



Public Health
England

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Plenary Session 3 - UK Case Study

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Background

Established framework for pharmaceutical and technology evaluation

- Medicines Act – MHRA, ARSAC
- NICE, HTA
- Government funded centres eg ImPACT
- Government Advisory Committees
- NRPB/HPA/PHE



Introduction

- The Justification of Practices Involving Ionising Radiation Regulations 2004
- Associated guidance on their application and administration June 2015
- Advantages of approach
- Case studies

NB these Regulations and guidance address all practices



The Justification of Practices Involving Ionising Radiation Regulations 2004

Implement Article 6(1), 6(2) and in part 6(5) of Council Directive 96/29/Euratom

Address generic justification of classes of practices involving exposure to ionising radiation

Prohibit

- the addition of radioactive materials to certain goods
- import and export of certain goods
- allow for individual justification of medical exposures where the practice is not generally justified



The Justification of Practices Involving Ionising Radiation Regulations 2004

Regulations are in 8 parts including:

- interpretation and general
- general principles
- applications and determinations
- procedures
- information, consultation and publicity
- personal ornaments, toys and cosmetics
- justification of classes or types of practice involving medical exposure
- enforcement and offences



The Justification of Practices Involving Ionising Radiation Regulations 2004

- identify the Justifying Authority eg the Secretary of State
- set out transitional arrangements
- address new practices, review of existing practices, determination of new practices
- address application procedure and form of applications and decisions
- specify time for determining applications



The Justification of Practices Involving Ionising Radiation Regulations 2004

- provision etc of information
- Inquiries and hearings
- consultation includes HSE, FSA and NRPB/HPA/PHE
- Schedule 1 – Enforcement Powers
- Schedule 2, 3 and 4 – Offences by bodies corporate etc (for UK)



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

- defines justification, a practice, classes or types of practice, the Justifying Authority, existing practices
- explains the process of application
- indicates from whom the Justifying Authority seeks information
- clarifies the decision process (communication, fees, timelines, information on register etc)
- explains enforcement, offences, penalties
- Annex 1 – Principles, Annex 2 – Existing types/classes of practice



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

3 components

- purpose
- classes or types of practice
- lead department



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

Example of types or classes of practice outside medical field:

- component 1 (purpose)
 - generation of electricity by nuclear reactors
- component 2 – (classes or types of practice)
 - operation of Magnox power stations
 - operation of advanced gas-cooled power stations
 - operation of pressurised water power stations
- component 3 (lead Department)
 - DECC



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

Medical Exposure (1):

- purpose – diagnosis (medical)
- classes or types of practice – radiography, fluoroscopy, CT, in-vivo nuclear medicine and in-vitro nuclear medicine
- Lead Department – Department of Health



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

Medical Exposure (2):

- purpose – treatment (medical)
- classes or types of practice – interventional radiology, in-vivo nuclear medicine, teletherapy, brachytherapy, radiography (for planning purposes), fluoroscopy (for planning purposes), CT and neutron activation analysis
- Lead Department – Department of Health



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

Medical Exposure (3):

- purpose – occupational health screening
- classes or types of practice – radiography and in-vitro nuclear medicine
- Lead Department – Department of Health



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

Medical Exposure (4):

- purpose – health screening
- classes or types of practice – radiography and in-vitro nuclear medicine
- Lead Department – Department of Health



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

Medical Exposure (5):

- purpose – medical and biomedical research
- classes or types of practice – radiography, fluoroscopy, interventional radiology, CT, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy, brachytherapy and neutron activation
- Lead Department – Department of Health



The Justification of Practices Involving Ionising Radiation Regulations 2004 - Guidance

Annex 2 – Classes or type of practice existing prior to 13 May 2000

Medical Exposure (6):

- purpose – medico-legal procedures
- classes or types of practice – radiography, fluoroscopy, interventional radiography, CT and in-vivo nuclear medicine
- Lead Department – Department of Health



JOPIIR Guidance – Annex 2

Purpose	Classes or type of practice	Lead department
Diagnosis – medical	Radiography, fluoroscopy, CT, in-vivo nuclear medicine, in-vitro nuclear medicine	Department of Health
Treatment – medical	Interventional radiology, in-vivo nuclear medicine, teletherapy, brachytherapy, radiography and fluoroscopy (for planning purposes), CT, neutron activation	Department of Health
Occupational health screening	Radiography, in-vitro nuclear medicine	Department of Health
Health screening	Radiography, in-vitro nuclear medicine	Department of Health
Medical and biomedical research	Radiography, fluoroscopy, interventional radiology, CT, in-vivo nuclear medicine, in-vitro nuclear medicine, , teletherapy, brachytherapy, neutron activation	Department of Health
Medico-legal procedures	Radiography, fluoroscopy, interventional radiography, CT, in-vivo nuclear medicine	Department of Health



The Justification of Practices Involving Ionising Radiation Regulations 2004 – Advantage of Approach

- provides a general approach for all types or classes of exposures
- addresses new practices rather than variations of existing practices
- has clearly defined process with appropriate consultation
- does not delay unduly the introduction of new techniques



The Justification of Practices Involving Ionising Radiation Regulations 2004 – Case Study 1

Individual Health Assessment using CT

- existing class or type of practice ?
- reviewed by Department of Health with appropriate consultees
- considered to be diagnosis medical (early diagnosis)
- added into application/scope of Ionising Radiation (Medical Exposure) Regulations 2011
 - “the exposure of individuals as part of their own medical diagnosis or treatment including any exposure of an asymptomatic individual”



The Justification of Practices Involving Ionising Radiation Regulations 2004 – Case Study 2

Use of x-rays for sports performance assessment

- not currently a medical exposure (but will be in 2018)
- existing class or type of practice ?
- review by Department of Health with appropriate consultees including COMARE
- process is on-going