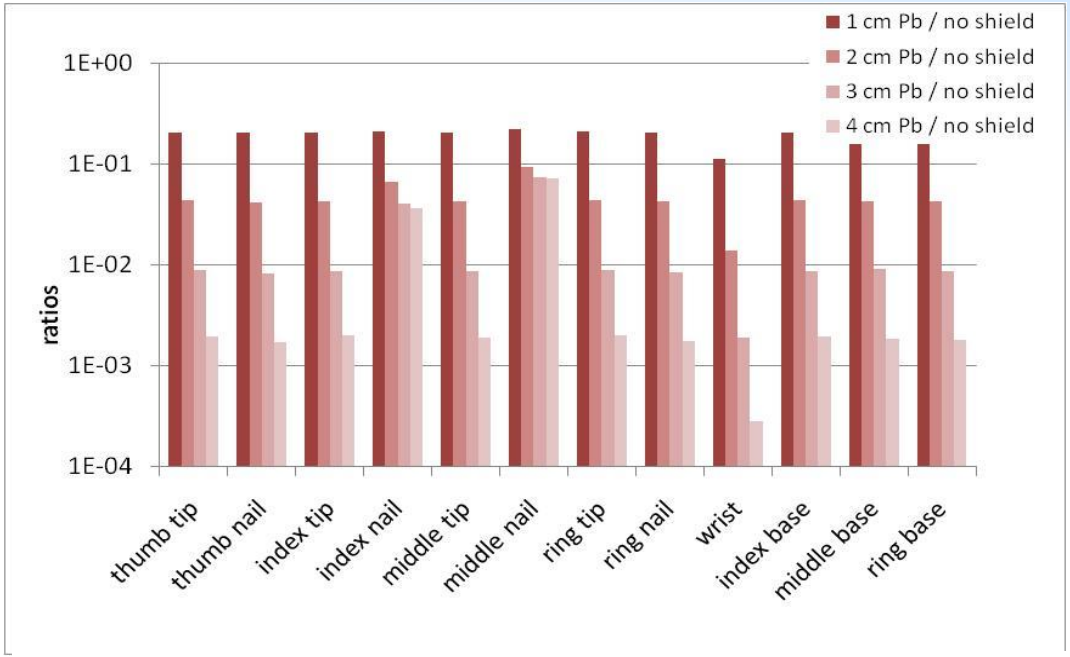
The previous calculated doses per procedure should led to reaching:

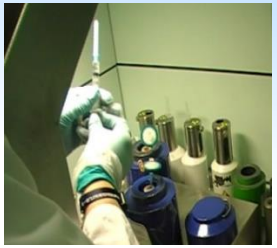
-The extremity dose limit in less than 9 procedures

-The effective dose limit in less than 67 procedures

The examination cannot be implemented without optimization of protection

Vial shield efficiency: Preparation scenarios (F18)





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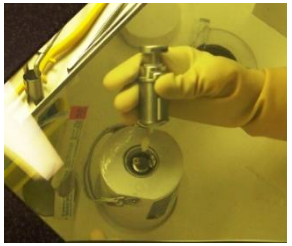
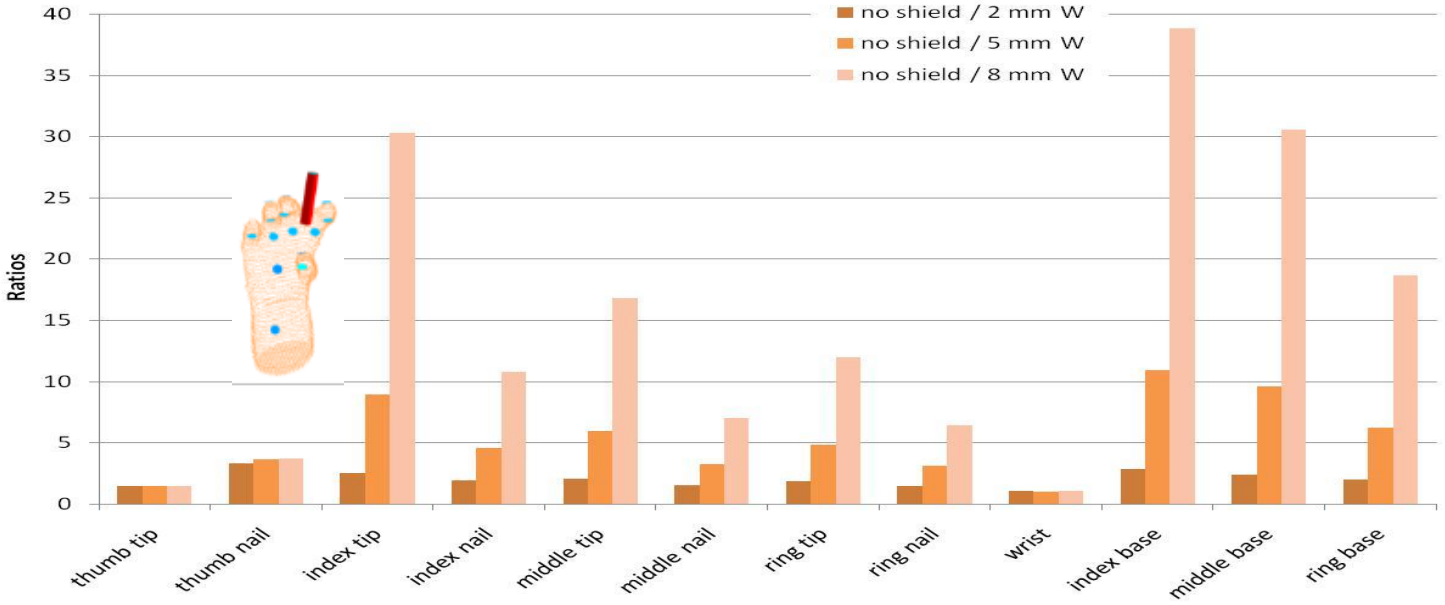


3 cm Pb provides 2 orders of magnitude in dose reduction

The vial shield is provided with the vial for the transport

For simplification reasons we will make the hypothesis that it costs nothing for the medical department as provided for transport

Syringe shield efficiency and cost: Injection scenarios (F18)



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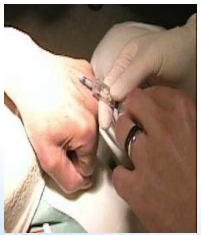

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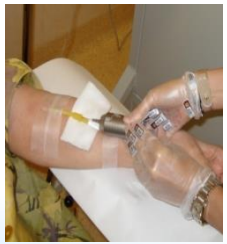

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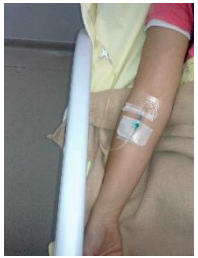


F-18: (best is 8 mm W)

5 mm W provide in average a protection factor of 10

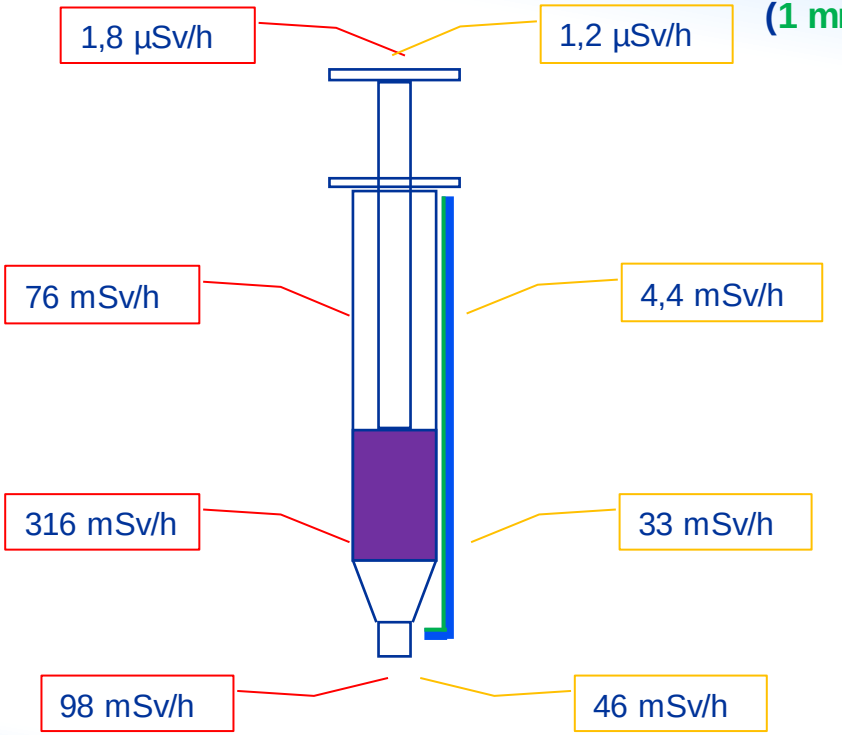
It costs around 3 k€

Syringe shield efficiency

No shield

Shielded

(1 mm PTFE* + 6 mm W)



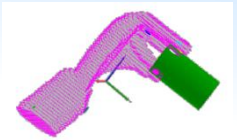
400 MBq F-18 2 ml

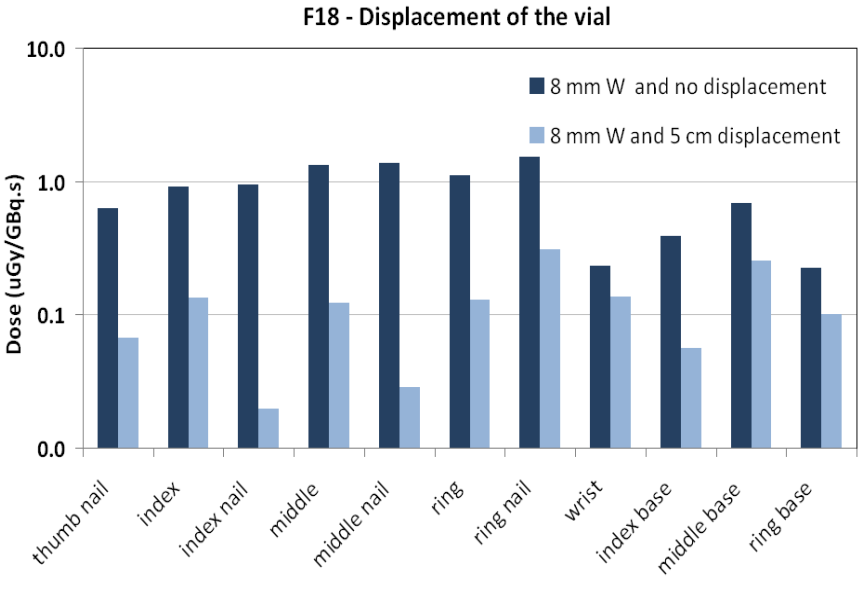
Measures from
Sebastien Balduyck

*PTFE = Polytetrafluoroethylene

Tools – forceps efficiency and cost F18

F-18 vial source shielded with 8 mm W at 5 cm distance.





The effectiveness of using **forceps** is also demonstrated when working with shielded sources.

The cost of such a forceps varies from 5 to 10 Euros

ORAMED: Eurados winter school
Picture SB; cost data french RPO network

Shielded hot cell with glove box for preparation

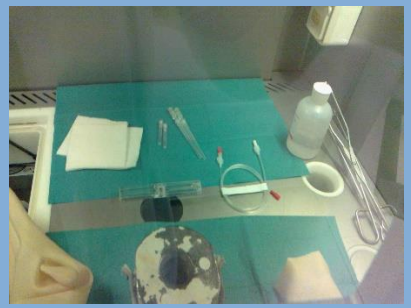


There exist different types of hot cells, however the use of such a hot cell is to allow a reduction of the effective dose by a factor 33 and to suppress totally the risk of contamination during the preparation phase

While the purchase cost of such a shielded hot cell is around 100 to 110 k€.

Picture SB data Toulouse university hospital

Use of absorbing blotter for preparation



The absorbing blotter can be used inside or outside the shielded cabinet if any.

It is not reuseable of course, and costs 0,2 euro

Picture SB data Toulouse university hospital

Shielded carriage or shielded wallet for transport to injection room

Or

+

The use a a shielded carriage or wallet will always come as a “plus” with regards to the shielded syringe; it will reduce to nearly nihil the exposure during the transport of the syringe from the preparation location to the injection room.

The cost of a shielded wallet is 1k€, but then there is a need of a normal carriage for supporting the wallet.

The cost of a shielded carriage (normal carriage including a shielded tank) is between 2 to 2.5 k€

Mobile shield and transparent screen for injection

The efficiency of such a shielded mobile screen is between 2 to 3 orders of magnitude for the worker's effective dose.

While its cost is comprised between 8 to 15 K€

Use of a catheter

The use of a catheter will reduce by 4 the time of injection. It will also allow to rinse the needle before to withdraw it after injection reducing to 0 the contamination risk at that time .

Its cost, including the extension cables, is around 1 euro per patient

Use of gloves and mask

The use of gloves and mask aims mainly at reducing the contamination, due to the high range of energy of F18, the weight of the gloves should be too important for reducing efficiently the external dose.

Therefore it is only needed to make use of latex or nitrile gloves (for a single use)

Their efficiency is nearly 100% against external contamination
Their cost is 0,05 to 0,2 Euros per pair

As for the mask its efficiency depends mainly from the way it is worn. When well worn the efficiency is also nearly 100% for inhalation
Their cost is around 0,3 Euros per unit

Complementary training

With a one or two days specific complementary training including practical exercises one can expect:

to totally avoiding the contamination risk and
to reducing by 10 to 30% the EWT and
to making good use of the adapted tools

(but that should not be taken into account several times as different options)

Training is complementary to the different protection tools and without it, may be these tools should not be well used

Such a training should cost between 500 and 700 Euros per individual

Audio video - system with the “patient boxes and PET room”

This allows to give the right advices to the patient both during his rest and the PET examination

It is technically mandatory during the PET examination, and useful during the “rest time”. As a side effect it allows suppressing all not useful exposure due to the proximity to the patient during these phases

We can envisage the installation of a video audio system between the control room and three patient boxes plus the PET room, for around 2 to 3 k€; this cannot be considered as a cost for radiological protection purpose only: either we consider it is a “no cost” for radiological protection as it is mandatory for technical reason, or we distribute the cost over these two reasons. For simplification here we will consider consider it as a no cost option.

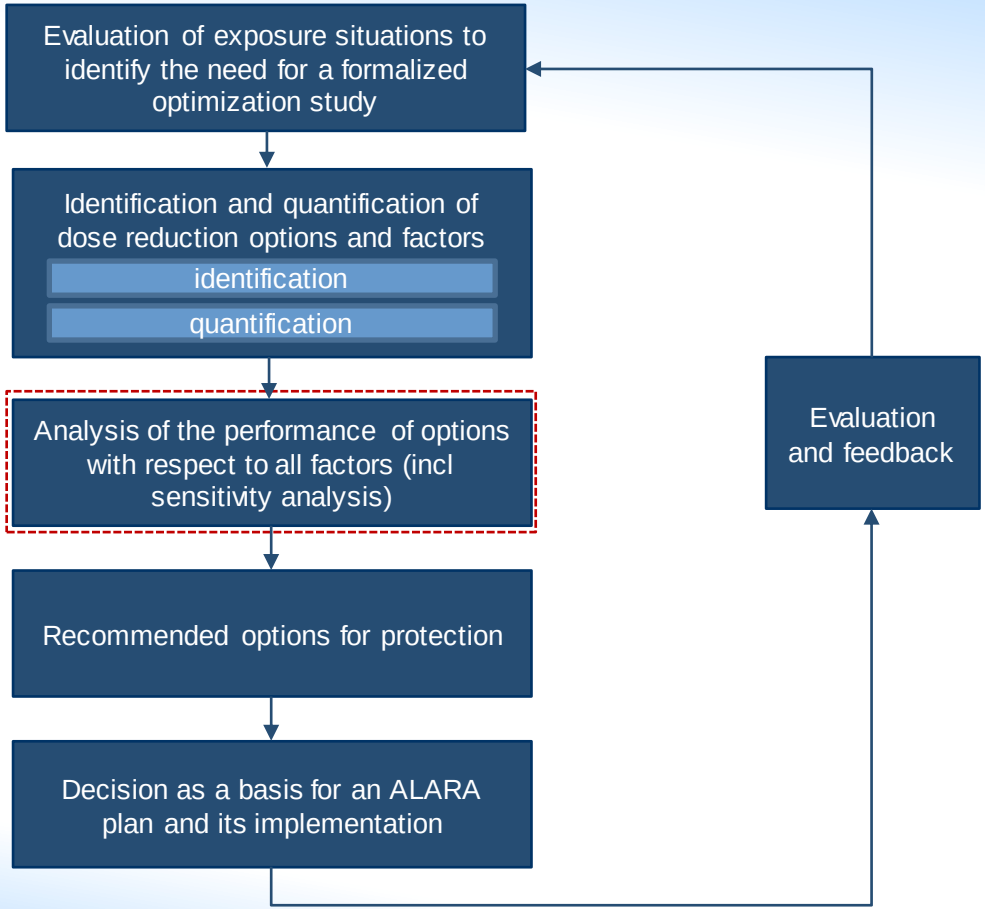
Arrows painted on the floor between patient boxes and PET room in old facilities

Can we envisage the painting of arrows on the floor from the room of rest to the PET CT room?

For all “valid” patients it will allow suppressing the effective dose due to accompanying them during 1 to 2 mm on that way

If the distance to the patient is 1 meter the avoided dose is comprise between 0,25 and 0,5 μSv per patient (15 μSv per hour during 1 to 2 mm). Which, under the hypothesis of 10 patients per day and 200 working days leads to a range of : 0,5 to 1 man.mSv avoided annually

The cost of the installation may be estimated to 50 € for the painting and 500 € for the audio system purchase and installation.
It has to be renewed every five years


Evaluation of exposure situations to identify the need for a formalized optimization study
Identification and quantification of dose reduction options and factors
identification
quantification
Analysis of the performance of options with respect to all factors (incl sensitivity analysis)
Recommended options for protection
Decision as a basis for an ALARA plan and its implementation
Evaluation and feedback

Analysis

We will first take care of all actions reducing doses at no cost or even reducing cost

In a second time we analyse the costly options and combination of options and check which are reasonable?

Synthesis of criteria for all Options with NO Cost

Action	Worker Dose reduction	Impact on patient dose	Complemen-tarities
1 Installing video and audio	Suppressing not useful doses	NO	C to all
2 Optimising F18 quantity	Modifying all doses in a same proportion	Modifying all doses in a same proportion	C to all
3 Keeping vial shielded during preparation	> Up to 5 times	NO	C to all
4 Having the right behaviour - When mandatory to stay besides the patient after injection, be at 1m min -When hanging the full syringe, not take it close to the needle - when withdrawing the syringe if a catheter is used, first rinse and then take it off.	Reduce effective dose Reduce extremity dose Reduce extremity dose and contamination risk		C to all

Options with NO Cost

All actions reducing doses with no cost are complementary

One of them reduce both doses to the patient and to all the workers

No other criterion has to be taken into account

Therefore the "reference" for optimisation should include them as a mandatory basis in all decision making process as well as in all trainings

We will now analyse the options with costs

Dose reduction factors synthesis Table (options with costs)

	Dose to the hands	Effective dose	Contamination Risk	C or S
1 gloves	No effect	No effect	Total for external	C all
2 mask	No effect	No effect	Total for inhalation	C all but 5
3 forceps	> 10	> 10	small	C all
4 syringe shield	> 10	>10	Not the purpose	C all
5 shielded hot cell with glove box	No effect	>33	No more during preparation	C all
6 use of blutter	No effect?	No effect?	reduce in post preparation	C all
7 shielded wallet or carriage	2 to 3 orders of magnitude	2 to 3 orders of magnitude	Not the purpose	C all
8 use of catheter	4	4	No more risk during syringe withdrawal	C all
9 mobile shielding	No effect	2 to 3 orders of magnitude	Not the purpose	C all
10 adapted extra training	Good implementation of all other options	Good implementation of all other options	Good implementation of all other options	C all

It is interesting to note that nearly all options are complementary

Purchase Costs

	Purchase cost	Number of uses or duration
1 Pair of gloves	0,1€	One time
2 mask	0,3€	One time
3 forceps	10 €	4 years
4 syringe shield	3000 €	10 years
5 shielded hot cell	100000 €	10 Years
6 blutter	0,2 €	One per day
7 shielded wallet or carriage	2500 €	10 Years
8 catheter	1 €	One per patient
9 mobile shielding	10000 €	10 Years
10 adapted extra training	500 €	Every five years per individual

Of course you should have to check the practices against your own country's data.

Hypothesis from survey among RPOs in France

Annual costs calculation in € (waste excluded)

Assumption: 2000 procedures per year; 3 workers
yearly operation cost = procedure cost x 2000
amortisation= investment/ duration

Type of Action	Operating cost per procedure	Investment cost	yearly operating Costs	Amortisation per year	total cost per year
1 Pair of gloves	0,1		200	0	200
2 mask	0,3		600	0	600
3 forceps		10		2,5	2,5
4 syringe shield		3000		300	300
5 shielded hot cell		100000		10000	10000
6 blutter			44		44
7 shielded wallet or carriage		2500		250	250
8 catheter	1		2000		2000
9 mobile shielding		10000		1000	1000
10 adapted extra training		1500		300	300

Annual costs ranking by increasing cost of combination of options per “independent phase”

We can consider 4 phases as quite independent in terms of protection actions:

The preparation

The transport

The injection and

The PET exam (no option with a cost is related to that 4th phase)

We will rank the options and combinations per increasing costs for each phase and perform optimisation for each phase.

One option is common to the three first phases: the syringe shield. We will split its cost into 3 equal parts (300 /3= 100 € per year)

Annual costs ranking by increasing cost of combination of options preparation phase

	Type of Action	total cost per year (€)
0	**no action**	0
3	**for**ceps	2,5
6	blutter	44
4	**syr**inge **sh**ield	120
3+ 4	**For + Syr Sh**	122,5
1	Pair of gloves	200
2	mask	600
5	shielded Hot Cell	10000
3+4+ 5	**For + Syr Sh + HC**	10122,5

We will in a first step not take care of blutter, mask and gloves which have nearly no impact on external doses

All remaining actions are complementary

Cost per effective dose saved in preparation phase

Type of Action	Total cost per year €	Dose red factor	Annual collective dose Man mSv	Delta cost (a)	Delta dose (b)	Ratio a/b € per man mSv	Reasonable ?
no action	0		300				
forceps	2,5	15	20	2,5	-280	0,01	YES
~~***syr**inge **sh**ield*~~	~~*100*~~	~~*15*~~	~~*20*~~	~~*97,5*~~	~~*0*~~	No interest alone	
For + Syr Sh	102,5	15 x 15	1,3	100	-18,7	5,3	YES
~~shielded Hot Cell~~	~~10000~~	~~33~~	~~9~~	~~9897~~	+	No interest alone	
For + Syr Sh + HC	10102,5	15 x 15 x 33	0,04	10000	- 1,26	7936	**NO** if just for effective dose reason

The use of forceps and syringe is more than reasonable

The use of hot cell cannot be justified just for effective dose reduction reason

Annual costs ranking by increasing cost of combination of options transport phase

	Type of Action	total cost per year (€)
0	**No action**	0
4	**syr**inge **sh**ield	100
7	shielded **Wa**llet or carriage	250
4 + 7	**Sy Sh +Wa**	350

All actions are complementary

Cost per effective dose saved in transport phase (1) (exercise)

Type of Action	total cost per year €	Dose red factor	Annual collective dose Man mSv	Delta cost 1	Delta dose 2	Ratio ½ € per man mSv	Reasonable ?
No action	0		100				
syringe **sh**ield	100	15	?	?	?	?	?
shielded **Wa**llet or carriage	250	500	?	?	?	?	?
Sy Sh +Wa	350	15 x 500	?	?	?	?	?

Please determine the ratios in these three cases . Is the combination wallet and syringe shielding reasonable?

Cost per effective dose saved in transport phase (2)

Type of Action	Total cost per year €	Dose red factor	Annual collective dose Man mSv	Delta cost 1	Delta dose 2	Ratio 1/2 € per man mSv	Reasonable ?
No action	0		100				
syringe **sh**ield	100	15	6,7	100	93,7	1	YES
shielded **Wa**llet or carriage	250	500	0,2	150	6,5	23	YES
Sy Sh +Wa	350	15 x 500	0,01	100	0,19	526	depending

In reality the syringe has been already shielded therefore we go directly from the syringe shielded as a reference to the combination which gives: delta cost 250 / delta dose - 6,69 = 37 euro per avoided man mSv : this is very reasonable

Annual costs ranking by increasing cost of combination of options injection phase

	Type of Action	total cost per year (€)
0	**no action**	0
4	**syr**inge **sh**ield	100
9	**Mo**bile shielding	1000
8	**Cat**heter	2000
4+9+8	**Syr Sh+ Mo+ Cat**	3100

All actions are complementary

Cost per effective dose saved in injection phase (1) (exercise)

Type of Action	Total cost per year €	Dose red factor	Annual collective dose Man mSv	Delta cost 1	Delta dose 2	Ratio 1/2 € per man mSv	Reasonable ?
no action	0		200				
syringe **sh**ield	100	15	?	?	?	?	?
Mobile shielding	1000	100	?	?	?	?	?
Catheter	2000	4	?	?	?	?	?
Syr Sh+ Mo+ Cat	3100	15 x 100 x4	?	?	?	?	?

Please determine the ratios in these four cases. Which one are reasonable?

Cost per effective dose saved in injection phase (2)

Type of Action	total cost per year €	Dose red factor	Annual collective dose Man mSv	Delta cost 1	Delta dose 2	Ratio ½ € per man mSv	Reasonable ?
no action	0		400				
syringe **sh**ield	100	15	26,6	100	-373,4	0,26	YES
Mobile shielding	1000	100	4	900	-22,6	39,8	YES
~~***Cat**heter*~~	~~*2000*~~	~~*4*~~	~~*100*~~				~~*NO*~~
Syr Sh+ Mo+ Cat	3100	15 x 100 x4	1	2100	3	700	Quite expensive

Again the syringe and the mobile shielding are very reasonable; however
The use of the catheter just for reducing effective dose may be discussed

What is the impact of the extremities dose reduction?

We will not check again the efficiency of each action in terms of the reduction of the dose to the extremities; those actions which are already considered as reasonable will now be considered as part of the reference (all but the hot cell and the catheter).

The hot cell will have no impact on reducing the dose to extremities, this will not be therefore a reason for keeping that option.

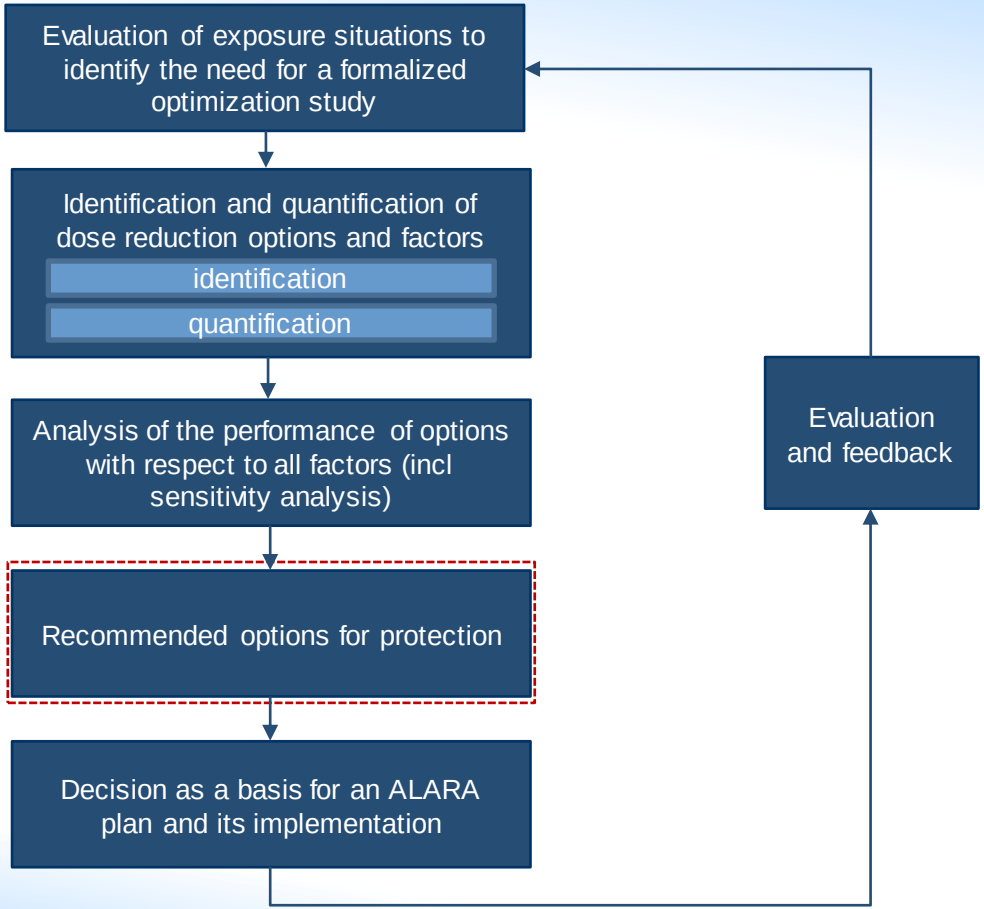
In the case of use of catheter the reduction by a factor 4 of the time of exposure during the injection will reduce as well the exposure to extremities. Is it then enough for justifying the use of catheter?

The criterion is not any more to be reasonable but to allow not exceeding the dose limit to extremities.

What is the impact of the extremities dose reduction?

Phase	Type of Action	Annual collective dose Per phase Man mSv	Cumulated Annual coll. Dose	Annual individual dose if 3 workers
preparation	**no action**	60000		
	optimum	266	P =266	
transport	No action	20000		
	optimum	2,6	P + T =268,6	
injection	**no action**	40000		
	Ref = syringe shield *(+ Mob Shielding)*	2666	P + T+ I = 2935	978
			The situation is not acceptable as the dose limit (500 mSv) is exceeded	
	Ref + catheter	2666/4 = 666,7	935,3	311

The use of the Catheter which was may be not reasonable for reducing effective dose appears necessary for keeping the 3 workers under the extremity dose limit (*we have not taken into account here the possibility it gives to rinsing the syringe before withdrawal*)


Evaluation of exposure situations to identify the need for a formalized optimization study
Identification and quantification of dose reduction options and factors
identification
quantification
Analysis of the performance of options with respect to all factors (incl sensitivity analysis)
Recommended options for protection
Decision as a basis for an ALARA plan and its implementation
Evaluation and feedback

Recommended classical options at the end of the first optimisation sequence (1)

Most “classical” radiation protection options must be implemented as reasonable from the effective dose reduction point of view; the catheter appears to be necessary for coping with the extremity dose limit, but even with that the extremity doses remain quite high and close to the limit.

The gloves, mask and blutter, while the contamination risk leads to quite low doses, should be considered as good practices with regards to their quite low costs; the most costly being the use of masks 600€ per year).

External effective dose reduction is not enough for justifying any kind of hot cell. Then what is important is the reduction it allows for contamination risks and one has to wonder about that risk and the rationale for such an investment both in terms of external irradiation and contamination reduction.

From our point of view it is not ALARA to deciding to invest for such an hot cell.

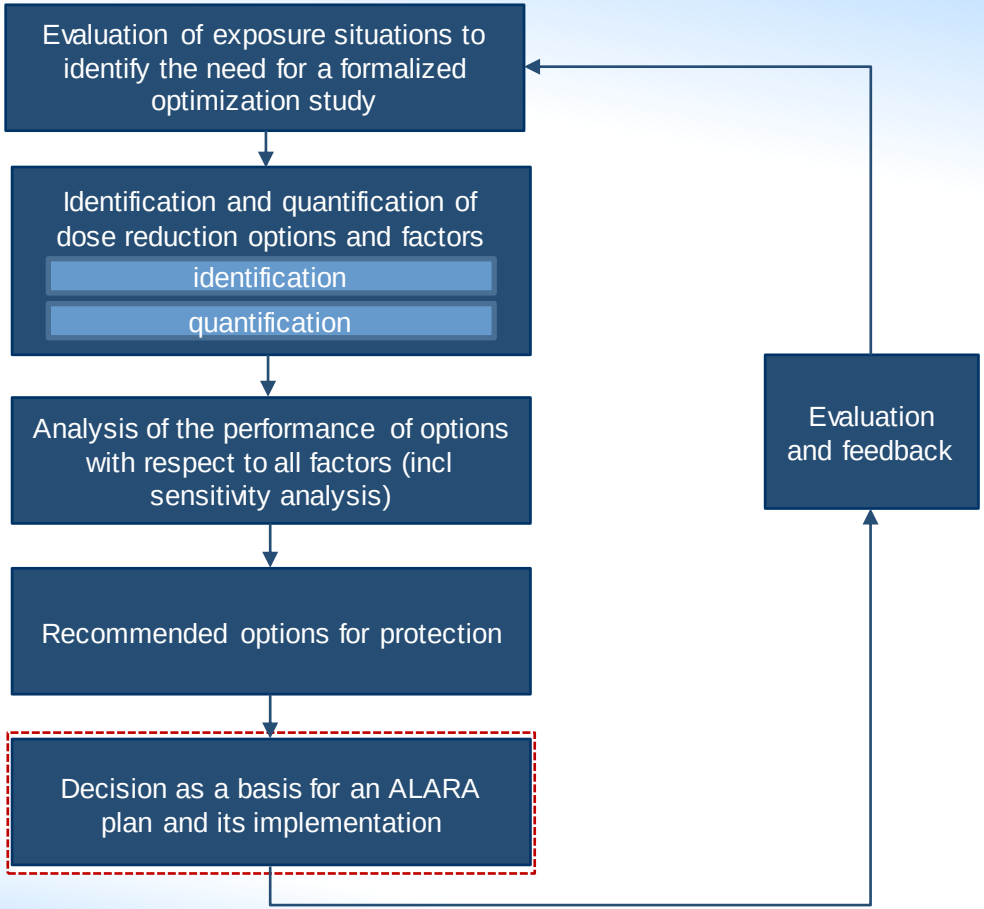
Recommended classical options at the end of the first optimisation sequence (2)

Whatever the solution the most important remaining part of the effective dose will be due to the exposure to the patient as a source during his rest and installation.

This should lead to 3 to 5 mSv worker with 2000 procedures per year and 3 workers, while the effective dose due to the preparation phase without the hot cell will not exceed 2 mSv per worker.

Therefore the option “more training” allowing to reduce the exposure during the steps (resting, withdrawal and installation) by 33 to 50% (by reducing the time and optimising the position) can be considered as absolutely reasonable: up to 6 man mSv for 1800 € per year i.e. less than 300 € per man mSv

As well if not done for other reasons the installation of audio video system appear mandatory both in the rest rooms and PET room.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Comparison of the optimized situation with European practices in ORAMED and other studies

ORAMED

The vial shielding is always used during the preparation phase.

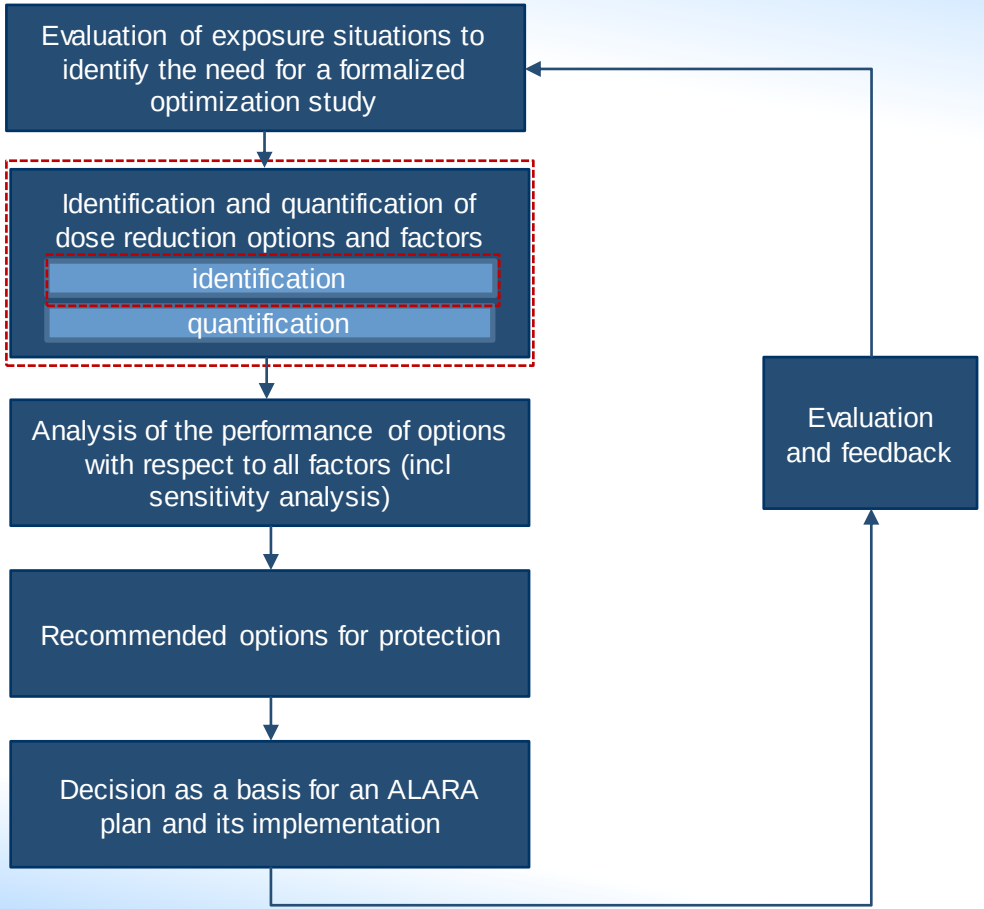
However this not the case of the syringe shielding: more than 40% of the workers do not use it during the preparation phase.

Most studies

The observed annual effective doses range still at several mSv per year while the estimated extremity doses remain often close to the limit

On the one hand the behaviour of the workers shall still be improved through training, while a new optimisation sequence shall be envisaged

Second optimization sequence: are they new options?



Yes in particular several totally automated manipulators for the preparation, transport and injection phases

They will reduce the residual effective dose during these phases as well as the extremity doses while suppressing the contamination risk

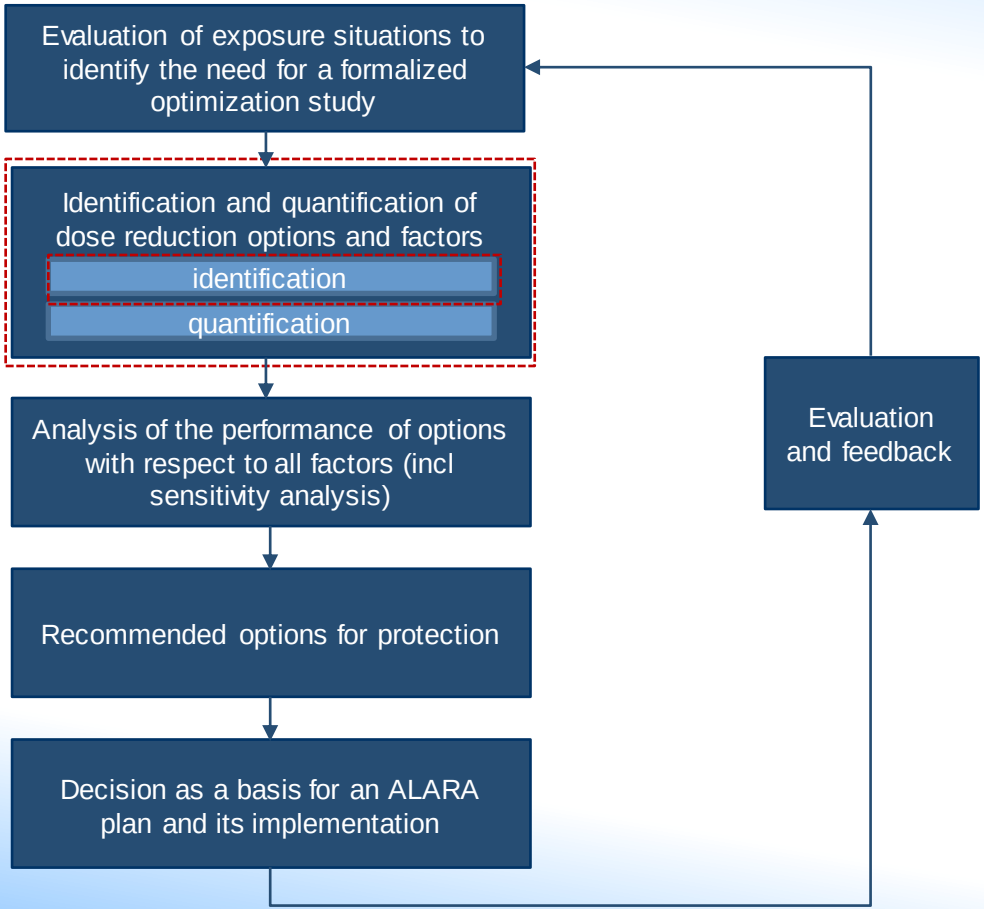
One automate preparation and injection system

- Système UniDose® de TRASIS
  shielding : 50 mm lead

- Carpule

- Injection device(the so called « mug »)
  Shielding : 24 mm W

Second radiation protection optimization sequence



The reference situation being the optimized one of the first sequence (all classical options but the hot cell), what will be the extra efficiency of the automate, as well as its extra costs?

Quantification of factors: efficiency

A study performed by IRSN demonstrate that the automat allow to reduce by a factor 10 and 2.5 the extremity dose respectively during the preparation and injection phase

While the efficient dose is not modified with regard to the one undertaken with the use of an hot cell for the preparation

Do not forget a potential breakdown? (1)

One big problem with any automatism is the possibility of failures which leads to go back to the manual procedures with some extra manipulations up to the repair of the automatism. There will then be no doses reduction during that period in comparison with the classical optimum.

This will also lead to some extra doses as the automatism allows to buy vials with 5 doses (multi dose vial) instead of a mono dose vial.
We have to be sure that the extra dose to cope with breakdown of the automatism will not overweight the savings in normal operation

Dose rates at the vial contact are 5, 4, 3, 2 times higher for the 4 first syringes preparation as far as the contribution of the vial is concerned. But the vial shield should reduce to nearly nihil that contribution to the worker doses (to be confirmed)

Do not forget a potential breakdown? (2)

The contribution of the syringe, if shielded, will be exactly the same as in the classical sequence

If we consider that the extra dose is marginal with regards to the classical optimum. Then the Automatism extra doses in case of breakdown will never overweight the savings in normal operation

What remains important is not to forget to keep all what is needed for manual preparation and injection (normal syringe and shielding; forceps; gloves; masks) as well as the knowledge and experience on how to perform it manually.

Quantification of factors: costs

As far as the cost is concerned, the investment is around 130 k€

While the operating costs are:

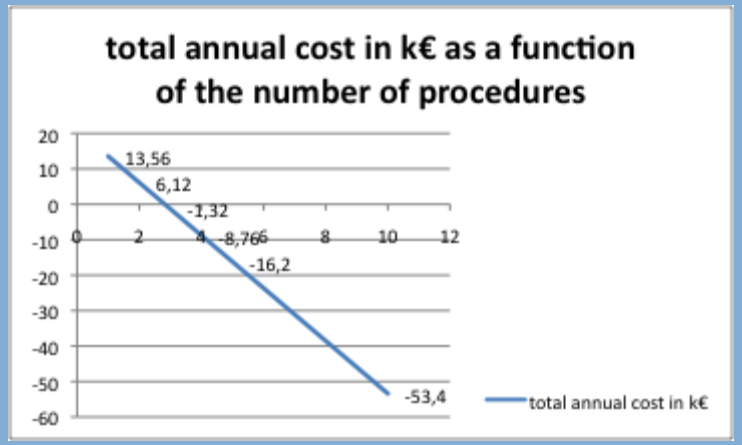
	Unit cost (€)
Daily preparation package	40
Carpule (one per procedure)	1.3
Syringe (one per procedure)	0.6
Valve anti backward flow + security connection (one per procedure)	0.9

There are also operating costs savings as due the automation of the preparation it is possible to buy one multi dose vial instead of 5 mono dose vials: the cost saving is around 40 Euro per procedure

Data from Thomas Geoffray
master in radioprotection 2011

Quantification of factors: total annual cost

The total annual cost will therefore be totally dependant of the number of procedures performed

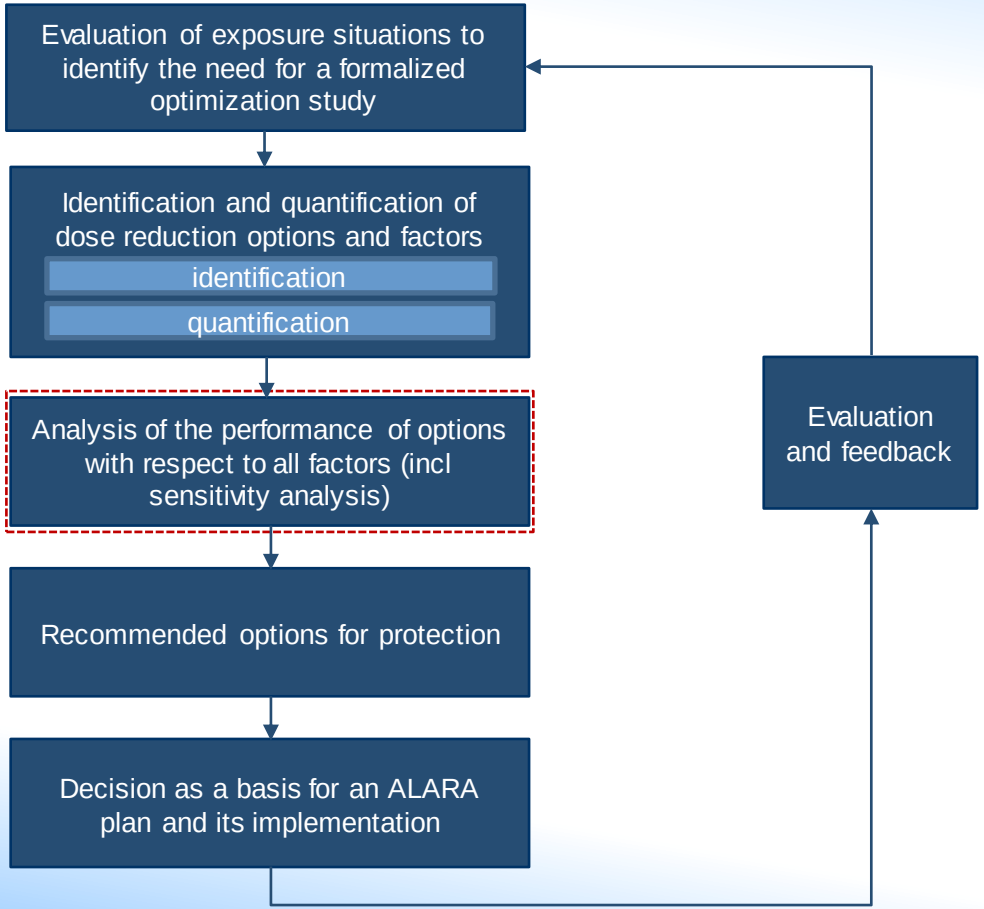


10 procedures per day during 200 days means 2000 procedures per year this leads to a negative cost of -53 k€

One can see that the total cost is nearly always negative when there is more than 500 procedure per year, it is positive but very low for less procedures

Data from Thomas Geoffray
master in radioprotection 2011

Second radiation protection optimization sequence



With the previous assumptions the analysis will be quite simple

Analysis of the performance (1)

We will make the analysis under the hypothesis of 2000 procedures per year

As for the efficiency we will focus on only two phases: preparation and injection as the option will have no differential impact neither on the doses of the transport (which were already quite nil) or of the installation.

Analysis of the performance (2)

		Effective dose		Extremity dose		Cost	
		Man mSv		mSv		K€	
Preparation	classical	1,3		266		0,1	
	automat		ε		27		
Injection	classical	1		667		3	- 53
	automat		< 1		266		
Total 2 phases		2,3	< 1	935	266		

The automat while not reducing a lot the effective dose allows a big reduction of the extremity doses: with 3 workers the maximum annual individual extremity dose will be lower than 100 mSv instead of more than 300 mSv

There is no more risk of exceeding the limit, and during these 2 phases the contamination risk is nearly avoided.

All this can be reached at no cost or even a large cost decrease

It is a win-win situation.

Analysis of the performance (3)
Is a sensitivity analysis useful here?

The maximum number of procedures per day found in the literature is around 20 (such a figure is reported in different articles for example in Japan). Which means 4400 procedures per year for 220 days (instead of 200 days taken previously).

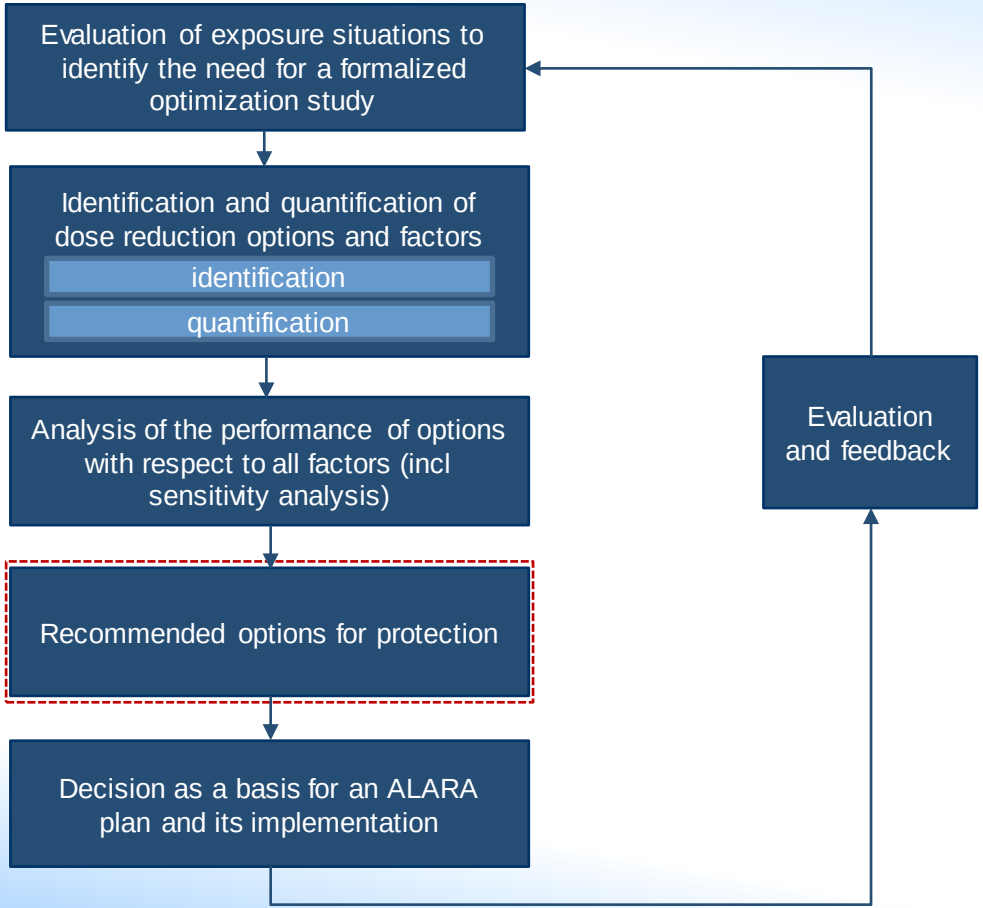
In such a case the effective dose remains lower than 2 man mSv for the above mentioned preparation + injection phases.

The extremity collective dose reach 585 mSv which leads to individual extremity dose of 293mSv if 2 workers; 195 mSv if 3 workers and 146 mSv if 4 workers. In all cases it cope with the extremity dose limit.

While the cost savings are nearly 143 k€

Modifying the number of procedures, of days of number of workers will not change any result

Second radiation protection optimization sequence (1)



So what is your recommendation?

Second radiation protection optimization sequence (2)

We have not spoken in a multi criteria point of view of the improvement in terms of ergonomics (reduction of the weight to be hanged by the worker in particular during the transport).

The first sequence optimization led to selecting all classical options but the hot cell.

The second sequence led to replace part of these by an automat which, as already said, should always be optimal in terms of risks management both radiological protection risks (extremities and whole body irradiation and contamination) as well as ergonomic risks.