

Regulatory update

- HSE issues
 - HSE inspections
 - Consent system – current approach, purpose of review, consultation, proposed system
 - Classification of workers
 - Designation of controlled and supervised areas (X ray and radionuclides)
- Other regulatory updates



HSE inspections – expected!

Inspections may be proactive (e.g. on basis of Consents) or reactive (following an application for a new Consent, reportable incident/accident or notifiable spills/releases)

Documentation may be requested to be sent prior to inspection

During the inspection, the inspector may

- ask about the workers and what they do
- look at any possible health risks arising from the work being undertaken
- look at any radiological facility or equipment that you have
- ask to see records or other documents
- take photographs/videos
- speak with employees or safety representatives

=> Feedback session *Hard line approach!*

Notice Type	Issue Date	Local Authority	Main Activity
Improvement Notice	20/12/2018	Liverpool	HOSPITAL ACTIVITIES
Improvement Notice	23/01/2019	Edinburgh UA	BIOTECHNOLOGY R&D
Improvement Notice	23/01/2019	Edinburgh UA	BIOTECHNOLOGY R&D
Improvement Notice	23/01/2019	Edinburgh UA	BIOTECHNOLOGY R&D
Improvement Notice	04/02/2019	Derby City UA	HOSPITAL ACTIVITIES
Improvement Notice	15/03/2019	Carlisle	VETERINARY ACTIVITIES
Improvement Notice	15/03/2019	Carlisle	VETERINARY ACTIVITIES
Improvement Notice	15/03/2019	Carlisle	VETERINARY ACTIVITIES
Improvement Notice	20/08/2019	City of London	HOSPITAL ACTIVITIES
Improvement Notice	20/08/2019	City of London	HOSPITAL ACTIVITIES

	Notice Type	Issue Date	Local Authority	Main Activity
board	Improvement Notice	11/11/2019	Cardiff UA	GENERAL PUBLIC ADMINISTRATION
board	Improvement Notice	11/11/2019	Cardiff UA	GENERAL PUBLIC ADMINISTRATION
ews	Improvement Notice	15/06/2021	Fife UA	HIGHER EDUCATION
yde	Improvement Notice	09/09/2021	Glasgow UA	FIRST-DEGREE LEVEL HIGHER ED
rust	Improvement Notice	11/11/2021	South Norfolk	HOSPITAL ACTIVITIES
sity	Improvement Notice	10/12/2021	Newcastle-upon-Tyne	FIRST-DEGREE LEVEL HIGHER ED

HSE enforcement actions...

General insufficiencies and failures in:

- risk assessment
- local rules/key working instructions
- contingency plans and rehearsals

Examples of more specific failures...

- No readily accessible means of terminating X ray beam in an emergency
- Inappropriate dosimetry (collar for eye doses) and no review
- No RA for override of X ray interlock, in-house maintenance X ray/CT system
- Access to CAs from public corridor
- Unsuitable storage for sources and waste
- Classification issues (later slide)

Etc, and those are only the improvement notices!

Coming changes... Consent under IRR17

Current approach and purpose of review

Current approach

- Risk assessed, proportional approach under IRR17 for all work
- Specified practices requiring Consent (licence) under IRR17 for higher risk work
- List of questions online, completed by responsible person, confirming essential compliance points
=> automatic issue of Consent (£25)
- One Consent per practice (single consent for similar work in different departments)
- Managed by Radiation Team, Safety Office (as for EA Permits)

Purpose of review

- IAEA review of UK regulation by Integrated Regulatory Review Service (invited, peer review)
 - Identified improvements in (mainly) safety regulation
- ⇒ changes to Consent for higher risk work – greater scrutiny
- ⇒ proactive inspection regime with the intention that every facility working under a Consent is to be inspected

IAEA mission observation and recommendation for the changes to the Consent process

Observation	Recommendation
Regardless of the regulatory process followed, applicants are never required to submit a safety assessment to the regulatory body. Thus, safety assessments are not submitted and subsequently assessed by the regulatory body prior to the granting of the authorisation.	R11 The ONR, HSE and HSENI should request the applicants seeking authorization for the safety significant activities and facilities to submit a safety assessment in accordance with IRR17, which should be reviewed before granting the authorization. When deemed necessary, the ONR, HSE and HSENI should be able to impose limits, conditions and controls on the authorized party's subsequent activities.

The University of Cambridge holds the following certificates of Registration and Consents

(these apply across all sites, even remote sites)

One **Registration** which covers the majority of “lower risk” University work

- All University work with radioactive materials and NORM (above certain concentrations)
- All University work with radiation generators (except accelerators and X ray irradiators which are covered by Consents)

Consents held by the University for higher risk work

- The deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products
- The deliberate administration of radioactive substances **to people or animals** for medical or veterinary diagnosis, treatment or research
- Working with a high-activity sealed source (HASS) (except for industrial radiography or industrial irradiation purposes)
- Industrial irradiation – this includes X ray irradiators used for research
- Operation of an accelerator (except when operated for industrial radiography or industrial irradiation purposes and except an electron microscope) - this includes the Linac and cyclotron

Consents we do NOT currently hold

Industrial radiography

- Although equipment designed for industrial radiography (taking of a image) is used in the University, HSE confirmed that the application was not classed as industrial radiography so Consent is not needed (however, this may change depending on HSE view!)

Operation of a facility for long-term storage or disposal of radioactive waste

- Although the Safety Office has a decay storage facility, HSE confirmed they did not intend this Consent to apply to smaller operators' waste stores, and is only intended for a very small number of significant waste handling sites around the country

Discharging significant amounts of radioactive material

- This applies to discharge (gaseous or as liquid effluent) above certain limits which vary for different radionuclides, but Consent is not needed for current work (but some work, e.g. O-15 and Zr-89 may require this Consent in the future)

Current questions for Consent

C1. Have you implemented an appropriate programme of monitoring or auditing of arrangements to check compliance with IRR17 for this practice?

C2. Has a manager with appropriate authority been identified and named as having overall responsibility for radiological protection for this practice?

C3. Has a radiation risk assessment been completed that has identified, where relevant:

- ways in which reasonably foreseeable radiation accidents could occur and the likelihood and potential severity of them;
- engineering control measures and design features in place, or planned;
- planned systems of work;
- estimated radiation dose rates to which anyone can be exposed and the action needed to keep doses as low as reasonably practicable?

C4. Where appropriate, will the management of any radiation source no longer used ensure that exposures to employees will be restricted so far as is reasonably practicable?

Cont...

C.5 Where appropriate, will the management of any radioactive waste ensure that exposures to employees will be restricted so far as is reasonably practicable?

C6. Do the engineering controls, design features and safety features of the facility and/or radiation sources restrict exposures to ionising radiation so far as is reasonably practicable?

C7. Are the engineering controls, design features and safety features of the facility and/or radiation sources properly maintained and, where appropriate, are thorough examinations and tests of these carried out at suitable intervals?

C8. Have contingency plans for all reasonably foreseeable radiation accidents identified in the radiation risk assessment been drawn up and, where appropriate, are rehearsals carried out at suitable intervals?

C9. Have you appointed and consulted a suitable radiation protection adviser (RPA) for this practice?

C10. For those employees engaged in the practice:

- Have they received appropriate training in radiological protection?
- Have they been informed and instructed regarding the radiological risks to their health from the practice and the precautions that should be taken?
- Will they receive updates/refresher training in radiological protection at appropriate intervals?

C11. Have those employees not engaged in the practice but who are likely to be affected by it received appropriate training, information and instruction in radiological protection and do you repeat this at appropriate intervals?

C12. Where appropriate, are suitable and sufficient quality assurance programmes in place for equipment used for medical exposure?

And various questions on doses...

Cont...

Consent under IRR17

Proposed system

Safety assessment (SA)

- Radiation Risk Assessment and Local Rules will form **part** of a safety assessment
- Other elements will be on sustained compliance
 - Management of the risk
 - Life cycle of the activity
 - Roles and responsibilities etc
- Much more detailed information will need to be supplied to HSE for all Consents
- HSE intend to review documentation (and may visit?) prior to issuing new Consents
- Significant additional resources needed (and cost of implementing)

Accelerator example

2

A general summary of the type of work to be performed with the accelerator(s) and the location(s) at which the practice is to be performed

The employer should provide information on the type of work to be performed with the accelerator(s). Where the accelerator(s) is to be used on small discrete premises a simple postal address will suffice. If the premises are larger, a postal address together with their location within those premises should be provided. If the applicant will be using accelerators at different premises those premises need only be separately specified if they have different postcodes but their location within those premises must be given.

Accelerator example

cont...

4

Details of the nature of the sources of ionising radiation to be used, or likely to be present including

- **Number, manufacturer(s), type(s) and energies of the accelerator(s)**

The manufacturer and 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.

Accelerator example

cont...

5

Estimates of the radiation dose rates to which anyone can be exposed

- The maximum dose rates outside any shielding to which employees and members of the public can be exposed to at each location
- The maximum dose rates which employees and members of the public can be exposed to at each location if an accident occurs
 - All of the above should include all relevant exposure categories – effective dose, equivalent dose (extremities, skin, eyes)
 - Estimates of annual doses in all relevant categories for employees and other persons.

The employer must provide estimates 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 7.5mSv h^{-1} outside any shielded enclosure. In all cases, all the relevant exposure categories (effective dose, equivalent dose [extremities, skin, eyes]) must be given as well as measurements or estimates of annual exposures in all relevant categories to employees, other persons and members of the public. Evidence that these are ALARP must also be given.

Accelerator example

cont...

6

A summary of the engineering control measures and design features already in place, or planned, to comply with the requirements of IRR17 Regulation 9 (Restriction of Exposure), associated with the work practice

- **Type and number of engineering control measures**
- **A plan of all the enclosures and their location within the facility**
 - **Includes location of interlocks, control panel(s) and other safety features. Includes shielding details.**

Engineering control measures and design features include but are not limited to mechanical and electrical interlocks, motion detection equipment, control panels, emergency stop arrangements, maze entrances, access restriction or prevention measures, photo-electric guards and video equipment. In all cases their type and numbers and mode of operation should be given and their location marked on a plan of the facility(s) and enclosure. The plan(s) must also show the type, nature and thickness of any radiation shielding and the location of the accelerator(s)

Our new office...



Be ready for HSE inspections ... and the new Consent system

Keep a safety management file with all information relating to the work/equipment – this might include (where relevant)

- A general summary of the type of work being performed with the accelerator(s) and the location(s) at which the practice is being performed
- Radiation protection policy and arrangements
- Risk assessments and local rules
- Details of the nature of the sources of ionising radiation to be used, or likely to be present
- Estimates of the radiation doses for the activity
 - Assessed/measured values
 - Dosimetry records - issue periods, approved dosimetry services, classification justification
 - Monitoring records - Overview of this and results
- A description of the engineering control measures and design features
 - Overview of engineering controls – type and function

Already cover many aspects of
safety assessment

Cont...

cont...

- Overview of the maintenance and tests schedules
 - Frequency , SQEP carrying these out
- Information on and results of Critical Examinations
- Information concerning the radiological protection training
 - Planned frequency and refresher training
- Information supplied to female employees concerning their work with ionising radiations in connection with pregnancy and breast feeding
- Possible radiation accident situations
- Details of the steps taken to prevent identified accidents and limit their consequences should they occur
 - Tools and training required, frequency of rehearsals

Be ready for the new Consent system

Other HSE issues...



Classification

An employer must designate as **Classified Persons** those likely to receive:

- an effective (whole body) dose > 6 mSv per year, or
- an equivalent dose > 15 mSv to the lens of the eye, or
- an equivalent dose > 150 mSv to the skin or extremities

Currently, based on reasonably foreseeable accidents relating mainly to the risk of skin contamination and potential skin doses, HSE expect classification of employees who

- Work in radiopharmacies or
- Dispense or administer radionuclides to humans or animals
(unless strong justification)

This is HSE's view on the basis of a limited number of reported accidents nationally

Classification is unlikely to be needed for other radiation work (including higher risk X ray work), but needs to be considered as part of the risk assessment

Other HSE issues...

Designation of controlled and supervised areas

X or gamma ray facility (where contamination is not applicable) – normally designate as a controlled area if

- The external dose rate in the area exceeds $7.5 \mu\text{Sv}$ per hour when averaged over the working day or
- The hands of an employee can enter an area and the 8-hour time average dose rate in that area exceeds $75 \mu\text{Sv}$ per hour

ACOP 17(1)

And (guidance*) if instantaneous dose rate exceeds $100 \mu\text{Sv}$ per hour

* Guidance = “good practice”, not compulsory, but if you follow the guidance you will normally be doing enough to comply with the law

Designation of controlled and supervised areas

For an X or gamma ray facility...

If an area is non-designated on basis that it is impossible to enter (body or only hands can enter), we need to justify the **QUALITY** of control measures – fail to safety under single fault conditions?

This is HSE's response to problems nationally relating to equipment designs, including:

- failure of interlocks
- failure to terminate X ray beam in timer mode
- failure of emergency stop
- failure of warning lights...

Other regulatory updates

Environment Agency

- Gillian Ingham has retired
- Alasdair FitzSimons-McKellar will be inspecting university sites – familiarisation visits and many inspections due!

CTSAs – various inspectors

Safeguards (later)

Office for Nuclear Regulation is actively inspecting universities – inspections of transport arrangements... (later?)

Any questions...?

