2nd PANHELLENIC CONGRESS OF MEDICAL PHYSICS
4-6 OCTOBER 2024| EUGENIDES FOUNDATION

Revamping Radiation Usage Consent Process in the UK: A Case Study from an NHS Radiotherapy Department and its Potential Impact

Marianna Koutrouli[1,2,3]

[1]The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK

[2]IPEM Radiation Protection SIG, York, UK

[3]ICRP Task Group 116, Ontario, Canada

NHS
The Newcastle upon Tyne Hospitals
NHS Foundation Trust

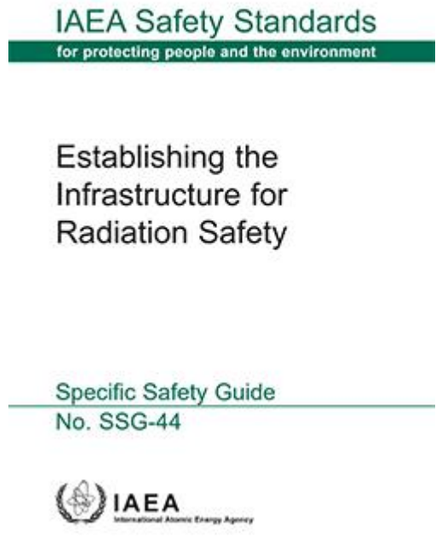
ICRP
INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

IPEM
Institute of Physics and Engineering in Medicine

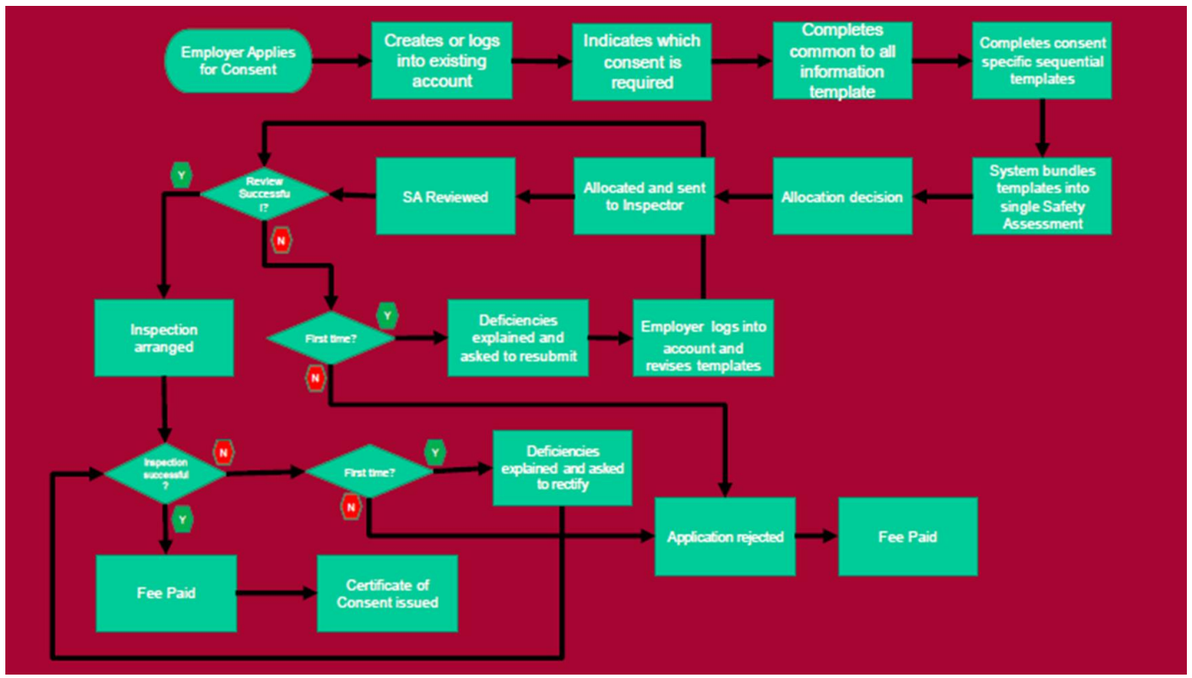
Background

The consent process in the UK for radiotherapy patients was recently updated following a review by the International Atomic Energy Agency (IAEA).

- IAEA IRRS Mission in Oct 2019
  - ➢Assessment of Regulatory framework
  - ➢Improvements required re regulatory oversight & inspection programmes
- Main change in relation to Consent process (Safety Assessment) – All existing consents will need renewal
- This review highlighted the need for stricter guidelines to ensure compliance with both national and international radiation safety standards, especially for the radiation work that involve high doses of radiation.
- These changes align with the *Ionising Radiations Regulations 2017* (IRR17) and Health and Safety Executive (HSE) protocols.
- The case study in this presentation looks at the re-consent process implemented in a radiotherapy department in the UK.
- It examines the possibility of a future trend towards stricter radiation safety guidelines and regulation globally and in Europe, especially as countries like Greece start introducing nuclear power in their energy markets.



Materials & Methods



New consent process – Safety Assessment and Inspection(s)

Preparing for re-consent in our RT department

- Create safety assessment audit template (using relevant templates from Health and Safety Executive - HSE)
- Identify the list of documents to locate and review
- Gather identified documents (and note the ones not there)
- Review the documents and fill in the audit template parts that are covered in the documents
  - essential documents, including local rules, maintenance schedules of safety features and PPE, personal monitoring policies and records, contingency plans, etc. Additionally, informal inspections were carried out to ensure staff compliance with the new guidelines, focusing on personal dosimetry awareness and adherence to local radiation safety rules
- Meet with senior members of RT department and fill in as much info as possible in audit template
- Do an informal “inspection” at the department confirming the gathered information (e.g. contingency plan awareness, proper wearing of personal monitoring) and general IRR17 compliance

Requirements and Contents of Safety Assessment

- Online sequential set of templates – downloadable in advance
- General (common) details
  - Name/address(es)/contact details
  - RPA details
  - Employee numbers (total; Rad W; Class W)
- Summary of work
- Summary of management arrangements
- Details of equipment/radioactive materials; frequency of administration/discharge
- Other sources of radiation exposure including RADON RISK ASSESSMENT (and monitoring)
- Dose rates
  - Within and outside controlled areas (max7.5uSv/hr)
  - Routine and accidents (+contamination levels)
  - Staff & public
  - Effective + equivalent dose rates + annual doses
  - Include dose rates from patients leaving area
  - Dose records required at inspection
- Engineering measures & Design features
  - Shown on sketch map with source(s), shielding and designated areas
- Maintenance & test schedules for above
- Results of Critical Examinations (assessment of the safety features in a designated area and its equipment – upon installation)
- Radiation Monitoring regime
  - Dose rate & contamination
  - Facility & surroundings
  - Equipment, personnel, records, review
  - Records available at inspection
- Details of personal dosimetry
  - Type/Issue period/ADS
  - Personnel monitored/management of process
- Classification rationale
  - Based on routine and potential accident doses
  - Expected by default for HASS, linacs, admin
- RP training provided
  - Staff groups, frequency, refresher
  - Dissemination of Loc Rules & contingency plans
  - Evaluation of effectiveness
- Information re pregnancy & breastfeeding
- Summary of potential accident situations & failure of contingency plans
  - Likelihood & consequences
  - Potential dose to employees & public
- Copies of local rules
- Copies of contingency plans

Consents

Work practices that require consent

- The deliberate **administration** of radioactive substances to people or animals for medical or veterinary diagnosis, treatment or research
- The deliberate **addition of radioactive substances** in the production or manufacture of consumer products or other products, including medicinal products
- Operation of **an accelerator**, except an electron microscope
- **Industrial radiography**
- **Industrial irradiation**
- Working with a **high-activity sealed source (HASS)**
- Working on any facility for the **long-term storage of radioactive waste or disposal of radioactive waste** (including facilities managing radioactive waste for this purpose)
- **Discharging** significant amounts of radioactive material with airborne or liquid effluent into the environment

Work practices that require consent in healthcare

In Radiotherapy:
- **Accelerator work**
- **HASS**

Safety Assessment Audit

The Content of Safety Assessments

The Use of an Accelerator: Continuing Consent

Section	Content	Guidance
1	A general summary of the type of work being performed with the accelerator(s	The employer should provide information on the type of work being performed with the accelerator(s).
2	A summary of the arrangements for managing radiation* protection. (*radiation refers to ionising radiation throughout this document)	The radiation protection responsibilities and duties of management must be specified with clear lines of reporting established. Reliance on the RPS and RPA for the management of radiation protection is not sufficient. Evidence should be provided to show that the applicant manages radiation protection at a senior level. Details of how Radiation Protection Supervisors (RPS) will be given sufficient time and resources to supervise the work so that it done in accordance with local rules should be given.
3	A. Details of the nature of the accelerators being used including the number, manufacturer(s), type(s) and energies of the accelerator(s). B. Information on other sources of radiation exposure that employees operating the accelerators may be exposed to.	A The type of each accelerator must be given together with the energies at which they operate and the energy range(s) of the functioning output beam(s). The total number of accelerators being used should be given and their location within each premises in which they are being used clearly stated. B (i) The results of the risk assessment for radon (ii) Details of other sources of radiation those engaged in work with the accelerator(s) are likely to be exposed to.
4	Estimates/measurements of the maximum radiation dose rates to which employees and members of the public can be exposed and personal dosimetry records • The measured maximum dose rates outside any shielding to which employees and members of the public can be exposed to at each location	The employer must provide estimates or measurements of the dose rates to which employees and others (not including patients where applicable) could be exposed during both routine operations and in the event of any reasonably foreseeable radiation accident. This will include the maximum dose rates outside any shielding to which employees and members of the public are exposed to at each location. These measurements must show that dose rates do not exceed 7.5μSvh^{-1} outside any shielded

0. Documentation

Document	Exists?(Y/N)	Location	Next Review Date	Comments
Trust / Departmental Policies/Procedures etc.				
Trust Radiation Safety Policy (including responsibility framework)				
Classification of Workers Policy				
Radiation Risk Assessments				
Local Rules				
Contingency plans				
Personal Dosimetry Policy/ Procedures				
Environmental monitoring Policy/Procedures				
Contamination monitoring Policy/Procedures				
Local QA Manual				
Departmental Equipment / Area Handover				
Maintenance and Test schedules for safety features				
Radiation Protection Training Policy				
Radon Risk Assessment				
Records (for last 2 years where ongoing)				
Critical Examination Certificates & Reports				
Equipment QA and Maintenance Records				
Radiation Protection training records (all relevant staff)				
Local Rules - signed declarations (all)				

List of identified documents (Policies/Procedures, Records, Other (RPC minutes, etc))

- **Each section from the SA template → to a section in the audit**
- **Identify policies/documents where the info should be in to review – or if not gather info update/create these documents**

10	The rationale for designating for those at work with the accelerators(s) as Classified Persons	The classification rationale for ensuring compliance with Regulation 21 of the IRR17 should be described. Classification is dependent upon routine likely exposures and/or the likely exposures as a result of an accident or incident. In most circumstances HSE and ONR expects those employees directly involved in work with an accelerator to be classified. If this is not the case the applicant must provide an adequate justification.
10	The rationale for designating employees as Classified Persons	The classification rationale ensuring compliance with Regulation 21 of the IRR17 should be described. Classification is dependent upon routine likely exposures and/or the likely exposures as a result of an accident or incident. In most circumstances. HSE and ONR expects those employees directly involved in work with HASS(s) to be classified. If this is not the case the applicant must provide an adequate justification.

10. The policy for designating employees as Classified Persons **(to be completed if not contained within personal monitoring or classification procedure)**

10.1 Briefly describe arrangements for classified workers.

Click here to enter text.

10.2 *In most circumstances HSE expects those employees directly involved in work with an accelerator/in nuclear medicine work to be classified.* Is there adequate justification for the employees that have not been classified?

Click here to enter text.

10.3 Is the classification of workers dependant on the results of risk assessment and routine monitoring and personal dosimetry?

Click here to enter text.

10.4 Is the classification of workers reviewed regularly? When?

Click here to enter text.

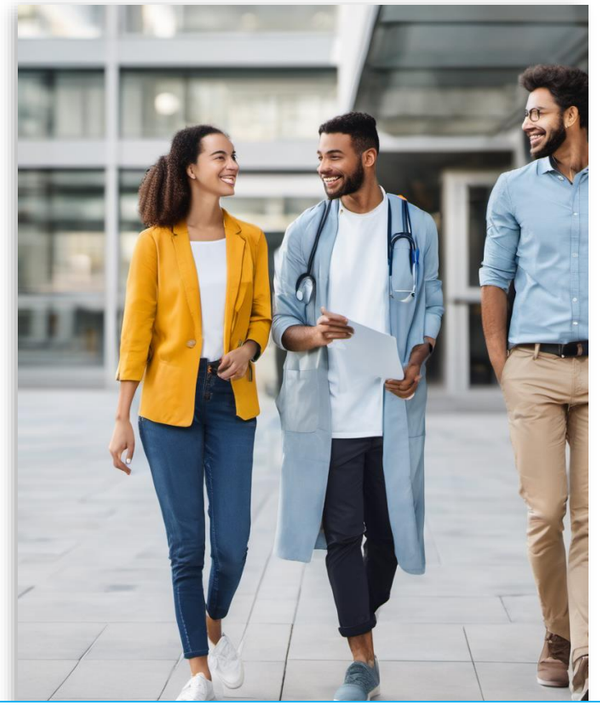
10.5 Are there any classified outside workers who work in the department either routinely or occasionally? If yes, briefly describe the relevant arrangements.

Click here to enter text.

Inspection and Results

Inspection

- Meet with senior members of staff and discuss and complete the missing information that could not be retrieved from document review
- Go around the department and talk to people of all levels and different professional groups (radiographers, engineers, etc)
- Ask and observe
  - Their training and records
  - Awareness of personal dose
  - Awareness of LRs
  - Awareness of contingency plans (especially for high risk areas)
  - Proper wearing of their personal dosimetry
  - Practice in general



10. Classification of Workers

Based on the risk assessment findings, there is no need for classification of any member of
the doses received by them are not expected to exceed a whole body dose level of 6 mSv,
other classification level, both for routine and accidental exposures. Also, certain outside
workers, such as manufacturer representatives who occasionally work in the NCCC radioth
department. However, it should be considered to add certain arrangements for these indi
the LRs of the department. It is, also, worth considering the addition of a brief justificatio
classifying any of the employees, in the risk assessments of the department.

Summary of Recommendations

Action is required to ensure compliance with the new HSE consent system, as detailed below:

- A more detailed list of the accelerators and HASS for Freeman and Carlisle sites: to include the type, manufacturer, energies and energy ranges of all the functioning output beams, for each accelerator; and the type, radionuclide, activity, age of each HASS and frequency that is used should be included in the list, as well as the frequency that is used.
- Radon monitoring of the underground areas of the Trust (including the Radiotherapy department) has been arranged by IPRS and review of the Trust radon risk assessment is due for approval in the next RPC meeting, in December.
- Locate the remaining surveys not already located for accelerator rooms 2, 5, 6, 9 in Freeman Hospital and two Carlisle accelerator rooms. Critical examination reports will only be required from the last two years, but dose survey data is required for all controlled areas.
- Detailed list of the engineering controls and design features should be provided for each controlled area of interest. This list should include the type, numbers and mode of operation of each control.
- Update and enhance room designs in LRs of each accelerator/HASS controlled area to incorporate all the necessary information, specified in section 5.
- Maintenance schedules for HDR safety feature testing, along with records of the corresponding reports, need to be readily accessible for inspections.
- An environmental monitoring policy document with a similar structure with the DR equivalent should be developed for NCCC Radiotherapy.

Result – Report

- List of recommendations and detailed findings for each template section
- Identified documents that should exist but were not found – to be located
- Recommended changes and updates to existing documents
- New documents to be drafted
- Information that needed for the SA but not available in any of the documents/not provided
- Any areas that need improvement as identified through the inspections (e.g. awareness of staff of their required training)
- Other actions departmental/trustwide (e.g. radon monitoring)

Discussion and Conclusions

- The IAEA's inspection of the UK's radiation safety framework highlighted key areas for improvement, particularly in radiation consent processes
- UK radiation safety framework and regulation is already considered stringent compared to other countries
- The IAEA's focus on aligning national regulations with international safety standards suggests that similar recommendations may soon apply to other countries, including Greece and other European countries
- This alignment could lead to a global shift toward stricter radiation safety protocols.
- With Greece considering the introduction of nuclear energy, the country's radiation safety framework may need to expand to cover both healthcare and energy sectors.
- Radiation safety in healthcare, particularly in radiotherapy and nuclear medicine departments, will likely become more stringent to comply with the same laws that govern nuclear energy

Potential Healthcare Impact:

As Greece aligns its safety regulations with international standards, healthcare organisations may need to adopt more rigorous safety measures. This may include more frequent safety audits, enhanced staff training (radiation safety awareness), stricter personal dosimetry monitoring, potential classification of employees, enhanced record keeping, contingency plans planning and rehearsing and more structured radiation safety management.

maria.koutrouli@nhs.net

The Newcastle upon Tyne Hospitals
NHS Foundation Trust

INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

IPEM
Institute of Physics and Engineering in Medicine