



Department
of Health

Regulatory Triage Assessment – Department of Health Basic Safety Standard Directive 2013/059/EURATOM

This regulatory change has a low cost to business and so a full impact assessment is not required. The Regulatory Triage Assessment (RTAs) is not intended to be a full assessment of costs and benefits. This document is a requirement of the Regulatory Policy Committee (RPC) to ensure that costs to business are considered in a proportionate way on low impact regulations. (This enables appraisal and scrutiny to be focussed on regulatory measures with the most significant impacts on business.)

The government's Better Regulation Framework Manual defines 'business' as follows:

Business: An undertaking that engages in business activities, irrespective of legal form. Includes sole traders, partnerships, and incorporated companies, and businesses not registered in the UK but which operate in the UK. Unless specified otherwise, "business" also refers to voluntary or community bodies.

'Business' does not include public bodies such as NHS hospitals. The RTA is meant only to assess impacts on 'business', as defined above.

For more information on the RPC scrutiny process and guidance see here: <https://www.gov.uk/guidance/the-regulatory-policy-committee-scrutiny-process>

Regulatory Triage Assessment – Department of Health

Title of proposal	Basic Safety Standard Directive 2013/059/EURATOM
Expected date of implementation	06 February 2018
Origin (Domestic/International etc.)	EU
Date	27/06/17
Lead Policy Contact	Trudy Netherwood
Lead Analytical Contact	Claire Cormie
Reason for Triage Assessment	Regulatory changes that have low costs to business, are not 'gold-plated' and so qualify for Fast Track.
Is the policy in scope of OI30?	No

Please provide a brief description of the policy proposal

The EURATOM Treaty provides for the establishment of uniform safety standards to protect the health of patients, workers and of the general public against the dangers arising from ionising radiation.

Basic standards were first agreed in 1959 and have been revised several times. This directive is the latest revision and repeals a number of existing directives. The majority of the requirements of the Directive are already implemented in the UK; there are additional licensing, recognition and notification requirements.

- The new BSSD requires licencing for the administration of radioactive substances for the purposes of diagnosis, treatment or research. The current regulatory system involves Doctors being issued with certificates by Health Ministers following the advice from the Administration of Radioactive Substances Advisory Committee (ARSAC) whose appointed members are mainly specialist doctors. The new requirements will mean the introduction of licences for both Doctors and Employers and a fixed fee. Most applicants will be from the NHS.
- The BSSD requires that arrangements are in place for the recognition of Medical Physics Experts. DH as the UK Competent Authority has asked a not-for-profit company known as RPA2000 to undertake the recognition of new MPEs from February 2018. Applicants will have to pay a fee to RPA2000 in order to undergo the recognition process.
- The change in the regulations also adds a notification requirement for underexposures in radiotherapy.

How many businesses are likely to be affected?

It is expected that around 300 sites will apply for licenses in the first year and that of these about 39 will be non-NHS. It is estimated that there are around 900 MPEs and that 5%, 45, will be exclusively non-NHS employees.

What are the main impacts for business? Are these impacts direct or indirect?

- 1. Compulsory recognition of Medical Physics Experts (MPEs)** – the cost to business is to new MPEs who are exclusively non-NHS employees of (a) the cost of the time taken to complete an application, (b) the registration fee; and the cost to all exclusively non-NHS MPEs of (c) an annual renewal/maintenance fee. These limited costs fall on workers not businesses themselves and therefore are indirect.
- 2. Licensing system for the administration of radioactive substances** – a proportion of license applications will come from non-NHS bodies, including private healthcare companies, pharmaceutical companies and universities. The impacts on these businesses come from the move from a range of certificates to a different range of licenses; this will benefit the applicants by saving their time, but will also introduce costs as there will be fees for some site and sponsor applications. The cost of applying for practitioner licenses is considered to be indirect because the costs falls on workers not businesses themselves. The cost of site and sponsor licenses is considered to be a direct cost as it will fall on businesses. The highest increases in cost are in the first year when existing sites are expected to apply for the newly introduced site licenses; the annual costs thereafter are lower, with higher costs every 5 years thereafter when site licences need to be renewed.

<p>3. <u>Notification of underexposures in radiotherapy</u> –the change in the regulations adds a notification requirement for underexposures in radiotherapy. A proportion of notifications will be non-NHS so there will be a limited cost to business. This is a direct cost to business.</p>	
<p>Please provide a quantification of the (direct) costs and benefits to business outlined above:</p> <p>The estimated annual costs for the first 10 years below have been rounded to the nearest £1,000.</p> <p><u>Total from the changes to the regulations:</u> total increase in the cost to business:</p> <p>Year 1: <u>£107,000 (£73,000 – £161,000)</u> (direct: £160,000 (£128,000 – £200,000) and indirect: -£54,000 (-£56,000 – -£39,000)).</p> <p>Years 2-5: <u>£83,000 (£52,000 – £132,000)</u> (direct: £136,000 (£108,000 –£171,000) and indirect: -£54,000 (-£56,000 – -£39,000)).</p> <p>Year 6: £93,000 (£61,000 - £144,000) (direct: £147,000 (£117,000-£183,000) and indirect: -54,000 (-£56,000 – -£39,000)).</p> <p>Years 7-10: £83,000 (£53,000-£133,000) (direct: £137,000 (£108,000-£172,000) and indirect: -£54,000 (-£56,000 – -£39,000)). These costs are made up of:</p> <ol style="list-style-type: none"> <u>1. Compulsory recognition of Medical Physics Experts (MPEs)</u>: total annual increase in cost to business: <u>£12,000 (£0 – £39,000)</u>, this is an indirect cost. <u>2. Licensing system for the application of radioactive substances</u>: total increase in cost to business: Year 1: <u>£95,000 (£73,000 – £122,000)</u> (direct: £161,000 (£128,000 – £200,000) and indirect: -£66,000 (-£56,000 – -£78,000)); Years 2-5: <u>£71,000 (£52,000 – £93,000)</u> (direct: £137,000 (£108,000 – £171,000) and indirect: -£66,000 (-£56,000 – -£78,000)), Year 6: £81,000 (£61,000 - £105,000) (direct: £147,000 (£117,000-£183,000) and indirect: -£66,000 (-£56,000 – -£78,000)); Years 7-10: £71,000 (£53,000 - £94,000) (direct: £137,000 (£108,000-£172,000) and indirect: -£66,000 (-£56,000 – -£78,000)). <u>3. Notification of underexposures in radiotherapy</u>–underexposures that would be significant enough to require notification are rare and an annual number could not be quantified. Only a small proportion of these would be non-NHS. Therefore there will only be a low cost to business. This cost is not quantified. 	
<p>Please provide details of other costs and benefits that are likely to result from the policy:</p> <p>It is not expected that there will be any significant direct health benefits from the regulation changes. These regulations consolidate and update existing legislation and the beneficial health effects in reducing exposures to ionising radiation are largely implemented already in the UK. The changes that have impacts on the cost to business will also impact on NHS costs. There is not expected to be any change in the staffing for administering the licensing scheme. However, with the introduction of fees for some applications, some of the cost is transferred from PHE to the NHS and business. After netting fees income off the change in NHS costs, the benefit to the healthcare system as a whole from the regulation changes are savings estimated to total: year 1: £140,000 (£24,000 - £215,000); years 2-5: £206,000 (£113,000 - £264,000); year 6: £181,000 (£79,000 - £246,000); years 7-10: £205,000 (£111,000 - £263,000). This is made up of MPE recognition: -£228,000 (-£138,000 – -£351,000) per year; and licensing: year 1: £368,000 (£353,000 – £375,000); years 2-5: £434,000 (£402,000 – £463,000); year 6: £409,000 (£384,000 - £430,000); years 7-10: £433,000 (£402,000 - £462,000). Health system costs/savings have an opportunity cost/benefit in terms of health. CQC may require an extra 0.5 FTE due to the change in the regulations, which would add a small extra cost to the estimates above of the cost to the health system.</p>	
<p>Policy signoff (SCS): Ailsa Wight</p>	<p>Date: 29/06/2017</p>
<p>Senior Analyst signoff: John Henderson</p>	<p>Date: 29/06/2017</p>
<p>Better Regulation Unit signoff: Tim Wouters</p>	<p>Date: 29/06/2017</p>

ANNEX

Recognition of Medical Physics Experts

The changes to the regulations mean that it will become compulsory for MPEs to attain recognition. There is currently a voluntary scheme in place, including a voluntary grandfathering scheme for any unrecognised MPEs, with a fee of £30. The fee to apply for recognition under the new compulsory scheme will be £300, so there is a strong incentive for existing MPEs to ensure they are recognised before the new regulations come into force. Given this strong incentive, it is assumed that all existing MPEs will already be recognised.

The annual cost of the changes in the regulations is from the cost of annual applications by new MPEs and the cost of existing MPEs paying an annual maintenance fee of £30 to stay on the register. It is estimated that there are around 800 existing MPEs who are already registered. Expert best estimates of the total number including any currently unrecognised (900) and of the proportion of MPEs who will be exclusively non-NHS employees (5%) are used in the central cost estimate. It is assumed that the total number of MPEs will not grow over time.

It is assumed that there will be 50 new MPE applications each year (expert best estimate) in the central cost estimate. The cost for new applicants consists of the application fee of £300 and the cost of their time taken to complete their application. The Management Board of RPA 2000, which recognises Radiation Protection Advisors (RPAs), estimated the length of time taken to complete an application to become a recognised RPA at 40-80 hours. This is used as the estimate for MPEs in this analysis for reasons of similarity. The unit cost per hour of 'health based scientific and professional staff - radiographer' time from the PSSRU Unit costs of health and social care 2016 was used as the time cost of an MPE. New MPEs applying for recognition are likely to be Band 8a, Band 7 and Band 8b were used as lower and upper estimates respectively.

These assumptions and the input ranges used are shown in Table 1 below. The cost of MPE recognition is treated as an indirect cost, in line with precedents set by similar costs, as they will fall on the individual and the employer (business) is not obliged to reimburse this cost.

Table 1: MPE Recognition	Low	Central	High
Total number of MPEs	800 (estimate of no. currently recognised)	900 (expert best estimate)	1000 (upper estimate assumption)
Growth in total number of MPEs over time	No growth – assumption		
Number of applications each year	-10% (=45)	50 (expert best estimate)	+10% (=55)
Proportion of MPEs who are exclusively non-NHS	0% (assumption that all work in NHS as well)	5% (expert best estimate)	10% (upper estimate assumption)
Working hours to complete application	<i>Expert estimate of 40-80 hours for RPA applications</i> 40 60 80		
Fee for application	£300		
Annual maintenance fee	£30		
Number of existing MPEs having to apply for recognition under the new regulations	Assumption – none		
Applicant MPE time cost per working hour	<i>PSSRU Unit costs of Health and social care 2016 - unit cost per working hour of: Hospital based scientific and professional staff - radiographer</i> Band 7 (£56) Band 8a (£66) Band 8b (£78)		

Licensing for the application of radioactive substances

With the changes in the regulations there will be a change from certification to licensing and the type of licenses/certificates required will change.

Under the current certification system separate certificates were required for therapy, diagnosis and research, and for each site worked at and for each research trial. Under the new system practitioners will be able to have a single license to cover therapy, diagnosis and research. Site licenses are being introduced as a separate type of license, for the site itself. Sponsor certificates/licenses are remaining in place, for research trials. The changes are expected to result in fewer applications in total, but with a different distribution of types.

Estimated numbers of applications of different types under the existing certification scheme and under the new licensing scheme are shown below in Table 2. Applications under the certification scheme are estimated from 2015-16 applications and estimates for the licensing scheme are PHE licensing team best estimates. A proportion of applications under the new regulations will be non-NHS. Under the certification scheme 13% of existing sites are non-NHS; this was used as the proportion of site license applications that will be non-NHS. It is assumed that there are no solely non-NHS practitioners, which may be an underestimate. Conversely it is assumed that all sponsor applications are non-NHS, which may be an overestimate. Non-NHS applicants include healthcare companies, pharmaceutical companies and universities. There are more applications in the first year of the licensing scheme than in subsequent years as existing sites will have to apply for their licenses when the new regulations come into force, and so there will be more renewals for that reason every 5 years thereafter.

Table 2: applications for certification and licensing per year, and time taken per application

Applicant	Type	Applications: certification			Applications: licensing			Hours taken
		NHS	Non-NHS	Total	NHS	Non-NHS	Total	
Site	new (first year)	0	0	0	261	39	300	4
Site	new (annual)	0	0	0	9	1	10	4
Site	variation	0	0	0	161	24	185	4
Site	notification	0	0	0	87	13	100	1.5
Site	Renewal (6 th year)	0	0	0	261	39	300	1.5
Site	Renewal (annual)	0	0	0	9	1	10	1.5
Practitioner	new	952	101	1053	50	0	50	4
Practitioner	addition	103	14	117	130	0	130	4
Practitioner	renewal	206	8	214	220	0	220	1.5
Practitioner	extension (research)	48	2	50	50	0	50	4
Practitioner	variation (research)	2	2	4	185	0	185	4
Sponsor	new (multicentre)	0	170	170	0	170	170	4
Sponsor	new (single centre)	0	60	60	0	60	60	4
Sponsor	new (low dose)	0	20	20	0	20	20	4
Sponsor	variation	0	10	10	0	10	10	4
Sponsor	notification	0	100	100	0	100	100	1.5

Table 3: license application fees

Site (new)	£	329
Site (variation)	£	235
Site (renewal)	£	141
Sponsor (new - multicentre)	£	517
Sponsor (new - single centre)	£	423
Sponsor (new - low dose)	£	235
Sponsor (variation)	£	329

Fees will be charged by the PHE licensing team for new applications and variations to site licenses, but not for notifications. Fees will also be introduced for sponsor applications, as with site licenses this will be for new applications and variations but not notifications. See Table 3.

It is expected that MPEs will complete the site applications, while practitioners are usually Consultants. It is not certain who would complete sponsor applications, so it has been assumed that they will be Consultants as an upper estimate of the potential cost. The unit cost of applicant time is estimated using the PSSRU Unit Costs of Health and Social Care 2016. The unit cost of time of 'hospital based scientific and professional staff – radiographer' is used for MPEs. It is expected that MPEs completing applications would be Band 8b, so this is used as a central estimate. Band 8a is used as a lower estimate and Band 8b scaled up by (Band 8b unit cost / Band 8a unit cost) is used as the upper estimate. The unit cost of time of 'Consultant – Medical' was used for practitioner and sponsor applications, for upper and lower estimates this unit cost is scaled up and down using ratio between the Band 8b and Band 8a MPE unit costs of time.

The assumptions and input ranges used in this analysis to estimate the impact of the change from certification to licensing are shown in Table 4 below.

Table 4: Licensing	Low	Central	High
Numbers and types of applications with the certification scheme	PHE estimates - based on 2015-16 applications data (see Table 2)		
Numbers and types of applications with the new licensing scheme	-10%	PHE best estimates (see table 2)	+10%
Growth in the annual number of applications over time	No growth – assumption		
Proportions of each type of application that are NHS, non-NHS	PHE best estimates and assumptions. As described in text and see Table 2.		
Time taken for applications	PHE best estimates of time taken for each type with the new IT system in place (see Table 2). Time taken to apply for a license should not differ from the time taken to apply for certification.		
Applicant for site applications	Medical Physics Expert (MPE)		
Applicant for practitioner applications	Consultant – Medical		

Applicant for sponsor applications	Consultant - Medical (probably an overestimate of the cost)		
MPE applicant time cost per working hour	<i>PSSRU Unit costs of Health and social care 2016 - unit cost per working hour of: Hospital based scientific and professional staff - radiographer</i>		
	Band 8a (£66)	Band 8b (£78)	Band 8b scaled up by 8b/8a (=£92)
Consultant applicant time cost per working hour	<i>PSSRU Unit costs of Health and social care 2016 - unit cost per working hour of: Hospital based doctors - Consultant Medical (best match)</i>		
	Scaled down by 8a/8b from above (=£114)	Unit cost (£135)	Scaled up by 8b/8a from above (=£160)

The number of applications under the new regulations has been scaled up and down by 10% to reflect that we may have under or overestimated the numbers.

The cost of site and sponsor applications are categorised as direct costs, the cost will fall on the business, which will use an employee to make these applications. Practitioner applications are treated as indirect costs, on the same rationale as MPE recognition costs are.

Notification of underexposures in radiation

No cost is estimated. There is an intention to extend reporting requirements to include underexposures in radiotherapy, but there have been very few of these in the past. It is possible to correct small underexposures within the treatment period in most cases and these would not be reported. In the past 25 years, there has only been one major underexposure incident where this was not possible. The change in the regulations is more a matter of being comprehensive. Given the rarity of any underexposures that would require notification, the cost change should be minimal and is not quantified.

PSSRU Unit costs of health and social care 2016 - <http://www.pssru.ac.uk/project-pages/unit-costs/2016/>