IFMP WORKSHOP IN IONIAN UNIVERSITY, CORFU, GREECE

Thursday 9/11/2017 8:30

# RADIATION PROTECTION AND PREGNANCY IN MEDICINE

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One of the more sensitive problems in radiation protection arises when the person irradiated is, or possibly is, pregnant.

This lecture deals with the risks that may arise.

It considers the regulatory environment for the different groups, such as patients, staff, the public, and if the radiation is deliberate or inadvertent.

It considers advice that may be offered to those working in the area, and those who may have to counsel those irradiated.

It considers the advice and risks in the context of the progress of normal pregnancies and in the context of radiobiological findings on damage to the foetus/embryo.

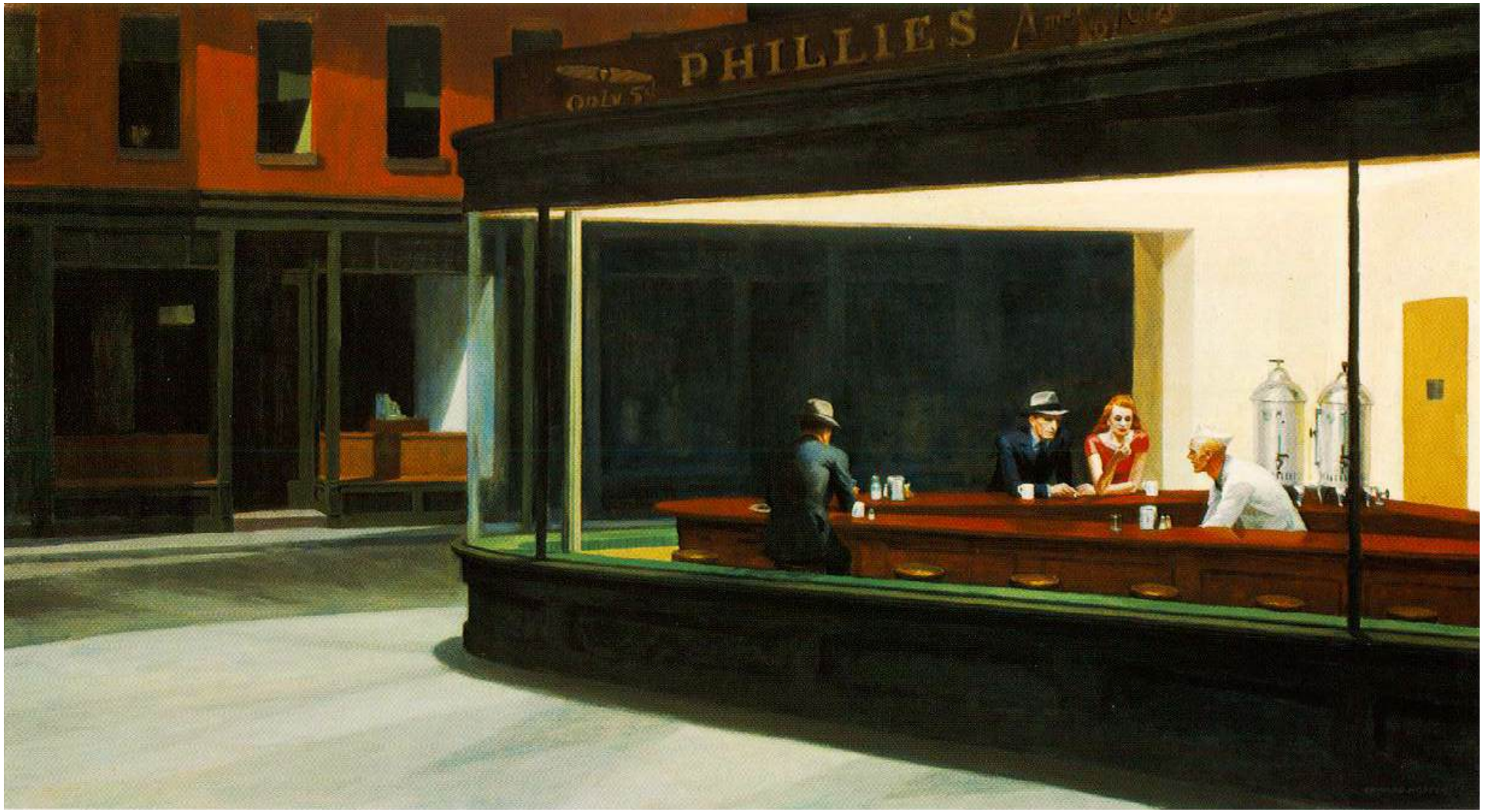
Finally, it reviews the issue of terminations in the diagnostic radiology context.

# Radiation Protection and Pregnancy

*Prof Jim Malone*

*Trinity College Dublin*

*Robert Boyle Foundation*




1. Radio-biological and Risk;

2. Regulatory/Good Practice, Occupational and Medical

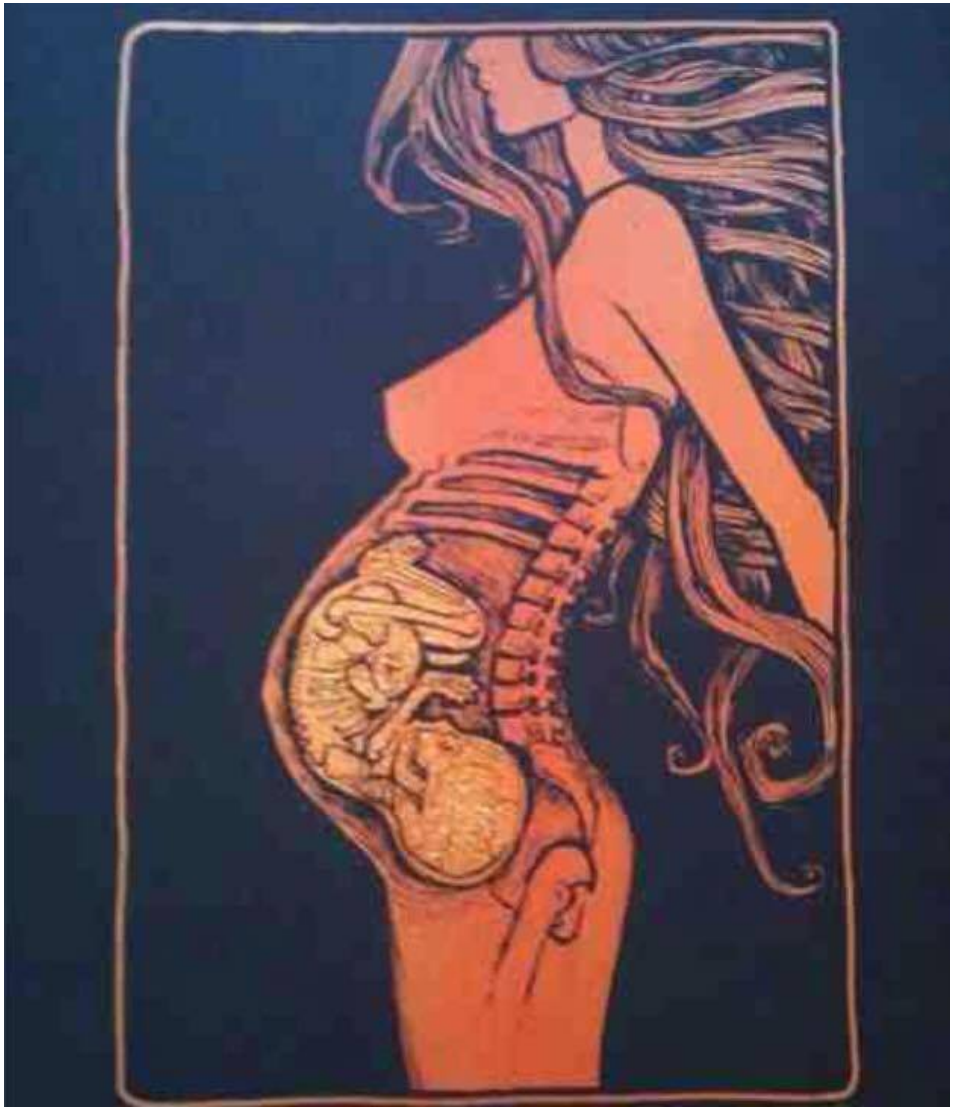
3. Some Advice including Credibility

4. Conclusions

# **Context**: Risks in an unexposed pregnant population

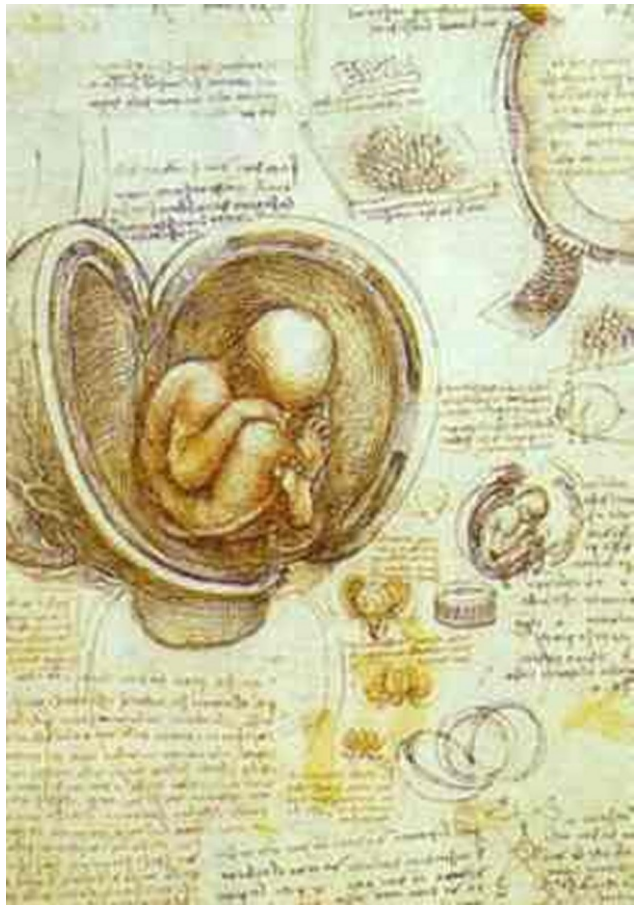
- Abortion (Spont) >15%
- Incidence of genetic abnormalities 4-10%
- Intrauterine growth retardation 4%
- Incidence of major malformation 2-4%

Note fear/distrust in exposed populations



# Embryo/Foetal Responses Include:

- Pre-natal or neo-natal death
- Congenital abnormalities
- Growth impairment
- Reduced intelligence
- Genetic aberrations
- Increase in risk of cancer



Classification as Deterministic & Stochastic

# Radiation Effects in Unborn

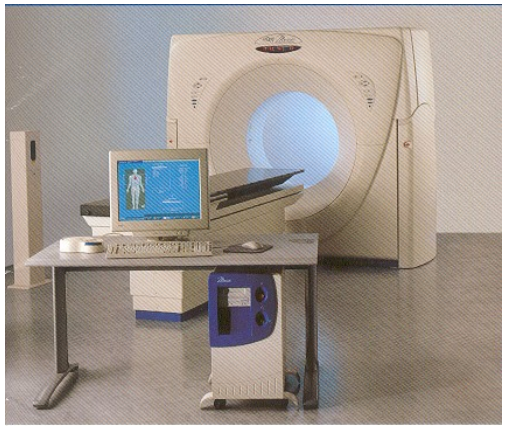
**Deterministic**

- Decrease/loss of organ fn due to cell death/damage
- Includes: implantation failure; death, malformation, growth/mental retardation

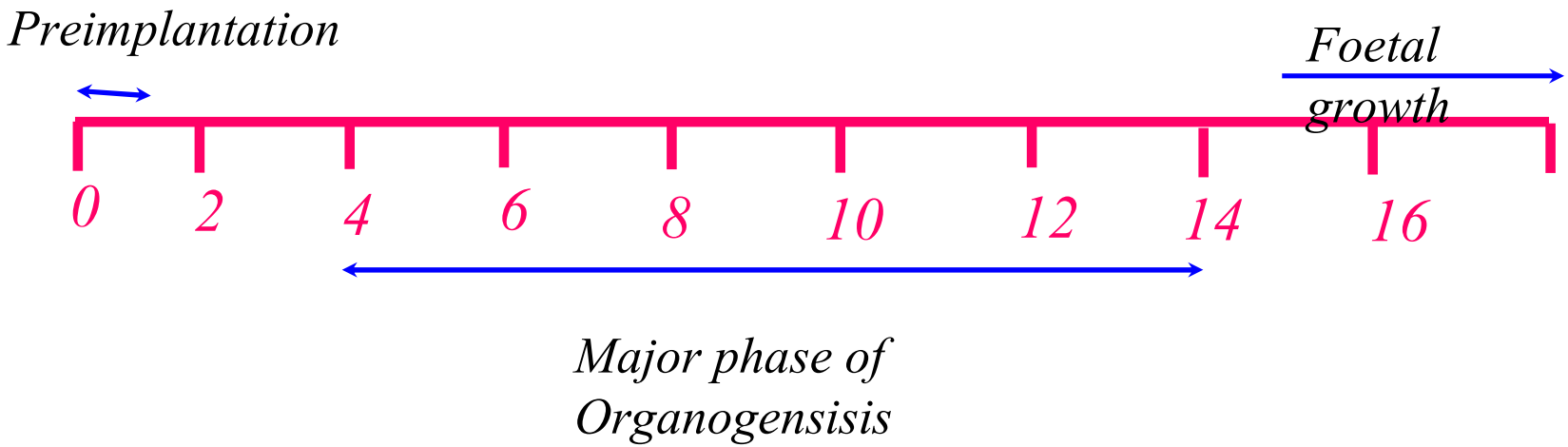
- Dose must exceed threshold
- Malformations, eg. CNS associated, have a threshold ~ 100-200mGy
- >3 Pelvic CT; Possible in Interventional

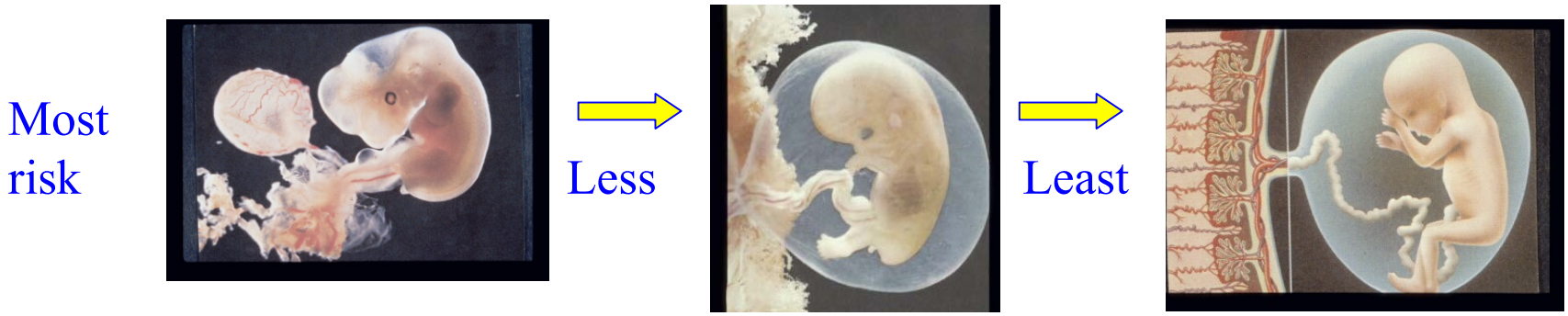
# Radiation Induced Malformations

- Malformations, often CNS associated, have a threshold of typically 100-200mGy,
- 100mGy is not reached with 3 pelvic CT scans or 20 x-rays
- These levels can be reached with interventional procedures or with radiotherapy



# Dependence on Developmental Phase



# Radiation Effects in Unborn 2

**Stochastic**

- Changes at cellular level
- Leukaemia, cancer and hereditary diseases
- No threshold; probability proportional to dose
- Foetus: ~about same risk of cancer as children
- Leukaemia 1 in 40,000 for 1mGy
- Other 1 in 29,000 for 1mGy
- Natural Level(UK) to age 15: 1 in 650.
  25mGy will double natural risk of fatal cancer
  Relative risk may be as high as 1.4

# Another Way of Looking at It

| Dose to conceptus (mGy) above natural background | Probability of no malformation | Probability of no cancer (0-19 years) |
|---|---|---|
| **0** | **97** | **99.7** |
| **1** | **97** | **99.7** |
| **5** | **97** | **99.7** |
| **10** | **97** | **99.6** |
| **50** | **97** | **99.4** |
| **100** | **97** | **99.1** |
| **>100** | **Possible, see text** | **Higher** |

# Regulatory and Legislation

- See new EC Directive and IAEA BSS
- **EC: RP 100**
- UK HPA Document, 2009.
- Irish IAPM et al Document, 2017
- BSS REQUIRES employee should not normally need to be moved from radiation work
- Note also general regulations for pregnant women at work, for good guidance on principles
- Limit: Embryo/Fetus ICRP (1mSv) NCRP (5mSv)

# Monthly Staff Doses

| | |
|---|---|
| Radiographers: | <0.1mSv - 0.3mSv |
| Intervent RadiolCardio/: | <0.1mSv - 0.5mSv |
| Nurses (Interventional): | <0.1mSv - 0.2mSv |

# Practical Protection of Staff 1

- Local Rules and monitoring
- Declare pregnancy once confirmed
- Protective clothing and protective shields
- Education and training
- Ensure adequate monitoring of staff using ionising radiation

# Practical Protection of Staff 2

- Minimise time/distance spent with radiation
- Do not hold patients during x-ray procedures
- Pregnant staff should not be assigned as escort nurses for nuclear medicine patients
- Reassignment of staff

# Protection of Patients

- European and National legislation
  - New EC Directive
  - IAEA BSS
  - National Legislation transposing EC Directive (2018)
- Dose limits do not apply; DRL's may be available
- Must consider patient and unborn child
- Good practice;  Advice from professional bodies
- Practice highly variable throughout the EU
- Reasons for variable practice would seldom stand up to public scrutiny

| Modality | Examination<br>Non Applicable (<1mGy) |
|---|---|
| X-ray | Skull |
| X-ray | Teeth |
| X-ray | Chest |
| X-ray | Thoracic Spine |
| X-ray | Breast (Mammography) |
| X-ray | Abdomen |
| X-ray | Barium Meal |
| X-ray | Pelvis |
| X-ray | Hip |
| CT | Pulmonary Angiogram |
| CT | Pelvimetry |
| CT | Chest and Liver |
| CT | Head and/or Neck |
| $^{99m}$Tc | Lung Ventilation Scan (Technegas) |
| $^{99m}$Tc | White Cell Scan |
| $^{99m}$Tc | Lung Perfusion Scan |
| $^{99m}$Tc | Thyroid Scan |
| $^{99m}$Tc | Lung Ventilation Scan (DTPA) |
| $^{99m}$Tc | Renal Scan (MAG3,DMSA) |
| $^{51}$Cr | GFR Measurement |
| $^{81m}$Kr | Lung Ventilation Scan |

| Modality | Examination: Low<br>Foetal 1-10 mGy | Childhood cancer risk/ examination |
|---|---|---|
| X-ray | Barium Enema | 1 in 10,000<br>to<br>1 in 1,000 |
| X-ray | Intravenous Urography | |
| X-ray | Lumber Spine | |
| CT | Lumber Spine | |
| CT | Abdomen | |
| $^{99m}$Tc | Bone Scan | |
| $^{99m}$Tc | Cardiac blood pool scan | |
| $^{99m}$Tc | Myocardial Scan | |
| $^{99m}$Tc | Cardiac Blood Pool Scan (Exametazine) | |
| $^{99m}$Tc | Renal Scan (DTPA) | |
| $^{201}$Tl | Myocardial Scan | |
| $^{18}$F PET | Tumour Scan | |
| | | |
| | **Examination: High<br>Foetal Dose 10-50 mGy** | |
| CT | Pelvis | 1 in 1,000<br>to<br>1 in 200<br>Natural childhood cancer risk ~ 1 in 500 |
| CT | Pelvis and Abdomen | |
| CT | Pelvis, Abdomen and Chest | |
| $^{99m}$Tc | Myocardial (SPECT rest-exercise protocol) | |
| $^{18}$F PET/CT | Whole Body Scan (F-18) | |
| | | |

# Practical Measures to Protect Patients

- Assess if patient pregnant
- If it can not be out-ruled, treat as pregnant
- If pregnant , review justification, consider alternatives, or deferring
- Optimise with respect to radiation protection of unborn child as well as mother
- Estimate foetal dose before, and calculate or measure it after exam
- Involve mother in all discussions

**Emergency: may not be possible to follow exactly**

# Informed Consent and Understanding
(ICRP 84, RP 100, Report of ICRP TG 94)

- The pregnant patient (and worker) has a right to know the magnitude and type of….. effects that might arise from in utero exposure
- Risk is negligible below1mGy
- Higher doses: more detailed explanation
- Woman's consent is frequently overlooked

# Present Requirements (SI)

- Prescriber, practitioner, radiographer must ask the patient if she is pregnant or breast-feeding
- Answer to be recorded in writing
- Patient to be treated as if pregnant, if it can't be excluded
- Abdominal and pelvic exposures: special attention, justification and optimisation for mother and child
- See new IAPM Irish advice

# Protection of Pregnant Patients

**10 Day Rule -** Examinations are only carried out in the first 10 days of the menstrual cycle.

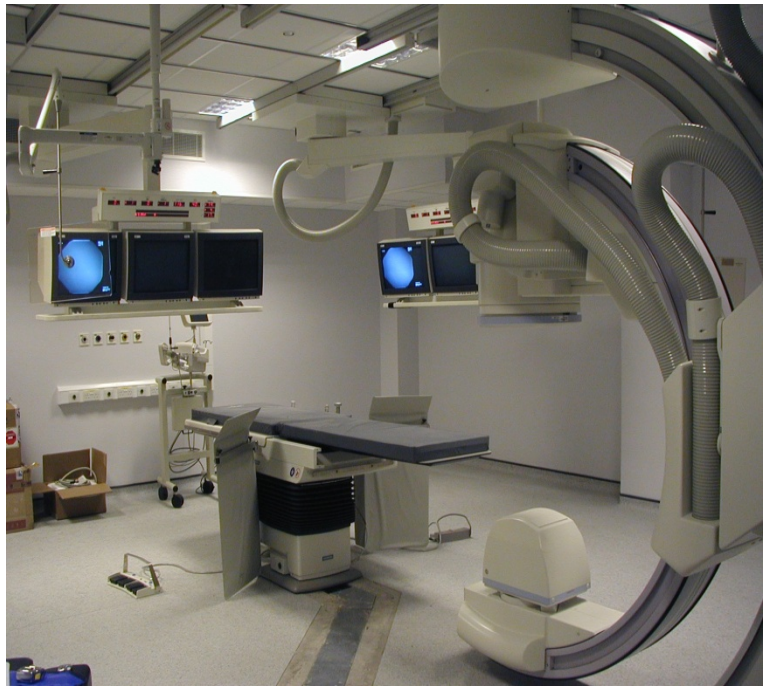
**28 Day Rule -** Exposures OK until period missed, ie, during the first four weeks following LMP.

**RCR -** 10 day rule for high dose examinations, otherwise proceed (see IAPM).

**Pregnancy Testing** – Fraught (see IAPM).
Can't be a "A Little Bit Pregnant"

# Higher Dose Procedures

- Interventional fluoro may give foetal doses in the range of 10-100mGy or more
- Dose and risk assessment essential by competent person
- Informed consent required – explanation of risk



# Remember that -----

- Lack of knowledge is responsible for great anxiety and probably for unnecessary terminations
- For most patients, radiation exposure is medically appropriate and foetal risk minimal
- It is seldom necessary to consider termination following diagnostic exposure.
- Communication by a person the patient is likely to trust is crucial.

# Termination of Pregnancy…

- High fetal doses (100-1000 mGy) during late pregnancy are not likely to result in malformations or birth defects since all the organs have been formed
- A fetal dose of 100 mGy has a small individual risk of radiation-induced cancer. There is over a 99% chance that the exposed fetus will **NOT** develop childhood cancer or leukaemia

# Termination of Pregnancy (cont'd)

- Termination of pregnancy at foetal doses of less than 100 mGy is **NOT** justified based upon radiation risk
- At fetal doses in excess of 500 mGy, there can be significant foetal damage, the magnitude and type of which is a function of dose and stage of pregnancy
- At foetal doses between 100 and 500 mGy, decisions should be based upon individual circumstances, and credible, experienced counselling which patient will find trustworthy should be provided

# Conclusions

Review of Radiobiology, Regulation and Good Practice

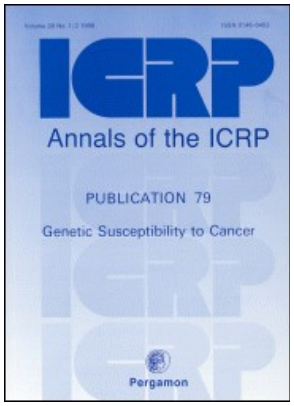
In Europe dose constraint of 1mSv to Unborn child

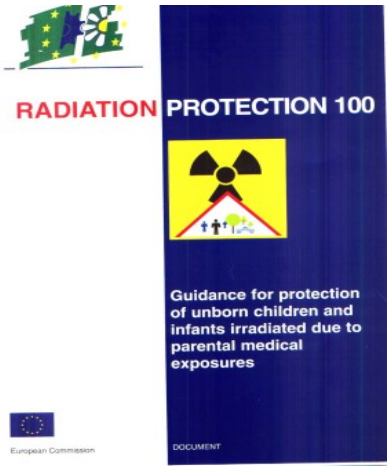
Termination seldom if ever necessary for diagnostic exposures.

Consent and involving the woman essential

# Some References


1. ICRP 84 ; Pregnancy and Medical Radiation
2. EC. Radiation Protection 100 ; Guidance for protection of unborn children and infants --.
3. Radiation Protection 118: Referral guidelines for imaging
4. HPA, UK, 2009. Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation RCE 9
5. Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures. 2017. Irish Association of Physicists in Medicine (IAPM and others). In press awaiting final legal for of transposition of new EC Directive.




6. Project will be put up on my ResearchGate Page

# Biological Effects in Unborn 1

## Deterministic Effects

### *0 - 3 Weeks*

- Failure to implant or death of embryo

### *3 - 8 weeks*

- malformation of organs
- threshold of the order of 100mGy
- some risk of foetal death for doses > 500mGy

### *8 - 25 weeks*

- shift in IQ, 30 IQ points per Sievert for weeks 8-15, smaller shift in the following 10 weeks

### *> 25 weeks*

- lower risk period

[Insert Logo here]

# Rejustification Form (Paediatric)

| | | | |
|---|---|---|---|
| Patient Name | | | |
| DOB | ___/___/_____ | Procedure | |
| MRN | | Date | ___/___/_____ |

| **1. To be completed by the Prescriber/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 Parent/Guardian if the patient 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: | |

[Insert Logo here]

# Pregnancy Status Declaration Form (Paediatric)

| | | | |
|---|---|---|---|
| Patient Name | | | |
| DOB | ___/___/_____ | Procedure | |
| MRN | | Date | ___/___/_____ |

| **1. To be completed by the Parent/Guardian of a patient undergoing a low or high fetal dose procedure** | | | |
|---|---|---|---|
| **Explanation of the risks associated with this procedure** | | | |
| We are legally obliged to establish your child's pregnancy status in advance of this procedure.<br>Radiation exposure of an unborn child may slightly increase the risk of childhood cancer.<br>It is very important that you inform staff performing the procedure if there is **<u>any</u>** possibility your child is pregnant | | | |
| Has your child begun menstruating?<br>If No, please proceed to the end of the form and sign | Yes [ ] | No [ ] | |
| Is there any possibility your child may be pregnant? | Yes [ ] | No [ ] | Don't Know [ ] |
| If pregnant, how many weeks? | | | |
| The first day of your child's last menstrual period was: | ___/___/_____ | | |

| | |
|---|---|
| **2. Parent/Guardian Signature** | |
| **3. Staff Member Signature** | |

[Insert Logo here]

# Rejustification Form (Adult)

| | | | |
|---|---|---|---|
| Patient Name | | | |
| DOB | ___/___/_____ | Procedure | |
| MRN | | Date | ___/___/_____ |

| **1. To be completed by the Prescriber/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: | |

[Insert Logo here]

# Pregnancy Status Declaration Form (Adult)

| | | | |
|---|---|---|---|
| Patient Name | | | |
| DOB | ___/___/_____ | Procedure | |
| MRN | | Date | ___/___/_____ |

| **1. To be completed by all patients undergoing a low or high fetal dose procedure** | | | |
|---|---|---|---|
| **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 patient if she has missed a period, if periods are absent or in the case of a high fetal dose procedure, the date of her LMP does not fall within the last 10 days** | |
|---|---|
| **Relevant information that may assist in ruling out pregnancy (tick as appropriate)** | |
| No intercourse since last normal menses | |
| Hysterectomy or Bilateral Oophorectomy (surgical removal of both ovaries) | |
| Postmenopausal (no menstrual periods for 1 year for women > 50 and 2 years for women < 50) or < 4 weeks Postpartum | |
| A patient is correctly and consistently using an acceptable method of contraception (see below) | |

| | |
|---|---|
| **3. Patient Signature** | |
| **4. Staff Member Signature** | |

**Acceptable Methods of Contraception**

- Insertion of the contraceptive implant (Implanon) within the previous 3 years
- Insertion of the levonorgestrel Intrauterine System (IUS) (Mirena or Kyleena) within the previous 5 years
- Insertion of the Jaydess IUD within the previous 3 years
- Insertion of the Copper Coil IUD within the previous 5-10 years (depending on expected life of coil)
- Depo-provera injection within the previous 3 months
- Tubal Ligation
- Consistent and correct use of a Combined Oral Contraceptive Pill / Progesterone Only Pill / Transdermal Contraceptive Patch (Evra) / Combined vaginal ring (Nuvaring) within the past 1 month

**Appendix 3**

# Non Applicable Procedures (i.e. examinations where fetal dose is < 1mGy)*

**[To be amended to take account of dose at local hospital]**

| Modality | Examination | Typical fetal dose range (mGy)* | Risk of childhood cancer per examination |
|---|---|---|---|
| X-ray | Skull | 0.001 – 1.0 | < 1 in 1,000,000 to 1 in 10,000 |
| X-ray | Teeth | | |
| X-ray | Chest | | |
| X-ray | Thoracic Spine | | |
| X-ray | Breast (Mammography) | | |
| X-ray | Abdomen | | |
| X-ray | Barium Meal | | |
| X-ray | Pelvis | | |
| X-ray | Hip | | |
| CT | Pulmonary Angiogram | | |
| CT | Pelvimetry | | |
| CT | Chest and Liver | | |
| CT | Head and/or Neck | | |
| $^{99m}$Tc | Lung Ventilation Scan (Technegas) | | |
| $^{99m}$Tc | White Cell Scan | | |
| $^{99m}$Tc | Lung Perfusion Scan | | |
| $^{99m}$Tc | Thyroid Scan | | |
| $^{99m}$Tc | Lung Ventilation Scan (DTPA) | | |
| $^{99m}$Tc | Renal Scan (MAG3,DMSA) | | |
| $^{51}$Cr | GFR Measurement | | |
| $^{81m}$Kr | Lung Ventilation Scan | | |

***Note:** Typical fetal doses given above are taken from the EPA ORP leaflet *"Guidance on the protection of the unborn child during diagnostic medical exposures"* [1]

**Appendix 2**

# Low Fetal Dose Procedures (see sec. 3.5)

**[To be amended to take account of dose at local hospital]**

| Modality | Examination | Typical fetal dose range (mGy)* | Risk of childhood cancer per examination |
|---|---|---|---|
| X-ray | Barium Enema | 1.0 - 10 | 1 in 10,000 to 1 in 1,000 |
| X-ray | Intravenous Urography | | |
| X-ray | Lumber Spine | | |
| CT | Lumber Spine | | |
| CT | Abdomen | | |
| $^{99m}$Tc | Bone Scan | | |
| $^{99m}$Tc | Cardiac blood pool scan | | |
| $^{99m}$Tc | Myocardial Scan | | |
| $^{99m}$Tc | Cardiac Blood Pool Scan (Exametazine) | | |
| $^{99m}$Tc | Renal Scan (DTPA) | | |
| $^{201}$Tl | Myocardial Scan | | |
| $^{18}$F PET | Tumour Scan | | |
| | | | |
| | | | |
| | | | |

***Note:** Typical fetal doses given above are taken from the EPA ORP leaflet *"Guidance on the protection of the unborn child during diagnostic medical exposures"* [1]

**Appendix 1**

# High Fetal Dose Procedures (see sec. 3.4)

**[To be amended to take account of dose at local hospital]**

| Modality | Examination | Typical fetal dose range (mGy)* | Risk of childhood cancer per examination |
|---|---|---|---|
| CT | Pelvis | 10 - 50 | 1 in 1,000 to 1 in 200<br><br>Natural childhood cancer risk ~ 1 in 500 |
| CT | Pelvis and Abdomen | | |
| CT | Pelvis, Abdomen and Chest | | |
| $^{99m}$Tc | Myocardial (SPECT rest-exercise protocol) | | |
| $^{18}$F PET/CT | Whole Body Scan (F-18) | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
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| | | | |
| | | | |
| | | | |
| | | | |

***Note:** Typical fetal doses given above are taken from the EPA ORP leaflet *"Guidance on the protection of the unborn child during diagnostic medical exposures"* [1]

European Communities (Medical Ionising Radiation Protection (Amendment Regulations (SI 303 of 2007) HSE, March 2010.

[4] Advice on exposures to ionising radiation during pregnancy, National Radiological Protection Board, College of Radiographers and Royal College of Radiologists, 1998

[5] Protection of Pregnant Patients during Diagnostic Medical Exposures to ionising radiation. Advice from the Health Protection Agency, The Royal College of Radiologist and the College of Radiographers, March 2009

[6] Hart D, Hillier MC and Wall BF, 'Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK – 2005 Review', Chilton, HPA-RPD-029, 2006

[7] Shrimpton PC, Hillier MC, Lewis MA and Dunn M, 'Dose from Computed Tomography (CT) Examinations in the UK – 2003 Review', Chilton, NRPB-W67, 2005

[8] ARSAC, 'Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources, HPA, 2006

[9] Radiation Protection 100. Guidance for protection of unborn children and infants irradiated due to parental medical exposures. European Commission (1998)

[10] EU Council Directive 2013/59/EURATOM Basic safety standards for protection against the dangers arising from exposure to ionising radiation

[11] Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. FSRH Guidance Contraception for Women Aged Over 40 Years. (July 2010)

[12] National Consent Policy, HSE May 2014 hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy

[13] AAPM Report No. 50 Fetal Dose from Radiotherapy with Photon Beams

- The treating medical team and RSO/RPO must be notified and this must be documented in the patient's healthcare record (if available) with the advice / instructions and their name clearly stated
- A single adverse incident report form must be used for reporting the incident or near miss giving a brief description and actions taken to manage the event
- The facts of any incident affecting the clinical care of the patient must be documented in the patient's healthcare record (if available) and correctly signed by the person documenting the event when Open Disclosure has taken place
- The dose to the fetus should be carefully estimated by an MPE
- The RPA/MPE/RPO/RSO is responsible for investigating the incident and whether any local practices or systems require change so as to reduce the likelihood of a similar incident occurring.

### 6.7 Open Disclosure (Communication with Patient, Relatives, Staff)

6.7.1 In the event of inadvertent fetal exposure, information pertaining to the incident must be disclosed to the patient by the prescriber in consultation with the RSO/RPO/RPA/MPE http://www.hse.ie/opendisclosure/

6.7.2 The patient should be given a prompt and truthful explanation about the incident

### 6.8 Procedure to be followed on detecting a serious safety event

6.8.1 Serious incidents require a thorough investigation including escalation to relevant external bodies as appropriate in accordance with the Safety Incident Management Policy, HSE, 2015. The purpose of the investigation is to identify the key factors that contributed towards the incident occurring and the contributory factors that underpinned these.

## 7.0 Monitoring and Audit Procedures

This policy is monitored on an on-going basis by *(alter as per local arrangements)*

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## 8.0 References and Related Documents


[1] Guidance on the protection of the unborn child during diagnostic medical exposures EPA ORP (formerly RPII), May 2010

[2] S.I. No 478 of 2002 European Communities (Medical Ionising Radiation Protection) Regulations 2002

[3] Guidelines on responsibilities in European Communities (Medical Ionising Radiation Protection) regulations (SI478 of 2002) as amended by the

- That after initial consent the pregnancy status is not rechecked
- That they must inform staff immediately if they believe they have become pregnant

## 6.5 Procedures on Patients known to be Pregnant

6.5.1 The procedure may go ahead with optimisation provided that:

- The Prescriber / Practitioner has justified the exposure and recorded the decision on the Rejustification Form and/or [Request Form] [Order Comms] [RIS]
- The patient (or parent/guardian if relevant) has completed and signed the Rejustification Form

6.5.2 The Operator shall keep a record of the procedure details. The Operator or RSO/RPO shall communicate all relevant details to the MPE/RPA for assessment of the fetal dose. This information should also be documented *(enter local arrangements for recording of fetal dose risk assessments)*

6.5.3 The MPE/RPA shall ensure that the Reporting Radiologist is made aware of the fetal dose. The Radiologist may consider including this information as part of the report or as an addendum to the report. *(Alter as per local arrangements)*

6.5.4 Where a pregnant patient requires radiotherapy, the dose to the fetus should be carefully estimated by an MPE. This may involve making phantom measurements which should help decide whether or not to use bespoke shielding for a particular treatment. The treatment technique and plan should also be reviewed in conjunction with the radiation oncologist to determine whether any modifications or shielding could reduce the dose to the fetus. There must be a record of dose estimates and shielding where used. In addition, the patient must be made aware of the potential risks to the fetus and consent to treatment.

Relevant publications such as AAPM Report No. 50 should be consulted for further guidance [13]

## 6.6 Procedure to be followed in the event of inadvertent fetal exposure

6.6.1 Local hospital guidelines on reporting of incidents should be followed. If these are not available, the following procedure should be adhered to:

- The person detecting the incident is required to ensure the safety of the person placed at risk and take any necessary actions

- A patient is correctly and consistently using an acceptable method of contraception:
  - Insertion of the contraceptive implant (Implanon) within the previous 3 years
  - Insertion of the levonorgestrel Intrauterine System (IUS) (Mirena or Kyleena) within the previous 5 years
  - Insertion of the Jaydess IUD within the previous 3 years
  - Insertion of the Copper Coil IUD within the previous 5-10 years (depending on expected life of coil used)
  - Depo-provera injection within the previous 3 months
  - Tubal Ligation
  - Consistent and correct use of Combined Oral Contraceptive Pill / Progesterone Only Pill / Transdermal Contraceptive Patch (Evra) / Combined Vaginal Ring (Nuvaring) within the past 1 month

6.4.2 The use of radiotherapy or chemotherapy agents does not rule out pregnancy

6.4.3 This policy does not advocate the use of or reliance on routine urine pregnancy testing as it is unreliable in early pregnancy and false negatives are common. However if pregnancy testing is used, local hospital guidelines on their use (urine or serum) should be followed. If these are not available, the following procedure may be considered:

- Ideally a woman should provide a first morning urine specimen to allow sufficient time for hCG levels to concentrate in the urine, but random samples can be used. Urine held for a shorter duration may give a false negative result in very early pregnancy.
- A negative pregnancy test adds weight to the exclusion of pregnancy, but only if **≥ 3 weeks** since the last episode of unprotected sexual intercourse (UPSI).
- hCG testing may be appropriate for women with erratic cycles / oligomenorrhea, who aren't using acceptable forms of contraception and where the timing of ovulation is unknown.

6.4.4 For patient receiving radiotherapy treatment, the Pregnancy Status Declaration Form covers the entire radiotherapy process. However there may be a significant period of time between signing of the Pregnancy Status Declaration Form and commencement of radiotherapy treatment. Therefore there must be documented evidence to show that the patient has been made aware

- Of the risks of radiation exposure to the fetus. This should be recorded in the consent to treatment.
- That it is a requirement not to get pregnant during radiotherapy treatment or in the period between localisation CT and radiotherapy treatment and that it is advisable not to get pregnant for a period after treatment is complete.

- If the procedure is not deemed clinically urgent and justified, it should be rescheduled to a later date.

### 6.3 Low Fetal Dose Procedures

6.3.1 For low fetal dose procedures, the following workflow should be applied:

*a) Patient has indicated they are not pregnant and have not missed a period*

- The procedure may go ahead

*b) Patient has indicated they are not pregnant and have missed a period. If the patient can reasonably rule out pregnancy (sec 6.4):*

- The patient (or parent/guardian if relevant) should complete section 2 of the Pregnancy Status Declaration Form
- The procedure may go ahead

*c) Pregnancy cannot be ruled out regardless of stage in menstrual cycle*

- The prescriber and practitioner's advice should be sought with regard to the clinical urgency and the justification for the procedure
- Consideration should be given to the use of alternative imaging modalities which do not use ionising radiation
- If the procedure is deemed clinically urgent and justified, the decision should be recorded on the Rejustification Form and/or [Request Form] [Order Comms] [RIS].
- The patient (or parent/guardian if relevant) is asked to sign the relevant section on the Rejustification Form
- The procedure may go ahead with optimisation taking into account both the mother and possible fetus
- If the procedure is not deemed clinically urgent and justified, it should be rescheduled to a later date.

### 6.4 Ruling out Pregnancy

6.4.1 Health professionals can be reasonably certain that a woman is not currently pregnant if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- A patient is postmenopausal (see 3.9)
- A patient has had a hysterectomy
- A patient has had a bilateral oophorectomy (surgical removal of both ovaries)
- A patient has not had sexual intercourse since last normal menses
- A patient is within 4 weeks postpartum

consistent choice or is obviously unable to understand and use the information and choices provided. Actions should be in line with those specified in the hospital's guidelines on consent and the relevant legislation [12]

6.1.5 If a patient is unable to respond to questioning because of illness, the Prescriber or Practitioner should be consulted

## 6.2 High Fetal Dose Procedures

6.2.1 Scheduling of women of childbearing potential for high dose procedures can be made in one of two ways [5]:

1. Apply the 10 day rule or
2. Appointments are made in the normal way and the workflow in 6.2.2 applied

6.2.2 For high fetal dose procedures, the following workflow should be applied:

a) *Patient has indicated they are not pregnant and procedure falls within the first 10 days of their LMP*

- The procedure may go ahead.

b) *Patient has indicated they are not pregnant and procedure does <u>not</u> fall within the first 10 days of their LMP. If the patient can reasonably rule out pregnancy (sec 6.4):*

- The patient (or parent/guardian if relevant) should complete section 2 of the Pregnancy Status Declaration Form
- The procedure may go ahead

c) *Pregnancy <u>cannot</u> be ruled out regardless of stage in menstrual cycle*

- The prescriber or practitioner's advice should be sought with regard to the clinical urgency and the justification for the procedure
- Consideration should be given to the use of alternative imaging modalities which do not use ionising radiation
- If the procedure is deemed clinically urgent and justified, the decision should be recorded on the Rejustification Form and/or [Request Form] [Order Comms] [RIS]
- The patient (or parent/guardian if relevant) is asked to sign the relevant section on the Rejustification Form
- The procedure may go ahead with optimisation taking into account both the mother and possible fetus

- In the event that a patient is pregnant, might be pregnant or cannot exclude the possibility of pregnancy, review (in conjunction with the practitioner) the justification for a procedure
- Record the information in the appropriate section of the [Request Form] [Order Comms] [RIS] *(alter as appropriate for local use)*

6.1.2 When the patient attends for the procedure, the Radiographer/Operator should (as per 5.4):

- Ensure that correct patient identification and procedure matching is undertaken and that any queries are discussed with the practitioner
- Ensure the Pregnancy Status Declaration Form is completed and sign as a witness
- Explain to the patient the risks of radiation exposure to the fetus. A brief but simple explanation of the risks of radiation exposure to the fetus should be given, e.g.

  *"Is there any possibility that you could be pregnant?"*

  "*I have to ask because radiation exposure in pregnancy may slightly increase the risk of childhood cancers above the natural baseline level*"

- In conjunction with the practitioner and MPE/RSO/RPO, optimise a procedure if a patient is pregnant, might be pregnant or cannot exclude the possibility of pregnancy
- If the patient is under 16 years of age, the parent or guardian must be present and sign the paediatric version of the Pregnancy Status Declaration Form
- Seek advice from the Prescriber/Practitioner/MPE/RSO/RPO/ Departmental manager if there are concerns regarding certain situations or uncertainty about pregnancy status

6.1.3 If a patient is unable to respond to questioning because English is not their native language, an interpreter proficient in the patient's language is required to facilitate translation (an exception may be made in emergency situations). Where practicable, this is best achieved by using a professional interpreter. The use of family (in particular children) and friends should be avoided if at all possible [12]

6.1.4 If a patient is unable to respond to questioning because of learning difficulties, the operator must work on the presumption that the patient has the capacity to make decisions about their care and to decide whether to agree to or refuse an examination. No other person such as a family member, friend or carer can give or refuse consent to a health or social care service on behalf of a patient who lacks capacity to consent unless they have specific legal authority to do so. The possibility of incapacity and the need to assess capacity formally should only be considered, if, having been given all appropriate help and support, a patient is unable to communicate a clear and

- Ensure that correct patient identification and procedure matching is undertaken and that any queries are discussed with the practitioner
- Ensure the Pregnancy Status Declaration Form is completed and sign as a witness. This form should be [scanned into NIMIS/RIS] [filed in….] *(alter as appropriate for local use)*
- Ensure that the risks of radiation exposure to the fetus are explained to the patient and that they are given an opportunity to ask questions
- Ensure that the patient is asked as to whether she is or might be pregnant and that her answer is recorded in writing [1]
- In conjunction with the practitioner and MPE/RPO/RSO when available, optimise a procedure if pregnancy cannot be ruled out
- Seek advice from the practitioner, departmental manager or an MPE/RPA/RSO/RPO if there are concerns regarding certain situations or uncertainty about pregnancy status

5.5 **Administration Staff:** It is the responsibility of administration staff to ensure that scheduling arrangements are made in accordance with this policy

5.6 **MPE/RPA:** It is the responsibility of the MPE/RPA to

- Provide advice regarding fetal dosimetry
- Provide advice regarding the optimisation of a procedure if pregnancy cannot be ruled out
- Provide advice on all aspects of radiation protection

## 6.0 Procedures / Guidelines

### 6.1 Standard Operating Procedure

6.1.1 For all applicable patients (see 4.0), the prescriber should (as per 5.2):

- Ensure the procedure is justified
- State the reason for requesting the particular procedure and provide relevant clinical history on the request
- Seek (with the practitioner) where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure
- Enquire as to the patient's pregnancy status and date of LMP and record this on the request
- In the case of an anaesthetised patient, the prescriber should establish pregnancy status prior to anaesthesia. If the pregnancy status has not been established prior to anaesthesia, the prescriber must document the justification for continuing with the procedure (without knowing the pregnancy status) in the patient notes
- In the case of an unconscious patient where pregnancy status cannot be established, the prescriber and/or practitioner must document the justification for continuing with the procedure

## 4.0 Scope

This policy applies to any radiography, fluoroscopy or computed tomography examination involving irradiation between the diaphragm and symphysis pubis and to any radionuclide imaging procedures [1]. Section 6.4.4 applies to all radiotherapy procedures

## 5.0 Roles & Responsibilities

5.1 It is the responsibility of the [Departmental Manager/RSO/RPO/RPA/MPE] *(alter as appropriate for local use)* to ensure that all relevant staff are familiar with this procedure and to ensure that the procedure is adhered to

5.2 **Prescriber:** It is the responsibility of the prescriber to:

- Ensure the procedure is justified and provide the practitioner with all relevant information as part of the procedure request [1]
- State in writing the reason for requesting the particular procedure [3]
- Enquire as to and provide the practitioner with the pregnancy status and date of LMP of women of childbearing age for all ionising radiation exposures where the dose to the fetus is expected to be above 1mGy [1]
- Seek (with the practitioner) where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure [3]
- In conjunction with the practitioner, review the justification for a procedure in the event that a patient is pregnant, might be pregnant or cannot exclude the possibility of pregnancy [1]

5.3 **Practitioner:** It is the responsibility of the practitioner to

- Ensure that the risks of radiation exposure to the fetus are explained to the patient
- Ensure that the patient is asked as to whether she is or might be pregnant and that her answer is recorded in writing [1]
- In conjunction with the prescriber, review the justification for a procedure in the event that a patient is pregnant, might be pregnant or cannot exclude the possibility of pregnancy [1]

5.4 **Operator:** In most cases this will be a Radiographer or Radiation Therapist. In some cases a Radiographer may be present when a Medical Specialist carries out an exam involving ionising radiation and thus becomes the operator. It should be noted that in certain restricted circumstances the operator may be a Medical Physicist or a person authorized to operate a DEXA or Dental system that satisfies the requirements outlined in section 4 of SI 303 [3]. It is the responsibility of the Operator to:

periods are absent or in the case of high fetal dose procedures if the patient's date of LMP does not fall within the last 10 days.

3.12 **Prescriber**:

a) A person whose name is entered on the register established under Section 26 of the Medical Practitioners Act 1978
b) A person whose name is entered on the register established under Section 26 of the Dentists Act 1985
c) A person whose name is entered on the register of nurses as maintained by Nursing and Midwifery Board of Ireland established by the Nurses Act 1985 and who meets the standards and requirements set down by the Nursing and Midwifery Board of Ireland from time to time to allow them to refer individuals for medical exposures to a practitioner
d) A person whose name is entered on such other register or registers as the Minister may, from time to time, establish in relation to persons who are entitled to refer individuals for medical exposure to a practitioner and who meets such other requirements as the Minister may prescribe from time to time

3.13 **Radiation Therapist:** A person who has successfully completed an approved course of training for that category of persons and who is registered with CORU

3.14 **Radiographer:** A person who has successfully completed an approved course of training for that category of persons and who is registered with CORU

3.15 **Rejustification Form:** This form is to be completed by the Prescriber or Practitioner if the patient is pregnant or if pregnancy cannot be ruled out and where the exposure of the fetus is justified

3.16 **Risks of radiation exposure to the fetus:** The radiation dose to the embryo or fetus that is likely to result from any routine diagnostic procedure in current use should present no risk of causing fetal death, malformation, growth retardation or impairment of mental development. Exposure of pregnant women to higher fetal dose procedures may however result in an increase in the risk of childhood cancer compared to those not undergoing a radiation exposure

3.17 **RPA:** Radiation Protection Adviser

3.18 **RSO/RPO:** Radiation Safety Officer/ Radiation Protection Officer

3.19 **Women of childbearing age**: An age range of 12 to 55 years is usually acceptable but should be used with caution

3.4 **High fetal dose procedure**: Any procedure resulting in a fetal dose that is likely to be above 10mGy. The list of high fetal dose procedures is shown in Appendix 1

3.5 **Low fetal dose procedure**: Any procedure in which the fetal dose is likely to be below 10mGy but above 1mGy. The list of low fetal dose procedures is shown in Appendix 2

3.6 **MPE:** Medical Physics Expert

3.7 **Operator**: A staff member (typically a Radiographer/Radiation Therapist or other medical specialist delegated the authority to carry out exposures under article 13, SI 478, 2002) who is authorised to carry out medical radiation exposures on patients

3.8 **Overdue period rule (also known as the 28 day rule)**: The procedure can take place provided the patient's menstrual period is not overdue and the patient has indicated she is not pregnant

3.9 **Postmenopausal:** No periods (amenorrhea) for one year if greater than 50 years of age or for two years if aged less than 50 years (provided there is no hormonal contraception being used) [11]

3.10 **Practitioner**: A Radiologist, Radiation Oncologist or Dentist who is:

a) A person whose name is entered on the register established under Section 26 of the Medical Practitioners Act, 1978 and who meets such other requirements as may be specified by the Medical Council from time to time to allow them to take clinical responsibility for an individual medical exposure

b) A person whose name is entered on the register established under Section 26 of the Dentists Act, 1985 and who meets such other requirements as may be specified by the Dental Council from time to time to allow them to take clinical responsibility for an individual medical exposure

c) A person whose name is entered on such other register or registers as the Minister may, from time to time, establish in relation to persons who are entitled to take clinical responsibility for an individual medical exposure and who meets such other requirements as the Minister may prescribe

3.11 **Pregnancy Status Declaration Form:** Women of childbearing age undergoing a low (see 3.5) or high (see 3.4) fetal dose procedure are asked to complete a Pregnancy Status Declaration Form indicating pregnancy status and date of LMP. This form also has a set of supplementary questions to help establish if pregnancy can be reasonably ruled out. These questions should be completed by a patient if she has missed a period, if

## 1.0 Policy Statement

It is the policy of [hospital name] to ensure that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during the medical exposure of women of childbearing age

## 2.0 Purpose

To outline the procedures to be followed when women of childbearing age are referred and present for a procedure involving the use of ionising radiation within [hospital name]

## 3.0 Glossary of Terms

For the purpose of these procedures, the following terms have the meaning hereby assigned them:

3.1 **10 day rule**: Application of the 10 day rule means that for a patient who has a regular 28 day menstrual cycle, the procedure should be scheduled to take place during the first 10 days of the menstrual cycle. Note: the 10-day rule is primarily a scheduling aid to reduce the possibility of irradiating women who do not know they are pregnant. Use of the 10-day rule in practice means that high foetal dose procedures should be scheduled within this 10-day period however the patient's particular circumstances should be taken into account

3.2 **Clinical Responsibility:** Responsibility regarding individual medical exposures attributed to a Practitioner, notably:

- Justification
- Optimisation
- Clinical evaluation of the outcome
- Co-operation with other specialists and staff, as appropriate, regarding practical aspects
- Obtaining information, if appropriate, of previous procedures
- Providing existing radiological information and/or records to other Practitioners and/or Prescribers, as required
- Giving guidance and information on the risk of ionising radiation to patients and other individuals involved, as appropriate
- Certain aspects of the practical implementation of clinical responsibility may be delegated to the Radiographer/Radiation Therapist or one or more individuals entitled to act in this respect in a recognised field of medical specialisation provided that individual has successfully completed such a course or courses in radiation safety as the Medical or Dental Councils may specify

3.3 **Date of LMP:** Date of the first day of the last menstrual period

| Revision History: | Ver. | Issue Date | Change | Section No |
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