

Radiation Protection of the Fetus during Diagnostic Radiology in an Adult Hospital



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Radiation Protection of Pregnant Women

- **Radio-biological**
 - Scientific basis for risk
- **Legal Framework**
 - European/national
- **Communication**
 - Communication of risk
 - Knowledge base of clinical staff
 - Education of patients
 - Informed consent
- **Personal/Individual**
 - Perception and acceptance of risk



Context

For diagnostic radiology

- Radiation Dose to the embryo or fetus should present no risk of causing fetal death, malformation, growth retardation or impairment of mental development (HPA UK, 2009)
- Majority of diagnostic medical procedures, [giving fetal doses up to 1mGy], additional risk of childhood cancer is less than 1 in 10,000 (HPA UK, 2009)
- Patients **and** their unborn children are protected by legislation
- Many guidance documents available
- No dose limits



Requirements of 2013/59/EURATOM



Article 62

1. **Referrer or practitioner**, as appropriate, **must inquire**, whether the individual subject to medical exposure **is pregnant** or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure.

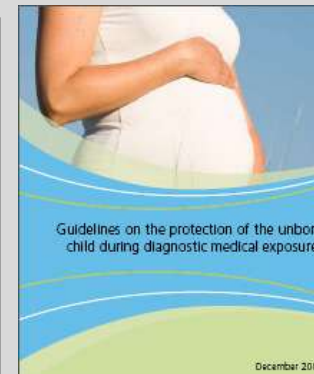
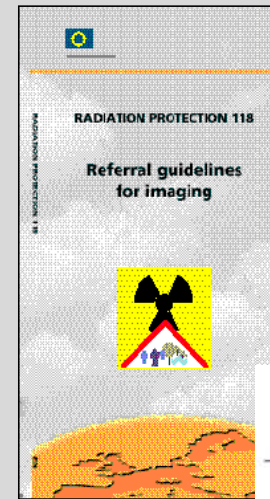


2. **If pregnancy cannot be ruled out** and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, **special attention** shall be given to the **justification**, particularly the **urgency**, and to the **optimisation**, taking into account both the expectant individual and the unborn child.



Guidance Documents

- RP 100 developed to support 97/43/Euratom
- Variations in approach between different documents
- No consensus on how to deal with various issues
- Differences in how and when 10 and 28 day rules applied
- Need for robust, clear, agreed local protocols that are in line with current legislation



Health Protection Agency

Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation

Advice from the Health Protection Agency, The Royal College of Radiologists and the College of Radiographers

ATION PROTECTION 100

Home - **Guidelines** - **Pregnancy and protection of the fetus**

Pregnancy and protection of the fetus

irradiation of a fetus should be avoided wherever possible. 30 The primary responsibility for identifying such patients lies with the referring clinician, but radiology staff must also check the pregnancy status of patients when they attend for examinations and must be aware that some tests may have elapsed since the clinician completed the request card.

Women of reproductive age presenting for an examination in which the primary beam irradiates the pelvic area (scarcely any ionising radiation between the diaphragm and the knees, directly or by scatter, as for a procedure involving radioactive tracers, should be asked whether they are or may be pregnant. If a patient cannot exclude the possibility of pregnancy, she should be asked if her period is overdue. 31

If the patient can exclude the possibility of pregnancy, the examination can proceed. The examination can also go ahead where pregnancy cannot be excluded, but the period is not overdue and the examination carries a relatively low dose to the fetus. However, where pregnancy cannot be excluded, the period is not overdue and the procedure involves a high dose, the procedure outlined below should be followed. High dose, in this context is defined by the Health Protection Agency (HPA) as any examination falling in the highest dose group (category 1) with a TDI value of more than about 10 mSv. In practice, the only investigations in this category will be pelvic or abdominal CT, complex fluoroscopy and a few nuclear medicine procedures.

If the patient is certainly pregnant, or if pregnancy cannot be excluded and the period is overdue, or the patient is not obviously pregnant, the justification for the proposed examination should be reviewed by the radiologist and the referring clinician, with a decision taken on whether to defer the investigation until after delivery, or until the next menstrual period has occurred. However, a procedure of diagnostic benefit to the mother may also be ordered (benefit to her unborn child, and a delay in an essential procedure may increase the risk to the fetus as well as to the mother. This consideration is especially relevant in the emergency situation. In all cases, if the radiologist and referring clinician agree that irradiation of the pregnant or possibly pregnant patient is clinically justified or is not clinically justified, this decision should be recorded and the patient must be kept fully informed. If it is decided that the irradiation is justified, the radiologist must ensure that exposure is limited to the minimum required to acquire the necessary information.

It is sometimes obvious that a fetus has been inadvertently exposed, despite the above measures, the main risk to the fetus, even at higher doses, is unlikely to justify the greater risk of invasive fetal diagnostic procedures (the example, anaesthetics) or those of termination of the pregnancy. If, in such instances, exposure has occurred, a medical physicist should make an individual risk assessment and the results should be discussed with the patient.

← Previous
Pregnancy

Next →
Imaging techniques

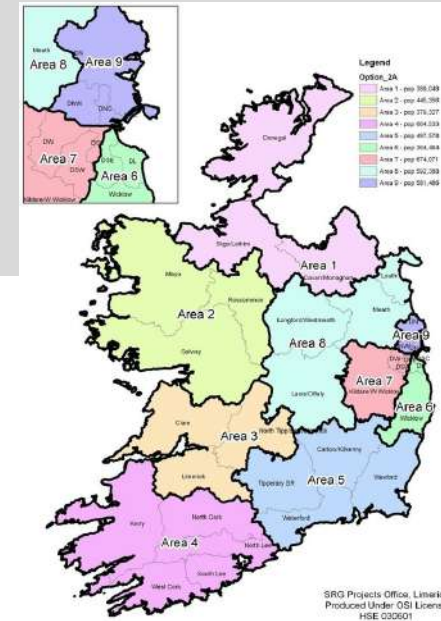
Issues

- What exams?
- What age groups?
- When do we ask?
- Who asks?
- How do we capture response?
- How do we deal with patients where status is unknown?
- How do we deal with patients on contraceptives?
- How do we deal with urgent exams?
- Do pregnancy tests have a role in this?
- How do we carry out the exam safely?



National Policy

- BSS does not prescribe exactly how this is done.
- National legislation should provide the framework
- Standardised approach across healthcare institutions can be helpful
- Irish policy developed with input from radiologists, radiographers, physicists, regulators, GPs , lawyers,....



[ENTER HOSPITAL LOGOS IF REQUIRED]

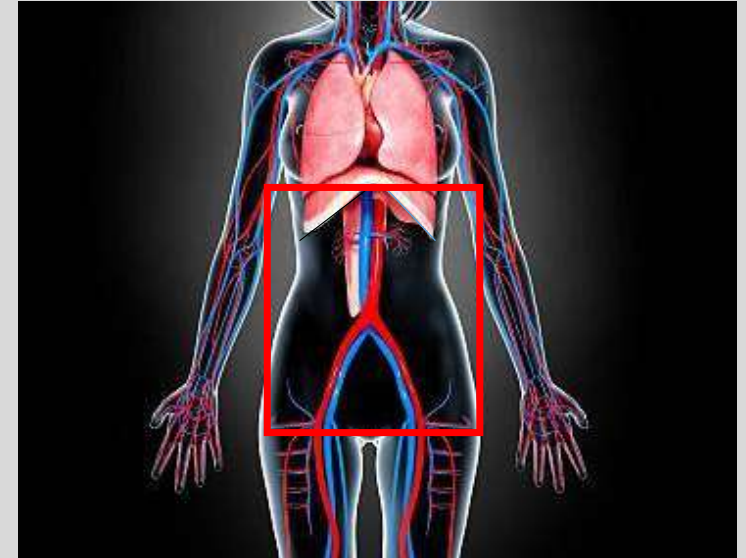
[Hospital name]	Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures.		
Document Number:	[No.]	Version No:	[Ver.]
Active Date:	[Date]	Review Date:	[Date 1 year from active date]
Document Author (s):	[Name of RSO/RPO and RPA]	Document Owner:	[Name of Practitioner in Charge]
Approved By:	[Name of Committee that Approved (i.e. Radiation Safety Committee)]	Date Approved:	[Date]
Related Documents:	[e.g. Radiation Safety Procedures/Local Rules, Local Hospital Consent Policy, Patient Identification Policy, Incident Reporting Policy]		
Key Stakeholders:	Name:	Title:	
		[Practitioner in Charge]	
		[RSM]	
		[RSO/RPO]	
		[RPA]	
	[MPE]		
Method of Communication:	[Enter method e.g. email]		
Method of Distribution:	[Enter method (e.g. intranet / Q Pulse etc.)]		
Responsibility for Implementation:	Stakeholders	Responsibility for evaluation and audit:	RPA, RSO/RPOs

Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures, Ireland 2017.

What exams & age groups

Relevant exams :-

- Any radiography, fluoroscopy or computed tomography examination involving irradiation between the diaphragm and symphysis pubis
- Any radionuclide imaging procedures
- 12 to 55 years



Exam Numbers Within Scope of Policy

- 900 Bed Hospital
- >120,000 X-ray and radionuclide imaging exams per year

Modality	Total number of Exams	Percentage within Scope of Policy
CT	24,986	11%
Radiography	89,117	<2%
Fluoroscopy	2,509	20%
Nuclear Medicine	2,023	31%
PET CT	3,229	10%
Interventional	2,327	22%



- Female patients 12-55 years
- X-ray exams irradiation between the diaphragm and symphysis pubis
- Any radionuclide imaging procedures

CT & General Exam Numbers Within Scope of Policy

Age Band	No of CT Exams	No of Radiographic X-ray Exams
16-20	50	66
21-30	223	192
31-40	418	314
41-50	1665	539
51-55	410	376
Total	2766	1487



- 3 CT scanners, 5 general rooms
- 25,000 CT scans per annum
- 90,000 general x ray exams

What needs to be done?

For relevant exams referrer and/or practitioner must

- enquire about the pregnancy status of the patient & LMP.
- ensure that the examination is justified
- provide the practitioner with all relevant information as part of the examination request.

For high dose examinations, involving greater than 10 mGy to the fetus

- 10 day rule should be applied.
- timing scaled according to cycle length.



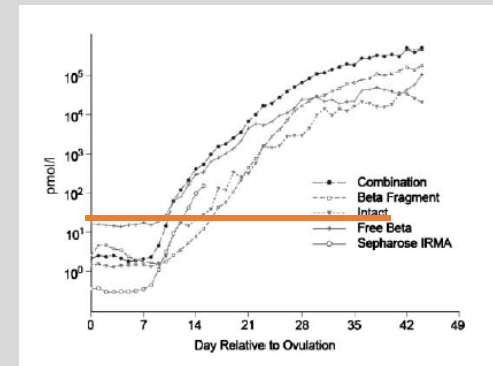
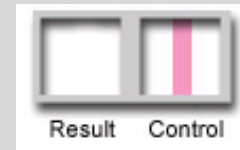
Issues with Establishing Pregnancy Status

- Long waiting times between referral and some exams
- Patient may not be certain of status
- Communication problems:
 - Language,
 - Deaf patients,
 - Cultural/social barriers
- Anaesthetised patients – need to establish pregnancy status as part of pre-op or admissions
- Unconscious/emergency patient – status may not be known
- Children
- Long term contraceptives
- Sometimes a urine pregnancy test is used to assist in decision making.
 - not reliable in early pregnancy,
 - should **not** be used to bypass the justification process



Use of Pregnancy Test

- **Legal requirement to enquire** if patient is pregnant, if relevant
- Pregnancy test not useful in ruling out pregnancy in very early stage of pregnancy (ie prior to day 28)
- Sensitivity typically $>25\text{mIU/ml}$ HCG (point of care tests)
- Lab tests more sensitive **but** still not useful before 8-10 days post conception
- Range HCG level post conception
 - 3 weeks LMP: 5 – 50 mIU/ml
 - 4 weeks LMP: 5 – 426 mIU/ml
 - 5 weeks LMP: 18 – 7,340 mIU/ml
- Pregnancy tests may be a useful source of additional information under certain circumstances but should not replace proper and direct enquiry



10 & 28 day Rules

10 Day Rule

Examinations involving ionising radiation are only carried out in the first 10 days of the menstrual cycle

28 Day Rule (Missed period)

Women of childbearing age could undergo medical exposures during the first four weeks following LMP. If a period is overdue and the patient can not be certain that she is not pregnant then consideration is given to postponing the examination



Application of the 10 day Rule

- There are situations where 10 day rule can not be easily applied or is not appropriate eg adolescents, peri menopausal females, previous hysterectomy etc.
- Referrer has option to waive 10 day rule but patient will still be asked about pregnancy status and confirm answer in writing
- Waiver an important feature of request as it allows clinically justified exams during pregnancy or possible pregnancy
- The referrer is waiving 'the use of the 10 day rule'
- They are **not** confirming that the patient is not pregnant
- Waiver can be used when
 - Exam urgent irrespective of status
 - 10 day rule impossible to apply
 - Pregnancy not possible (eg hysterectomy)
 -
- Each facility should establish the list of procedures for which 10 day rule will be applied

Example of Procedures where 10 day Rule applies

Modality	Examination
Fluoroscopy	Relevant x-ray guided procedures
CT	CT Pelvis, CT Abdomen Pelvis, CT Thorax Abdomen Pelvis.....
Nuclear Medicine	Myocardial Stress Rest Study, I-131 imaging....
PET CT	F-18 FDG Whole body..

Note: Each facility should establish the list of procedures for which 10 day rule will be applied

On the day of the exam

What happens when the patient presents for examination for which 10 day rule normally applies?

Establish and record the patients pregnancy status, LMP & explain reasons for enquiry

Scenario 1

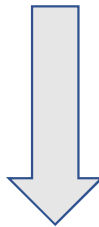
Patient has indicated she is not pregnant and is within the first 10 days of LMP



The procedure may go ahead

Scenario 2

Patient has indicated she is not pregnant and is not within the first 10 days of their LMP but the 10 day rule has been waived



The procedure may go ahead

Scenario 3

Pregnancy cannot be ruled out regardless of stage in menstrual cycle



Is an alternative imaging modality suitable?

No

Is Exam Urgent and Justified?

Yes

The procedure may go ahead

No

Patient is rescheduled

For **relevant** exams, a record will be kept indicating

- pregnancy status as advised by patient
- date of Imp

If the patient is outside the first 10 days of the menstrual cycle **and** the exam is one for which the 10 day rule is normally applied, then the exam is rescheduled or the radiographer documents why the 10 day rule is not being followed e.g.

- Exam urgent and justified
- Previous hysterectomy
- Periods absent/very irregular
- Contraception in use
-

Patient and radiographer sign the form which is scanned into the patient record for that exam

Scenarios 1, 2 & 3

Scenario 2

Pregnancy Status Declaration Form (Adult)			
Patient Name			
B	__/__/__	Procedure	
N		Date	__/__/__
1. To be completed by all patients undergoing a procedure for which the 10 day rule is normally applied Explanation of the risks associated with this procedure I have to ask because radiation exposure in pregnancy may slightly increase the risk of childhood cancers above the natural baseline level Is there any possibility that you could be pregnant? Yes [] No [] Don't Know [] The first day of my last menstrual period was: __/__/__			
2. To be completed by the Operator based on the information provided by the Referrer/Practitioner who waived the 10 day rule Basis for waiving 10 day rule (tick as appropriate)			
Exam urgent and justified			
Previous hysterectomy			
Periods absent /very irregular			
Contraception in use			
3. Patient Signature			
4. Staff Member Signature			
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Scenario 3

If patient is or might be pregnant **and** the exam is to go ahead, then a record is retained to indicate that this has been considered in the justification of the exam

- The referrer or practitioner signs the form to confirm justification
- The patient signs to confirm that the risks associated with ionising radiation during pregnancy have been explained and that she consents to proceed

Form is scanned into the patient record for that exam

Re-justification Form (Adult)			
Patient Name			
DOB	_/_/____	Procedure	
MRN		Date	_/_/____
1. To be completed by the Referrer/Practitioner if the patient is pregnant or pregnancy <u>cannot</u> be ruled out			
This procedure has been deemed clinically urgent and justified			
Signature:		MCRN	
2. To be completed by the Patient if she is pregnant or pregnancy <u>cannot</u> be ruled out			
The benefits and risks associated with this procedure have been explained to me and I consent to proceed			
Signature:			
This document is designed for online viewing. Printed copies, although permitted, are deemed <i>Uncontrolled</i> . Date of Printing 21/01/2021			
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Case Study 1

- 45 yo lady was referred for a CT Urogram
- For these exams, as fetal dose is likely to exceed 10mGy, 10 day rule usually applied
- Letter sent with appointment date, advising that it should be rescheduled if outside 10 days
- If the appointment date is not within 10 days LMP, patient rings to schedule an alternative date
 - Scheduling – 1/3 chance of appointment being within 10 day window
 - Long waiting lists mean that patients can be anxious about rescheduling



JANUARY						
Monday	Tuesday	Wednesday	Thursday	Friday	Sat / Sun	
		1	2	3	4	
					5	
6	7	8	9	10	11	
					12	
13	14	15	16	17	18	
					19	
20	21	22	23	24	25	
					26	
27	28	29	30	31		

Case Study 1 (contd)

- On presentation it was discovered that LMP > 10 days but patient confirmed not pregnant; signed to that effect
- Patient believed she was in early menopause
- Scan completed without incident
- Some months later during a follow up ultrasound, pregnancy was noted
- Fetus approx. 18 weeks
- Patient would have been 4-5 weeks pregnant at time of CT
- Fetal dose estimated to be 38mGy
- This fell within category of notifiable incidents
- Reported to regulator who followed up with a visit



Key question: Was the process sufficiently robust?

Follow up and Recommendations

- Regulator asked that existing policy be revised to
 - improve communication processes with patients in advance of the exposure
 - document reasons for excluding pregnancy
 - include an agreed definition of menopause
- Other actions:
 - communicate to referrers about their responsibilities in the referral process
 - communicate changes in documentation and shared learning to relevant personnel through staff meetings and general education sessions.



Case Study 2

- 33 yo female patient referred for CT Abdomen/Pelvis.
- Letter sent asking to contact department for appointment
- Appointment scheduled within the first 10 days of LMP
- On attendance patient confirmed not pregnant, advised date of LMP as 5 days previously, signed form
- CT Abdomen/Pelvis completed, radiology report issued.
- Some days later patient discovered she was pregnant and contacted department
- Patient had mistaken bleed in early pregnancy for period
- Dose to fetus estimated to have been 11mGy
- Incident reported to regulator, investigation report requested



Key question: Was the process sufficiently robust?

Follow up and Recommendations

- 10 day rule had been applied appropriately
- Patient confirmed that staff had asked about pregnancy status and had explained risks but she had been confident that she couldn't have been pregnant
- Communication and consent was documented
- Regulator satisfied that protocols had been robust and no further actions required
- Information and reassurance provided to patient



Notifiable Incidents



Exposure where none intended, including inadvertent Dose to fetus > 1 mGy.

Figure 1: Notifiable incidents reportable to MERU Notifiable Incidents

No dose intended/Incorrect patient exposed to > 1 millisivert (mSv).
Incorrect procedure.
Incorrect anatomy.
Incorrect radiopharmaceutical.
Diagnostic overexposure of an adult of more than twice the exposure intended that leads to >10mSv or 20 times the dose intended.
Diagnostic over exposure of a child of more than twice the exposure intended that leads to >3mSv or 15 times the dose intended.
Dose to foetus >1mSv.
Dose to the breastfed child >1mSv.
Deterministic effects as a result of interventional radiology.
Administration of a skin dose of 15Gy in a diagnostic environment.
Therapeutic dose given instead of diagnostic dose e.g. radioiodine.
Therapeutic nuclear medicine - administered activity different by 20% than intended.
Deterministic effects as a result of radiotherapy treatment.
Radiotherapy dose or volume variation from the total prescribed >10%.
Radiotherapy dose or volume variation from the fraction prescribed >20%.
Dose given to comforters and carers without consent greater than Medical Council guidelines of 3mSv for adults under 60 years of age and 6mSv for those over 60.
Any other radiation exposure incident considered to have serious patient safety implications.

MERU recommends using the HSE Safety Incident Management Policy (HSE, 2014a) and the HSE Guidelines for System Analysis Investigation of Incidents and Complaints (HSE, 2012a) when investigating and reporting on radiation safety

What do we tell patients after inadvertent exposure?

Open disclosure

- Patients should be told when things go wrong
- Most patients want to be told the truth
- Management of radiation incidents should be within the existing risk management framework of the hospital
- Communication with patient should follow existing hospital policy/guidelines
- MPE can provide referrer/practitioner with appropriate information on dose



Scanning Pregnant Patients

- Document Justification
- Select lowest dose technology available
- Consider use of collimation and scan length taking account of fetal position
- For nuclear medicine scans, consider reduction in activity and increased scan time
- Assessment of fetal dose can assist in optimisation
- IAEA recommend that for high dose exams, tailor exam and finish once diagnostic information is acquired
- Scanning needs and optimisation steps should be considered on a case by case basis.



Risk Communication

Justification and Optimisation are fundamental principles of radiation protection

Significant effort expended in minimising risk

Precautions inherent in radiation protection can contribute to heightened perception of hazard

yet

When an incident occurs, often the message is one of reassurance that the actual risk is very low

Challenge of managing individual and collective risk

Quantifying and communicating risk needs a range of approaches and how we present the risk strongly influences interpretation



Summary

- European and national legislation provide framework for medical exposures and includes protection of the fetus
- In diagnostic radiology, deterministic effects should not occur and effort directed towards minimising risk of stochastic effects
- Individual perception of risk is influenced by factors other than magnitude of hazard and must be considered
- Communication of risk should reflect uncertainty, be appropriate to the level of risk and should take account of the individual
- Increased awareness and education of healthcare professionals and patients important
- Appropriate and timely communication is central to managing this issue and requires input from scientific, technical, clinical and communication experts

