Health and Safety Executive

CD282: Consultation on the implementation of Directive 2013/59/EURATOM

-

Laying down of basic safety standards for protection against the dangers arising from exposure to ionising radiation

Questionnaire reply form

Completing this questionnaire

You can move between questions by pressing the 'Tab' / 'Shift-Tab' or 'Page Up' / 'Page Down' keys or by clicking on the grey boxes with a mouse. Please type your replies within the rectangular grey boxes, or click on the square grey boxes to select an answer (e.g. 'Yes' or 'No').

Respondent's details:

Name:	The Institute of Physics and Engineering in Medicine (IPEM), the Royal College of Radiologists (RCR), the Society and College of Radiographers (SCoR), the British Institute of Radiology (BIR)
Email:	markknight@nhs.net; consultations@rcr.ac.uk; MariaM@sor.org; peter.hiles@wales.nhs.uk
Town / City:	N/A
Telephone:	IPEM - 01622 225005; RCR - 020 7405 1282; SCoR - 020 7740 7240; BIR - 020 3668 2220

Job Title:	N/A
Postcode:	N/A
Street address:	N/A
Organisation:	Institute of Physics and Engineering in Medicine, The Royal College of Radiologists, Society and College of Radiographers, The British Institute of Radiology
Fax:	

What is the size of your organisation?

Choose one option:

Not applicable	☒	1 to 9 employees	☐
10 to 49 employees	☐	50 to 249 employees	☐
250 to 1000 employees	☐	1000+ employees	☐
Self-employed	☐		

Which sector are you from?

Choose one option:

Academic	☐	Charity	☐
Consultancy	☐	Industry	☐
Local government	☐	Member of the public	☐
National government	☐	Non-departmental public body	☐
Non-governmental organisation	☐	Pressure group	☐
Trade association	☐	Trade union	☐

If you chose 'Other' please specify:	Medical Sector

In what role will you be answering these questions?

Choose one option:

An employer	☐	An employee	☐
Health and safety professional	☐	Trade union official	☐
Training provider	☐		

Other – please specify:

A group of professional bodies in the medical radiation sector

Confidentiality

Please indicate below whether your comments can be made available to the public or if you want them to be confidential. (NB if you do not indicate your choice they will be made available to the public. This takes precedence over any automatic notes on e-mails that indicate that the contents are confidential.)

Public	☒
Confidential	☐

BSSD Consultation Questions

Q 1. Should HSE implement the Directive as proposed?

Strongly agree	☐
Agree	☒
Neither agree nor disagree	☐
Disagree	☐
Strongly disagree	☐

If you disagree, could you please state why?

Whilst we largely agree with the implementation of the Directive as proposed, we believe that some changes should be made.

Q 2. Do you have any comments on the draft 'Ionising Radiation Regulations 2017', Annex (i) Or those key requirements at Section 10, for example?

If yes please provide details.

Annex (i) by regulation number;

Reg 5

Guidance as to which types of practice would require only notification would be welcome.

Reg 6

Where an employer has a Nuclear Medicine practice (licensed under Reg 7), it is not clear as to whether they would also require a registration for the small sources used for QA and calibration purposes? Or are these small sources included as necessary to the licensed practice? This applies to both Nuclear Medicine and Radiotherapy.

Registration: In the UK, there are organisations which offer radiation exposure (low dose) to asymptomatic individuals for non-medical reasons e.g. measurement of fat composition using DEXA. Obviously, these organisations need to be registered with HSE but, as some of the practices they offer are not justified under JOPIR, how can public protection be assured.

Reg 7

Key Points

(4)(d, e, g) These are duplications of requirements under the HASS regulations and EA registration. Is it necessary to duplicate?

(5) When the HSE decides on what the conditions are, we consider they should consult. It is important that this is done quickly if employers have to demonstrate compliance with the conditions in order to secure a licence before the IRR17 regulations come into force.

(2(h)) What is a significant amount – does that mean non-negligible? If this is the basis for licensing an activity does it not have to be formally defined? Is the discharging of liquid waste arising from Nuclear Medicine a separate practice to the deliberate administration of radioactive substances?

(3) In order for the HSE to grant a licence for HASS, why does HSE not solely require evidence of compliance with the HASS regulations in the form of CTSA approval and an EA registration certificate or permit?

(4) More clarity is required, specifically;
(a) Whose responsibilities?
(b) Competency to do what?
(c) Define performance criteria
(f) Maintenance of the source itself?

(4)(d, e, g) These are duplications of requirements under the HASS regulations and EA registration. Is it necessary to duplicate?

(5) When the HSE decides on what the conditions are, we consider they should consult. It is

important that this is done quickly if employers have to demonstrate compliance with the conditions in order to secure a licence before the IRR17 regulations come into force. There could be a lot of work involved in meeting the conditions necessary to obtain a licence: would this effort be proportionate? Will it be used by the HSE in ensuring ongoing compliance and suitability to hold a licence for the practice?

(6) Regarding schedule (2); Staff competencies to do what?

Based on a Q&A session during an HSE Webinar a question revealed that there is the potential to need multiple licences for one site which again will be onerous and costly. *(26. Question: If a practice falls under two licensing categories, which one do you apply for a licence under? E.g. nuclear medicine falling under the deliberate administration to persons and practices discharging significant amounts with liquid effluent. Answer: That's two practices therefore two licences will be required.)* Following this logic, a site with a cyclotron, a radiopharmacy, a nuclear medicine department, discharging "significant amounts" of liquid effluent and having a source store/decay store (depending on what is meant by a facility for long term storage of radioactive substances) would need five licences. In addition to IRR, they would also need an ARSAC license under new IRMER and EPR/RSA permits/certificates as well. If these also need annual renewal this could be time consuming and costly.

In ACoP there is the requirement that when heading back into a room where an HASS has been used that a dosemeter with an audible alarm must be worn. This may affect HDR brachytherapy work and any other uses of HASS around the health service/medical physics services (ADSs, monitor calibration facilities) if they have not previously been using real-time electronic dosemeters and therefore an increased cost for purchase and calibration.

This is a good way forward, but there is concern about the "policing" of such licenses. Will HSE undertake more inspection visits or will this purely be based on trust and honesty?

Reg 9

(6a) What does 'during **at least** the remainder of the pregnancy' mean?
(6b) Is it for the employer or the regulations to define 'significant'.
(7) Does the pregnancy declaration need to be in writing? Regulation 15(c) states 'in writing', would it be helpful for this to be replicated here?
Consistency in approach is needed. However, is it necessary to specify in the legislation that the declaration must be in writing? Is that not something for ACOP or guidance?
ACoP 71; Experience elsewhere has suggested that it is beneficial to have this as ACoP for ensuring staff compliance.
ACoP 81; We agree with this deletion.
ACoP 83; Experience has shown that having reference to the ease of cleaning and decontamination of a surface is advantageous at the design stage. Retain ACoP as it is. This is as much a practical measure as was retained in ACoP 96 and 97.

Reg 10

(2) welcome additional text

Reg 12

(3) Clarity on the term average effective dose is required - is it the ensemble average to a critical group? Is this duplicating EA regulations?

Reg 13 Contingency plans
The definition of a radiation accident is here linked to the need to enact the contingency arrangements. Does that then mean that many "contingency plans" enacted for very minor incidents (e.g. small spills of activity) should not be classed in local rules as contingency plans? Perhaps this could be clarified in ACOP or guidance? Does this also mean the HSE proposes to link notification of a "significant event" with the requirements to keep records of an accident scenario and thus the contingency plans? (although the requirement for notification does not seem to feature in the draft regulations)
Also concerned about the impact of a potential requirement to issue with suitable dose meters or other devices, in either case from an "approved dosimetry service" (this is not always the case locally e.g. Electronic personal dosimeters, EPD, for instant feedback). It could also be considered as not proportionate for many low risk scenarios.

Reg 14
ACoP 232; we agree with the deletion here.

Reg 15
Key Points
2(a-c); these are duplication of EA requirements. Is this necessary?
It would help to have more clarity as to what is expected for non-classified workers and how HSE would envisage it being demonstrated.

Guidance would be welcome on how often training should be provided and what the HSE would regard as proportional. Could this be included in the IRR17 guidance?
a(ii) and (d) seem to be two different ways of saying the same thing – could the intended difference be clarified?
2(a-c); these are duplication of EA requirements. Is this necessary?

It would help to have more clarity as to what is expected for non-classified workers and how HSE would envisage it being demonstrated. For example, for a radiation protection department or company working at multiple employers, how do they demonstrate they have received sufficient training for each employer's controlled area? Do they have to have read and sign every set of local rules? Is a local rules summary sufficient etc.?

Reg 16
2(a) Should 'the medical examination prior to employment' be defined somewhere in regulation 25?
(3) Should the employee themselves be on this list? Experience has shown they have a pivotal role in the exchange of information.

For the first time there may be the situation that RPAs have a responsibility under the legislation (to share dose information). Up until now RPAs have only provided advice.

There is agreement with this proposal on the basis that temporary radiographic staff are often employed by various Agencies.

Reg 17
Key Points

ACoP 248(a); If a Controlled Area needs to be defined where the Instantaneous dose rate (IDR) is > 7.5µSv hr^{-1} this will have a significant effect on healthcare.
3(b); why is the supervised area eye dose limit one third of the member of the public dose limit?
ACoP 248(a); If a Controlled Area needs to be defined where the IDR is > 7.5µSv hr^{-1} this will have a significant effect on healthcare. As it stands in IRR99, many healthcare facilities have areas in which the IDR > 7.5µSv hr^{-1} but there is no need to designate a Controlled Area because there are no employees untrained in radiation protection entering that area. The removal of the clause relating to employees untrained in radiation protection means a Controlled Area must be designated in all cases. This regulation should clarify how intermittent exposures are covered.
Having to control areas beyond the walls for existing installations will be difficult to manage in the short term and the remedial actions required in the short to medium term will be very expensive and will have an effect on the provision of treatment to patients (i.e. equipment will need to be taken out of use whilst building works are undertaken). The 7.5uSv/hr value does not compute to a reasonable annual dose limit for continuous irradiation, since over 2000 hours one would get 15mSv rather than the limit of 6mSv given in the regulations themselves.

Adopting the standard in the IRR99 ACOP of 7.5µSv hr^{-1} averaged over a working day would reduce the impact of this provision.

The 7.5µSv hr^{-1} IDR requirement for a Controlled Area is not in the BSSD. This draft therefore appears to go over and above the requirements of the BSSD and it would be helpful to review whether this is consistent with government policy.

A shielding contractor has estimated that or a modern Flattening Filter Free radiotherapy bunker there would be an additional £76,000 cost per primary barrier (potentially both walls, floor and ceiling) to the build due to the 7.5µSv/h IDR requirement.

Consider combining (a) and (f) for clarity; i.e. the external dose rate in the area exceeds 7.5 microsieverts per hour unless the only work with radiation involves a radioactive substance dispersed in a human body, where the dose rate exceeds 7.5 microsieverts per hour'.

248(c); is 'significant' likely to be open to wide interpretation here?

Reg 18
5(c); we support this inclusion.

It would be helpful if there was guidance about the number of radiation protection supervisors within a department – is there a maximum number of employees that each RPS "polices")? It is also encouraging that part C is included in this Regulation which should ensure that RPS duties are part of a job plan.

Reg 19
(3) 'Specific training' in this context could have a significant effect on healthcare. In the case where a manufacturer's representative comes to demonstrate something used in conjunction with x-rays (i.e. a new catheter, contrast agent, contrast pump) does the employer refuse access unless they can provide evidence their employer has provided specific training, or does the employer need to spend time providing this training before they can attend a procedure? Is this proportionate to what could be a very short length of time in a Controlled Area?

This will have financial implications on one or both employers if it is necessary to provide training. It will have clinical implications if representatives are no longer permitted to attend and demonstrate improvements.

Why is direct supervision of the non-classified outside worker by local staff no longer adequate?

Personal monitoring should be undertaken for non-classified individuals based on risk assessment. A requirement for robust environmental monitoring should be in the Regulation, ACOP or guidance.

Reg 20
Key points
(2a) Dose rate has been defined in Regulation 2 as measured over one minute – it does not seem compatible with this definition to then allow the dose rate to be averaged over a suitable period in this regulation.

(2a) Dose rate has been defined in regulation 2 as measured over 1 minute – it does not seem compatible with this definition to then allow the dose rate to be averaged over a suitable period in this regulation.
Further, how can this be measured in areas where very low exposure times are encountered? These cannot be measured by any reasonably available dose monitor.
Is it acceptable to use in-beam measurements and estimate the likely surrounding dose rates by calculation? If passive monitors are left for extended periods they can only be averaged over a period of many hours (akin to TADR or TADR2000) and so are not compatible with the definition of dose rate in regulation 2.
Some guidance on what would be acceptable is required.

ACoP 348; The ACoP should not state 'must be tested at least annually' then also state that equipment may require testing more or less than that frequency. Either make a requirement for it to be tested and allow local decision through Risk Assessment or specify annually if there is sufficient reason to do so.

Reg 21
ACoP 376 – We agree that the ACoP should be reworded to provide clarification. This paragraph only considers effective dose rate. Should this be extended to equivalent dose rate to consider the need for classification in a new post on the basis of eye dose and extremity dose?

This is an example of where the ACoP finds it necessary to clarify what 'significant' means. The regulations and ACoP have many other uses of the word 'significant' where no such clarification is offered.

Reg 22
We support the change in record keeping from 50 to 30 years.

Reg 23
We support the move of ACoP 415 to guidance.

Reg 24
ACoP 420 – Text indicates that this paragraph is being redrafted, therefore, we are unable to comment. It is important that there is consultation on the redrafted wording when it becomes available since it could be used in enforcement action.

We support the move of ACoP 421 to guidance.

Reg 25
Key points
Will workers who have been classified due to eye doses have eye tests? If so the appointed doctor may not be appropriate to carry this out. There is also a lack of appointed doctors across the UK.

We support the move of ACoP 446 and 447 into the regulation as required by the Directive. We support the deletion of ACoP 448 and 466.

Will workers who have been classified due to eye doses have eye tests? If so the appointed doctor may not be appropriate to carry this out. There is also a lack of appointed doctors across the UK. Further guidance to the appointed Doctors on what medical examination should be performed may also be required.

Reg 29
We agree with the inclusion of theft to this regulation.
ACoP 494: we agree with the deletion.

Reg 31
Will the way this Regulation is presented be affected by SEPA making considerable changes to their own authorisation framework (consultation is concurrent with this one)?

Reg 32
ACoP 522: state that the existing ACoP will be moved to the Regulation; this does not seem to have been the case.

Reg 33
Approximately half of those questioned are in favour of Regulation 33 remaining in IRR17 instead of moving to IRMER. They think that the requirement for patient dosimetry should move to IRMER.

Reg 35
Key point
We would strongly request the inclusion of an explicit duty on the employee to wear any dose meter that is issued to them by their employer (when wearing them is a reasonable requirement)
It would have been operationally useful to explicitly state that Regulation 35 applies to non-classified workers in ACOP or guidance.
Schedule 3
Key point
From previous communication with HSE it was our understanding the subsidiary dose limit for a "woman of reproductive capacity" was to be removed but it is still in the

draft.
The removal of this subsidiary dose limit would be accepted as it is not part of BSSD and is not used in practice

General comments
It is felt that explanation of certain key terms could be improved; e.g. what is viewed by HSE as "significant"?

Q 3.1 Do you think that the proposed changes make the revised ACoP:

More easy to understand than the current ACoP?	☐
Less easy to understand than the current ACoP?	☐
About the same to understand as the current ACoP?	☒

If not, which parts are not clear and why?

Only worry is that some requirements being moved into "guidance" – is this going to be non-statutory guidance? If so, perhaps it would be seen as being less important. Example for 272 Reg 17(1)

Regarding 114 Reg 8(2) – other professional body PPE guidance should be cited as well as the HSE guidance.

362 Reg 19(4) – it is important that environmental monitoring is properly undertaken when personal dosimetry is not routinely offered for non-classified workers.

538 Reg 32(3)-(4); 539 Reg 32(3)-(4); and 540 32(3)-(4); – the points about a QA programme are still important and should be retained in regulation.

Q 3.2 Are there any impacts from revision of this ACOP that we should be aware of?

ACoP 248(a) and the requirement to designate a Controlled Area where the IDR exceeds 7.5µSv hr^{-1} regardless of whether those entering the area are trained in radiation protection or not will have significant operational and financial implications in healthcare across all modalities (i.e. Radiotherapy, Nuclear Medicine and Radiology (including dental)). As it is currently written, this will have a significant effect on the cost estimates in the Impact Assessment (which will be significantly increased).

The medical sector has repeatedly asked that the intermittent nature of X-ray generator workload be considered in the new regulations where this IDR is simply not helpful. Does the fact that the dose rate is not specified within the Directive make this "gold plating"?

ACoP 348; It depends on how this is written in its final form. At present, the ACoP states that monitoring equipment 'must be tested at least annually'. For some equipment used in low-risk areas this is likely to be too frequent which will lead to an unmerited additional cost. Costs will be proportionate if it is left to the employer and their RPA to assess how often the equipment should be tested.

ACoP 420 – It is important that there is consultation on the redrafted wording when it becomes available since it could be used in enforcement action.

Agency staff are frequently employed in the medical sector. There may currently be a degree of weakness in the dialogue between employees of other employers (the locum agency) and the hospital. Dialogue should have been happening anyway, but with the previous directive only concentrating on classified workers, this may need to be a change in culture.

ADS for the lens of the eye. It is mentioned in the document that there will need to be a significant improvement in the provision of this service. However, this will need to be implemented quickly and may be challenging within the timeline for legislation implementation.

P16 81 Reg 8 (2) seems ok to delete this reference to direct visualisation of fluoroscopy screens (do any still exist in medicine?)

Q 4. HSE is intending to implement changes to IRR on the 1st January 2018, which is 5 weeks earlier than the expected EU implementation deadline. See para 22 for the full reasons for this decision. Should HSE implement IRR on the 1st January 2018? If not, please give details.

Yes	☒
No	☐

If No, please state why ?

Yes. Implement the new IRR on 1st January 2018. However, be aware that lens of the eye ADS provision may take time to catch up.

The following questions relate to the cost estimates described in Chapter 2 of the Impact Assessment at Annex (ii)

Q 5.1 Additional costs arising from changes to the eye dose level

Does your organisation expect to classify any additional workers as a result of the proposed change in the classification level for eye doses from 45 mSv to 15 mSv?

Yes	☒
No	☐

If so, approximately how many? Please select:

Nil - 2	☐
2 - 5	☒
5 - 10	☐
10 - 15	☐
15 – 20	☐
20+	☐

Q 5.2 Does your organisation expect to implement any additional control measures to reduce eye doses in order to comply with the proposed 20 mSv eye dose limit?

Yes	☒
No	☐

If so, what types of controls? Please provide details of the likely costs of implementing these controls. Include where possible: purchase costs, installation costs, staff time, contractor costs.

IPEM has no employees working directly with ionising radiation, however it is aware that in diagnostic radiology departments across the UK, they will have to purchase at least one pair of lead glasses per interventional radiologist/cardiologist with a reasonable workload. Some staff members will require two pairs - prescription/non prescription. Prescription pair

will need updated with changes in eyesight.

Cost of shield:
- Secondary shields are likely to be required in interventional rooms on opposite side of table This has an indicative cost of 2 x £4000 if not installed during room installation/refurbishment additional installation and down time cost.

Existing theatres may have to be retrofitted for shields;
- Indicative cost of £7,200 to retrofit
- Estates time to visit theatre to assess suitability of installation involving Theatres,
- Vascular/Interventional Consultants, Theatre management staff, Physicist.
- 2 days Theatre down time – 1 day to retrofit, second day to deep clean.

Cost of Classification process (2-5 staff):
- Admin time 1hr (Senior Clinical Scientist)
- Medical Surveillance - Cost of medical examination
- Workers time to attend medical

Risk Assessment (work prior to installation of shield)
- Meetings with staff to discuss eye doses – 2-3 hours
    - Consultant Interventional Radiologists/Cardiologists/Surgeon
    - RPS Interventional/Theatres
    - Theatre manager
    - Clinical Scientist/RPA
    - Admin staff
- Analysis of eye dose data and workloads for RA Clinical Scientist time – 8 hrs
- Report to Radiation Safety Committee – 4 hrs

Some departments will start some start an audit of staff eye doses.

- Overall there is scepticism about the projected costs and additional PPE for complying with reduced eye dose limit. Additionally, more encouragement of the use of lead screens is required as these are not always deployed.

- The main ‘headline’ change in regulations concern a marked reduction in the classification level for eye dose (from 45 mSv to 15 mSv) and then even greater reduction in the proposed eye dose limit (from 150 mSv to 20 mSv). This will inevitably lead to the classification of at least some interventional radiologists, but potentially also some radiopharmacy workers and PET/CT staff. Further expense will be incurred by monitoring a significant workforce who will now be near to investigational or classification limits, who previously would simply not have been monitored for eye dose. These costings are underestimated.

- Furthermore, of note is also the increasing awareness of association of brain tumours by interventional radiologists/cardiologists in the side of the head closest to the radiation exposure. This requires side of head monitoring and a head shield, as the eye shielding alone will not protect.

Q 5.3 Does your organisation expect any impacts arising from the change in eye dose limit or classification level, other than those included in the Impact Assessment?

Yes	☒
No	☐

If yes, please provide describe these impacts and, where possible, quantify the additional costs arising from them.

In cases where a radiology department cannot find funds to install ceiling suspended eye shields, those shields cannot be retrofitted or they prove ineffective in reduce measured eye doses below 20mSv, the cost of employing additional vascular surgeons, cardiologists and interventional radiologists could run to £200K per annum per additional staff member. These additional members of staff would be required to maintain the provision of service.

A shielding contractor has estimated that or a modern Flattening Filter Free radiotherapy bunker there would be an additional £76,000 cost per primary barrier (potentially both walls, floor and ceiling) to the build due to the 7.5µSv/h instantaneous dose rate requirement.

The professional bodies need to ensure that staff are aware that the reduced eye dose may impact on some of their practice – for example interventional radiographers and radiology staff if they are not currently using PPE.

Q 6.1 Additional costs arising from changes to the definition of 'outside workers'.

The BSSD widens the definition of Outside Workers (OWs) to include non-classified OWs. Will the change in definition (i.e. to include non-classified outside workers in the definition of outside workers) have any impacts on your business?

Yes	☒
No	☐

Q 6.2 Please describe and, where possible, quantify, any additional costs that your organisation would incur because of the change in definition.

Regulation 19(3) means that non-classified outside workers will require specific training as outlined in regulation 19(2biii).

The training needs to be pursuant to Regulation 15, meaning it needs to have a component specific to the environment in which they will be working.
If a healthcare employer needs to provide training to every non-classified outside worker that attends there will be a significant cost burden.
Such attendance is a reasonably regular event – manufacturer's representatives will demonstrate their new or improved products during clinical procedures; the NHS will not purchase something it has not seen demonstrated.
If training pursuant to Regulation 15 takes 30 minutes to deliver the true cost burden could be as high as £100 per instance depending on the frequency of delivery. Estimating the number of instances per annum is difficult but could run to 10+ a year.
Is this proportionate to what could be a short length of time in a Controlled Area? Could the spirit of the regulations not be met by ensuring direct supervision of the individual when in the Controlled Area?

Q7 Additional costs from recording and analysing events that cause (or potentially cause) the contingency plan to be enacted (Regulation 13)

Q7.1

Does your organisation currently record and analyse events that cause (or which might potentially cause) a contingency plan to be enacted?

Yes	☒
No	☐

If 'No', approximately how many such additional events would you expect to record annually, if any, in order to comply with the proposed Regulation 13 – Contingency Plans?

The following response is what is found in many hospital Nuclear Medicine departments. "Events are recorded on the Trust eReporting system and subsequently managed and analysed. However incident reporting is not linked to whether a contingency plan is enacted (although they frequently overlap) so additional reporting will be required. It is hard to estimate number of incidents though as already stated in the impact assessment." So in short, we are doing the right thing, but will need to specifically report these issues.

Q 7.2

How much would it cost to record and analyse each specific event? (Please, as far as possible, describe how much time would be required, on average, the job title(s) of staff involved, and the cost of that time (i.e. the wage rate of the person(s) performing the task).)

Difficult to calculate. Dependent on the nature of the incident and whether it is a new or recurring event.

Q 8 Table 4, on page 48 of the Impact Assessment describes the changes to regulations that are not expected to lead to significant costs to business.

What do you think about HSE's assessment of these changes?

Strongly agree	☐
Agree	☒
Slightly agree	☐
Slightly disagree	☐
Disagree	☐
Strongly disagree	☐

If you disagree, please provide more details

Q 9. Do you have any other comments on the assumptions or cost estimates in Chapter 2 of the Impact Assessment for the changes to the Ionising Radiations Regulations?

Regarding estimating the number of workers who will be classified in healthcare as a result of changes to the eye dose limit; the HSE at no point has considered the increasing complexity of interventional procedures in radiology. PHE monitoring undertaken in 2013 or even 2015 might not be a good reflection of eye doses in the coming years. In the same way, the HSE's assessment of its own database may also fail to properly estimate the increased number of classified workers. Regarding the provision of training; current HSE estimates have not taken into account the need to provide training for outside workers under Regulation 19 pursuant to Regulation 15. Missing altogether – the HSE has not considered anywhere the cost of operational downtime and then the provision of additional shielding in healthcare due to the ACoP 248(a) now stating that if the IDR exceeds 7.5µSv hr^{-1} there is a requirement to designate a Controlled Area regardless of whether the staff in that area are trained in radiation protection or not. These costs are hard to estimate, but in Radiotherapy departments alone could run to several

hundred thousand pounds. UK wide, it is likely this will run to millions.

It seems unfortunate that a potential opportunity for some simplification or rationalisation of radiation safety monitoring was not taken, for instance, combining Environmental Agency requirements with these HSE requirements under a single umbrella may have reduced unnecessary duplication, saved time and money, without any detriment to patient safety, or in this case staff/public safety.

Impact assessment 230/231 It is not the case generally in the health service that outside workers in the same way as employees and therefore has the potential for a significant impact when considering the number of cat B outside workers across the sector.

The Graded Approach

BSSD requires the introduction of the Graded Approach to regulatory control, which is a risk-based system comprising of three levels (notification, registration and licensing). The Directive does not explain how the process for practices to notify, register or licence should work but it is implicit the system is robust and informs the system of regulatory control put in place by the Competent Authority. The Directive also allows the Competent Authority to extend the requirement to register or licence to certain practices based on regulatory experience and taking account of the expected/potential doses from the practice.

HSE acknowledges that the following proposals go beyond the minimum requirements of the Directive and have the potential to introduce costs to dutyholders, specifically:

- extending the scope of licensing to ensure that practices that pose the same risks are subject to the same regulatory controls;

- requiring the renewal of registrations and licenses to ensure up-to-date information on which to base our interventions

By proposing this HSE is going beyond the minimum requirements of the Directive but this will allow us to target inspections, provide up-to-date information on dutyholders, ensure the effective operation of the Graded Approach system and achieve a level of parity with some existing Government Regulators' approach in this area. It is expected registration and renewal will incur a fee. The fee(s) are unknown at this time.

Do you agree with HSE's approach for:

10.1 Extending the scope of licensing to ensure that practices that pose the same risks are subject to the same regulatory controls

If no, please explain why and provide any burdens imposed (including costs)?

In principle yes, but is the amount of work placed upon employers to demonstrate that they meet the conditions of the licence (as yet unknown) before the Regulations come into force proportionate given the level of scrutiny the application will receive (suggested to be none, or at least minimal)?

What justification is there for the significant increased cost and work involved in obtaining a licence compared to a registration unless the HSE intend to give a higher level of scrutiny to the application or undertake regular inspections of licensed employers?

Without licence conditions and ongoing inspections against those conditions, what is the justification for the renewal of a licence? If it's simply to inform the HSE that the practice is still undertaken, a requirement that the employer inform the HSE upon the cessation of the practice is a cost free method of ensuring the same outcome.

Would like to know about fees associated with this. We are concerned about multiple site organisations, and the impact and complexity this might bring.

Do you agree with HSE's approach for:

10.2 Requiring the renewal of registrations and licenses to ensure up-to-date information on which to base our interventions

If no, please explain why and provide any burdens imposed (including costs)?

If the justification for requiring renewal of licences and registration is having up to date information on which to base interventions, we feel that the HSE should be able to demonstrate that it is undertaking a proportionate number of interventions given the scope of the practices that are licensed and registered. It is our understanding that the HSE is currently only undertaking reactive investigations in response to matters reported to them as required by IRR99. If that is to continue, it is hard to see what benefit an up to date list of licensed and registered employers is to the HSE and it is difficult to justify the cost of renewal to employers.

Would it be possible to just notify of changes of practice rather than have the administrative burden and costs of renewals?

The graded approach for notification, registration and licence applications is not very robust. It is entirely based on trust with no need to evidence any of the requirements. There does not seem to be any intention to spot check or audit this process. It sounds as if it will be the employer completing the application and there is no advice regarding if this is a delegated task who might be qualified to do so.

Q 11. Are there any further comments you would like to make on the issues raised in this consultative document?

The professional bodies represented would like to see how IRR17 interfaces with the new

IRMER 2018 legislation.

- To accompany the legislation there will be a Code of Practice and also a large guidance document. Neither of these is yet available which makes thorough feedback for the consultation impossible, particularly regarding some costings. There is no doubt that this will lead to considerable cost for NHS Trusts. Many Trusts are significantly under prepared for this new legislation.

- One of the major issues is why both a Code of Practice and guidance notes are required?! This has the potential for conflict and weakening.

- **Page 54** – what is a medical examination and how will this help?
- **Page 58** – is it practical to define when old equipment becomes obsolete? For example if it gives x% more radiation that the current standard it should be replaced.

If the IT system is not in place by October 2017 for pre –registration will this result in two separate data sets; paper applications and then later electronic applications?

Thank you for taking the time to complete this questionnaire