



Department for
Business, Energy
& Industrial Strategy



Ministry
of Defence



Revised requirements for radiological protection: emergency preparedness and response

Government response

October 2018

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The response can be found on the BEIS section of GOV.UK:

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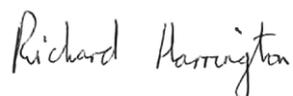
Ministerial Foreword



1. The UK has benefited from more than 60 years of clean and safe nuclear-generated electricity. The Government is committed to the safe and successful future of our nuclear and radiological sectors which provide a valuable contribution to our economy and our society.
2. All of our civil nuclear, defence nuclear, and radiological sites are operated to the highest safety standards, and there are stringent safety standards for the transport of radioactive material. All are independently regulated to ensure they are safe, secure and environmentally sound.
3. The risk of a radiation emergency is therefore extremely low, but there must be robust emergency preparedness and response arrangements in place for radiological emergencies, however unlikely they may be. The UK has well developed emergency response arrangements but we are committed to continuous improvement in our preparedness, drawing on international best practice.
4. I am therefore pleased to present the Government's response, in partnership with the Health and Safety Executive and Ministry of Defence, to our consultation on proposals to further strengthen Great Britain's already robust emergency preparedness and response arrangements for radiological emergencies. These changes will implement the emergency preparedness and response elements of the Euratom Basic Safety Standards Directive 2013 which applies learning following the Fukushima Daiichi accident. Even though the UK will be leaving the EU and the Euratom Treaty, the Government remains wholly committed to the highest standards in radiological safety – including emergency preparedness and response.
5. Since our consultation we have carefully considered the responses, conducted analysis to further develop our policy proposals and drafted Regulations. The draft regulations that give effect to our policy conclusions are published alongside this document. I intend to lay them in parliament in late 2018 and early 2019.
6. These changes will introduce a consistent approach to emergency planning and response across the civil nuclear, defence nuclear and radiological sectors. They are an outcome focused approach to regulation, based on evidence, and subject to enhanced transparency. They enhance our already robust emergency planning and response regime and introduce the new concepts of emergency worker and reference levels. They revise other existing definitions for increased clarity. We are improving planning on the ground through the introduction of new outline planning zones where this is appropriate and proportionate – in the language of the Directive, “commensurate”. We are improving communication requirements, and widening access to stable iodine as a key medical protective action.
7. These changes will help local authorities to better understand the risks and deliver commensurate planning, and help to ensure we are prepared in the

extremely unlikely event of a larger scale radiation emergency. Where possible, we are also looking to reduce and clarify the regulatory burden for duty holders.

8. We will continue to require the testing and exercising of emergency plans, but to strengthen our arrangements still further there will be an explicit requirement to take account of lessons learned as well as any substantive changes that could affect an emergency plan.
9. The Government also intend to develop a national plan for radiation emergencies that could extend beyond formal emergency planning zones, for radiological transport emergencies and for international events which could impact on the UK. This will ensure we remain at the forefront of responsible nuclear energy states, and reflects the importance the UK places on nuclear safety and our commitment to continuous improvement.
10. Our changes to the existing regulations are significant and we recognise that time is needed to comply with legal obligations, especially given that it is a criminal offence to fail to do so. We have worked with stakeholders to develop a fair and appropriate implementation timeframe, and have included a 12 month transitional period in the new regulations to give existing duty holders sufficient time to meet their revised regulatory obligations. There will be additional flexibility for the exercising of plans which have long lead times. Until that time, the current regulations will apply in full to existing duty holders.
11. We are grateful to all those who responded to the consultation and to the many organisations involved for their ongoing support in achieving this outcome, and for their contribution to the work of delivering the highest standards of emergency preparedness and response.



The Rt Hon Richard Harrington MP

Minister for Energy and Industry

Department for Business, Energy and Industrial Strategy

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Executive summary

12. This Government response document and the draft regulations published alongside it are presented jointly by the Department for Business, Energy and Industrial Strategy (BEIS), the Ministry of Defence (MoD) and Health and Safety Executive (HSE). Collectively, we are responsible for emergency response arrangements for the civil nuclear, defence nuclear and radiological sectors. This document follows on from and provides a response to our joint consultation (*Revised requirements for radiological protection: emergency preparedness and response*¹). It sets out our conclusions on how we intend to implement the emergency preparedness and response parts of the Euratom Basic Safety Standards Directive 2013/59/Euratom (BSSD 2013). It also sets our intention to keep in step, where appropriate, with international best practice such as that from the International Atomic Energy Agency (IAEA) and International Commission on Radiological Protection (ICRP).
13. On 23 June 2016, the EU referendum took place and the people of the United Kingdom (UK) voted to leave the European Union (EU). Until exit negotiations are concluded, the UK remains a full member of the EU and Euratom, and all the rights and obligations of being a Member State remain in force. During this period the Government will continue to negotiate, implement and apply EU and Euratom legislation, including the BSSD 2013.
14. The UK is committed to the highest standards in civil nuclear, defence nuclear and radiological safety, including standards for emergency preparedness and response. The UK's independent regulators, the Health and Safety Executive (HSE) and the Office for Nuclear Regulation (ONR), are respected globally and are subject to international peer review.
15. We have enjoyed over 60 years of safe nuclear power, and there is no change in the UK's assessment of the risk of a nuclear or radiological emergency from the civil nuclear, defence nuclear, or radiological sectors. The risk of a radiological emergency in the UK is extremely low. A stringent safety regime ensures that the probability and impact of radiation emergencies is kept as low as reasonably practicable. Nonetheless, for enhanced public protection, duty holders are required by law to plan appropriately for radiological emergencies. These changes deliver on our commitment to continuous improvement.
16. We received 71 responses to our consultation; the majority of responses were supportive of our consultation proposals and of having a consistent approach across the civil nuclear, defence nuclear and radiological sectors. A number of responses asked for additional clarity which we set out in in this document. Responses have helped to shape and refine our proposals in a number of key areas, including definitions, hazard evaluation, co-ordination planning, prior information to the public, testing, implementation and the development of a national plan. We are grateful for every response provided and for the input and

¹ <https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-emergency-preparedness-and-response>

the time each respondent has taken to help shape the future approach to emergency preparedness and response.

17. The policy conclusions set out in this document and the draft regulations published alongside it further demonstrate our commitment to continuous improvement. The changes we intend to take forward will deliver a consistent approach to radiation emergency preparedness and response across the civil nuclear, defence nuclear and radiological sectors. The key conclusions we set out and intend to take forward by laying the draft regulations in parliament are summarised below:
18. **Definitions:** we intend to introduce a new definition of radiation emergency, emergency worker and the concept of reference levels into the new regulations. The definition of radiation emergency reflects both the definition in BSSD 2013 and the latest IAEA definition. The definition of emergency worker in the regulations will set out the types of emergency worker. Other new regulations will set out that training is proportionate to the type of worker and the role they fulfil, and clarify that the disapplication of dose limits (up to 500mSv) for emergency responders is lawful in certain situations. We intend to introduce a national reference level of 100mSv which will apply as an annual dose from release through the response phases until the end of a 12 month period. Local authorities will be able to set lower local reference levels if they wish. Reference levels will act as a guide to help more effective emergency planning.
19. **Consistent approach to assessing the full range of risks:** we intend to require a site to identify all hazards that have the potential to cause a radiation emergency. They will be able to use existing assessments required under other regulations to do so, such as radiation risk assessments under the Ionising Radiations Regulations (IRRs), or safety cases under the nuclear licensing regime. This revised approach reflects the responses provided to us in our consultation. The range of risks will then be analysed through a standardised risk assessment framework and offsite consequences methodology. The key outcomes of this will be set out to the local authority in an easy to understand standardised consequences report to enable it to create the offsite emergency plan. It will include a technical distance for a recommended detailed emergency planning zone. This will be overseen by the regulator.
20. **Commensurate approach to emergency planning:** the consistent approach to assessing the full range of risks for a site that we have proposed will enable detailed emergency planning zones to be set by the local authority based on the characteristics of a site. It will enable effective emergency response plans to be developed and implemented more easily by the local authority. In addition to this, we propose to plan for 'unforeseen' emergencies by introducing outline emergency planning zones. These will be for less likely but more severe potential emergencies and so hold different requirements around communication and capabilities than detailed emergency planning zones. For the civil nuclear sector, the regulations set out default outline emergency planning zone distances informed by scientific evidence and modelling. Defence will establish emergency planning zones informed by scientific evidence and modelling, but these will not be set out in regulations. Radiological sector sites will assess outline emergency

planning zones with the local authority on a case by case basis. This reflects the potential risk held by each sector; each has the standardised approach to risk assessment at its centre.

21. **Stable iodine:** we have worked with the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health and Social Care (DHSC) to introduce changes to the Human Medicines Regulations to provide more flexibility to local responders. The changes allow stable iodine provision in a radiation emergency (or where one is likely) by a person named in an emergency plan under the Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR), or by a Category 1 responder as defined under the Civil Contingencies Act 2004 (CCA), without supervision from a pharmacist. As well as providing more flexibility to local responders, this change can increase the effectiveness of stable iodine as a medical protective action.
22. **Co-ordinated planning:** we intend to strengthen the role of the lead local authority and place a requirement on other relevant local authorities and duty holders to work together with the lead local authority to develop off site emergency planning.
23. **Testing:** we intend to continue with the existing requirement for emergency plans for detailed emergency planning zones to be tested in full at least every 3 years. This may be extended in exceptional circumstances with the agreement of the regulator. There will be an explicit requirement to take account of lessons learned and any material changes in the emergency plan. A proportionate approach to testing emergency plans for outline emergency planning zones will be undertaken, such as the use of modular testing. The local authority will be a single contact point for operators for the reasonable recovery of costs by participants in emergency plan testing, providing clear oversight and reducing duplication. We are also providing additional flexibility here, for example the planned programme of testing under current regulations can continue to apply until that programme of testing is complete given the long lead times.
24. **Transport:** we intend to remove references to transport from REPPIR. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDGs) will be amended to implement the requirements of the BSSD 2013 in relation to the transportation of radioactive materials, including through the addition of equivalent definitions of radiation emergency, emergency workers and a national reference level. ONR has been made the enforcing authority for the Ionising Radiations Regulations (IRRs) in respect of the transport of radioactive materials. We also propose that the provision of prior information to the public will be achieved through a requirement for ONR to publish generic information and advice on what to do in the event of a radiological transport emergency.
25. **Implementation:** we are proposing to incorporate into the new regulations a 12 month transitional period to ensure that existing duty holders have sufficient time to comply with their revised legal obligations. This would mean that the current regulatory regime would continue to apply for existing duty holders for 12 months after the new regulations came into force. Businesses that start working with

ionising radiations for the first time will have to comply with the new regulations from the outset. We have worked with stakeholders to ensure this provides a fair and appropriate implementation timeframe. Subject to the availability of parliamentary time, we intend to make and then lay the regulations that will replace REPPIR before Parliament in early 2019. A five year review clause will also be included in the regulations to ensure the regulations are effective and deliver on the Government commitment to continuous improvement. The regulations that will amend CDG will be made and then laid before Parliament in draft separately by the end of 2018 (again, subject to the availability of parliamentary time). We are proposing to incorporate into the new regulations a 12 month transitional period for existing duty holders, so the amendments would also take effect 12 months after they came into force.

26. **National plan:** in due course, the Government intends to develop a national plan for radiation emergencies which could extend beyond outline emergency planning zones. It would also cover transport emergencies and international events which affected the UK. It would build on and replace relevant parts of the current National Nuclear Emergency Planning and Response Guidance. This will ensure we remain at the forefront of responsible nuclear energy states, and are leading in the implementation of the latest IAEA best practice.

Crynodeb gweithredol

27. Mae'r ddogfen hon, sef ymateb y Llywodraeth, a'r rheoliadau drafft a gyhoeddir ochr yn ochr â hi yn cael eu cyhoeddi ar y cyd gan yr Adran Busnes, Ynni a Strategaeth Ddiwydiannol (BEIS), y Weinyddiaeth Amddiffyn (MoD) a'r Awdurdod Gweithredol Iechyd a Diogelwch (HSE). Gyda'n gilydd, ni sy'n gyfrifol am drefniadau ymateb brys yn y sector niwclear sifil, y sector niwclear amddiffyn a'r sector radiolegol. Mae'r ddogfen hon yn dilyn ein cyd-ymgyngoriad (*Revised requirements for radiological protection: emergency preparedness and response*²) ac yn cynnig ymateb iddi. Mae'n nodi'n casgliadau ar sut y bwriadwn weithredu'r rhannau o Gyfarwyddeb Safonau Sylfaenol Diogelwch Euratom, 2013/59/Euratom, ynghylch parodrwydd ar gyfer argyfwng ac ymateb iddo (BSSD 2013). Mae hefyd yn nodi'n bwriad i gyd-fynd, lle bo'n briodol, â'r arferion gorau rhyngwladol fel y rhai a geir gan yr Asiantaeth Ynni Atomig Ryngwladol (IAEA) a'r Comisiwn Rhyngwladol ar Ddiogelu Radiolegol (ICRP).
28. Ar 23 Mehefin 2016, cynhaliwyd refferendwm yr UE a phleidleisiodd pobl y Deyrnas Unedig i ymadael â'r Undeb Ewropeaidd (UE). Hyd nes y bydd y trafodaethau ymadael wedi dod i ben, mae'r Deyrnas Unedig yn parhau'n aelod llawn o'r UE ac Euratom, ac mae holl hawliau a rhwymedigaethau bod yn Aelod-wladwriaeth yn dal mewn grym. Yn ystod y cyfnod hwn bydd y Llywodraeth yn parhau i negodi, gweithredu a chymhwyso deddfwriaeth yr UE ac Euratom, gan gynnwys BSSD 2013.
29. Mae'r Deyrnas Unedig wedi ymrwymo i'r safonau uchaf mewn diogelwch niwclear a radiolegol mewn amddiffyn ac yn y byd sifil, gan gynnwys safonau ar gyfer

² <https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-emergency-preparedness-and-response>

parodrwydd ac ymateb mewn argyfwng. Mae rheoleiddwyr annibynnol y Deyrnas Unedig, sef yr Awdurdod Gweithredol Iechyd a Diogelwch (HSE) a'r Swyddfa dros Reoli Niwclear (ONR), yn cael eu parchu ledled y byd ac yn cael eu hadolygu gan gymheiriaid rhyngwladol.

30. Yr ydym wedi mwynhau dros 60 mlynedd o bŵer niwclear diogel, a does dim newid yn asesiad y Deyrnas Unedig o'r risg y ceir argyfwng niwclear neu radiolegol o'r sector niwclear sifil, y sector niwclear amddiffyn a'r sector radiolegol. Eithriadol o isel yw'r risg o argyfwng radiolegol yn y Deyrnas Unedig. Mae cyfundrefn ddiogelwch lem yn sicrhau bod tebygolrwydd ac effaith argyfyngau ymbelydredd yn cael eu cadw mor isel ag y bo'n rhesymol ymarferol. Serch hynny, er mwyn gwella diogelwch y cyhoedd, mae'r gyfraith yn ei gwneud yn ofynnol i ddeiliaid dyletswyddau gynllunio'n briodol ar gyfer argyfwng radiolegol. Mae'r newidiadau hyn yn gwireddu'n hymrwymiad i welliant parhaus
31. Cafwyd 71 o ymatebion i'n hymgyngoriad; roedd y mwyafrif o'r ymatebion yn cefnogi'n cynigion ymgynghori ac o blaid cael dull gweithredu cyson ar draws y sector niwclear sifil, y sector niwclear amddiffyn a'r sector radiolegol. Gofynnodd nifer o'r ymatebion am ragor o eglurhad, sy'n cael ei roi gennym yn y ddogfen hon. Mae'r ymatebion wedi helpu i lywio a mireinio'n cynigion mewn nifer o feysydd allweddol, gan gynnwys diffiniadau, gwerthuso peryglon, cynllunio ar gyfer cydlynu, gwybodaeth ymlaen llaw i'r cyhoedd, profi, gweithredu a datblygu cynllun cenedlaethol. Rydym yn ddiolchgar am bob ymateb a roddwyd ac am y mewnbwn a'r amser y mae pob ymatebydd wedi'i gymryd i helpu i lunio'r dull gweithredu yn y dyfodol ynglŷn â pharodrwydd ac ymateb i argyfwng.
32. Mae'r casgliadau polisi a nodir yn y ddogfen hon a'r rheoliadau drafft a gyhoeddir ochr yn ochr â hi yn dangos eto ein hymrwymiad i welliant parhaus. Bydd y newidiadau yr ydym yn bwriadu bwrw ymlaen â nhw yn sicrhau ymagwedd gyson at barodrwydd am argyfwng ymbelydredd ac ymateb iddo ar draws y sector niwclear sifil, y sector niwclear amddiffyn a'r sector radiolegol. Mae'r casgliadau allweddol rydym yn eu nodi ac yn bwriadu bwrw ymlaen â nhw drwy osod y rheoliadau drafft yn y Senedd wedi'u crynhoi isod:
33. **Diffinio:** rydym yn bwriadu cyflwyno diffiniad newydd o argyfwng ymbelydredd, gweithiwr brys a'r cysyniad o lefelau cyfeirio yn y rheoliadau newydd. Mae'r diffiniad o argyfwng ymbelydredd yn adlewyrchu'r diffiniad yn BSSD 2013 a diffiniad diweddaraf yr IAEA. Bydd y diffiniad o weithiwr brys yn y rheoliadau yn nodi'r mathau o weithiwr brys. Bydd rheoliadau newydd eraill yn nodi bod hyfforddiant yn gymesur â'r math o weithiwr a'r rôl y mae'n ei chyflawni, ac yn egluro bod datgymhwyso terfynau dosau (hyd at 500mSv) yn achos ymatebwyr brys yn gyfreithlon mewn sefyllfaoedd penodol. Rydym yn bwriadu cyflwyno lefel gyfeirio genedlaethol o 100mSv a fydd yn gymwys fel dos flynyddol yn sgil rhyddhau deunydd drwy'r cyfnodau ymateb tan ddiwedd cyfnod o 12 mis. Bydd yr awdurdodau lleol yn gallu pennu lefelau cyfeirio lleol is os ydynt yn dymuno. Bydd y lefelau cyfeirio yn gweithredu fel canllaw i helpu i gynllunio'n fwy effeithiol at argyfwng.
34. **Ymagwedd gyson at asesu'r ystod lawn o risgiau:** rydym yn bwriadu ei gwneud yn ofynnol i safle adnabod pob perygl a allai achosi argyfwng

ymbelydredd. Byddant yn gallu defnyddio'r asesiadau presennol sy'n ofynnol o dan reoliadau eraill i wneud hyn, megis yr asesiadau risg ymbelydredd sy'n ofynnol o dan y Rheoliadau Ymbelydredd Ioneiddio (IRRs), neu achosion diogelwch o dan y gyfundrefn drwyddedu niwclear. Mae'r ymagwedd ddiwygiedig hon yn adlewyrchu'r ymatebion a roddwyd inni yn ein hymgyngoriad. Bydd yr ystod o risgiau'n cael ei dadansoddi wedyn drwy fframwaith asesu risg safonedig a methodoleg sy'n ymdrin â'r canlyniadau oddi ar y safle. Nodir canlyniadau allweddol y dadansoddiad hwn i'r awdurdod lleol mewn adroddiad safonedig ar y canlyniadau a fydd yn hawdd i'w ddeall i'w alluogi i greu'r cynllun brys i fannau oddi ar y safle. Bydd yn cynnwys pellter technegol ar gyfer parth cynllunio brys manwl a argymhellir. Bydd hyn yn cael ei oruchwyllo gan y rheoleiddiwr.

35. **Ymagwedd gymesur at gynllunio ar gyfer argyfwng:** bydd yr ymagwedd gyson at asesu'r ystod lawn o risgiau ar gyfer safle yr ydym wedi'i chynnig yn caniatáu i barthau cynllunio brys manwl gael eu pennu gan yr awdurdod lleol ar sail nodweddion y safle. Bydd yn caniatáu i gynlluniau effeithiol ar gyfer ymateb i argyfwng gael eu datblygu a'u rhoi ar waith yn haws gan yr awdurdod lleol. Yn ychwanegol at hyn, rydym yn cynnig cynllunio ar gyfer argyfyngau 'annisgwyl' drwy gyflwyno parthau cynllunio brys amlinellol. Bwriedir y rhain ar gyfer argyfyngau posibl sy'n llai tebygol o ddigwydd ond yn fwy difrifol ac felly'n codi gofynion gwahanol o ran cyfathrebu a galluoedd na pharthau cynllunio brys manwl. O ran y sector niwclear sifil, mae'r rheoliadau'n gosod pellter diofyn ar gyfer parthau cynllunio brys amlinellol a hynny ar sail tystiolaeth wyddonol a gwaith modelu. Bydd y byd amddiffyn yn sefydlu parthau cynllunio brys ar sail tystiolaeth wyddonol a gwaith modelu, ond ni fydd rhain yn cael eu nodi mewn rheoliadau. Bydd safleoedd y sector radiolegol yn asesu parthau cynllunio brys amlinellol gyda'r awdurdod lleol fesul achos. Mae hyn yn adlewyrchu'r risg bosibl a geir ym mhob sector; ym mhob un mae'r dull safonol o asesu risg yn ganolog.
36. **ïodin sefydlog:** rydym wedi cydweithio â'r Asiantaeth Meddyginiaethau a Chynhyrchion Gofal Iechyd (MHRA) a'r Adran Iechyd a Gofal Cymdeithasol (DHSC) i gyflwyno newidiadau yn y Rheoliadau Meddyginiaethau Dynol er mwyn rhoi mwy o hyblygrwydd i ymatebwyr lleol. Mae'r newidiadau'n caniatáu i ïodin sefydlog gael ei ddarparu mewn argyfwng ymbelydredd (neu os oes un yn debygol) gan berson a enwir mewn cynllun brys o dan y Rheoliadau Ymbelydredd (Parodrwydd am Argyfwng a Gwybodaeth Gyhoeddus) (REPPiR), neu gan ymatebwyr Categori 1 fel y'u diffinnir o dan y Ddeddf Argyfyngau Sifil 2004 (CCA), heb oruchwyliaeth fferylllydd. Yn ogystal â rhoi mwy o hyblygrwydd i ymatebwyr lleol, gallai'r newid hwn gynyddu effeithiolrwydd ïodin sefydlog fel cam meddygol amddiffynnol hefyd.
37. **Gweithredu cydlynol:** rydym yn bwriadu atgyfnerthu rôl y prif awdurdod lleol gan ei gwneud yn ofynnol i awdurdodau lleol perthnasol eraill a deiliaid dyletswyddau gydweithio â'r prif awdurdod lleol i ddatblygu cynlluniau brys ar gyfer manau oddi ar y safle.
38. **Profi:** rydym yn bwriadu parhau â'r gofyniad presennol bod rhaid i gynlluniau brys ar gyfer parthau cynllunio brys manwl gael eu profi'n llawn o leiaf bob 3 blynedd. Gall hyn gael ei ymestyn o dan amgylchiadau eithriadol gyda chytundeb y rheoleiddiwr. Bydd gofyniad pendant bod rhaid ystyried gwersi a ddysgwyd ac

unrhyw newidiadau o sylwedd yn y cynllun brys. Defnyddir ymagwedd gymesur at brofi'r cynlluniau brys ar gyfer parthau cynllunio brys amlinellol, megis defnyddio profion modiwlaid. Bydd yr awdurdod lleol yn bwynt cyswllt sengl ar gyfer gweithredwyr o ran adennill costau rhesymol y cyfranogwyr wrth brofi cynlluniau brys, ac yn darparu goruchwyliaeth glir a llai o ddyblygu. Rydym hefyd yn darparu hyblygrwydd ychwanegol yn hyn o beth, er enghraifft gall y rhaglen arfaethedig o brofion o dan y rheoliadau presennol barhau i fod yn gymwys hyd nes y bydd y rhaglen brofi honno wedi'i chwblhau, o gofio'r amserau arwain hir.

39. **Trafnidiaeth:** rydym yn bwriadu dileu'r cyfeiriadau at dtrafnidiaeth o'r REPPIR. Bydd Rheoliadau Cludo Nwyddau Peryglus a Defnyddio Offer o dan Bwysedd (CDGs) yn cael eu diwygio i weithredu gofynion BSSD 2013 mewn perthynas â chludo deunyddiau ymbelydrol, gan gynnwys drwy ychwanegu diffiniadau cyfatebol o argyfwng ymbelydredd, gweithwyr brys a lefel gyfeirio genedlaethol. Mae'r ONR wedi'i wneud yn awdurdod gorfodi ar gyfer y Rheoliadau Ymbelydredd Ïoneiddio (IRRs) mewn perthynas â chludo deunyddiau ymbelydrol. Rydym hefyd yn bwriadu i wybodaeth gael ei darparu ymlaen llaw i'r cyhoedd drwy ei gwneud yn ofynnol i'r ONR gyhoeddi gwybodaeth a chynghor cyffredinol ar beth i'w wneud os ceir argyfwng trafndiaeth radiolegol.
40. **Gweithredu:** rydym yn bwriadu ymgorffori cyfnod pontio o 12 mis yn y rheoliadau newydd i sicrhau bod gan y deiliaid dyletswyddau presennol ddigon o amser i gydymffurfio â'u rhwymedigaethau cyfreithiol diwygiedig. Byddai hyn yn golygu y byddai'r gyfundrefn reoleiddio bresennol yn dal yn gymwys i'r deiliaid dyletswyddau presennol am 12 mis ar ôl i'r rheoliadau newydd ddod i rym. Bydd rhaid i fusnesau sy'n dechrau gweithio gydag ymbelydredd Ïoneiddio am y tro cyntaf gydymffurfio â'r rheoliadau newydd o'r cychwyn cyntaf. Rydym wedi cydweithio â'r rhanddeiliaid i sicrhau bod hyn yn cynnig amserlen ar gyfer gweithredu sy'n deg ac yn briodol. Cyhyd ag y bydd amser Seneddol ar gael, rydym yn bwriadu gwneud ac wedyn gosod y rheoliadau a fydd yn disodli'r REPPIR gerbron y Senedd yn gynnar yn 2019. Bydd cymal adolygu pum mlynedd hefyd yn cael ei gynnwys yn y rheoliadau i sicrhau eu bod yn effeithiol ac yn cyflawni ymrwymiad y Llywodraeth i welliant parhaus. Bydd y rheoliadau a fydd yn diwygio'r CDG yn cael eu gwneud ac wedyn eu gosod gerbron y Senedd ar ffurf drafft ar wahân erbyn diwedd 2018 (unwaith eto, cyhyd ag y bydd amser Seneddol ar gael). Rydym yn cynnig ymgorffori cyfnod pontio o 12 mis yn y rheoliadau newydd i'r deiliaid dyletswyddau presennol, ac felly byddai'r diwygiadau hefyd yn dod yn effeithiol 12 mis ar ôl dod i rym.
41. **Cynllun cenedlaethol:** maes o law, mae'r Llywodraeth yn bwriadu datblygu cynllun cenedlaethol ar gyfer argyfyngau ymbelydredd a allai ymestyn y tu hwnt i barthau cynllunio brys amlinellol. Byddai hefyd yn cynnwys argyfyngau trafndiaeth a digwyddiadau rhyngwladol a fyddai'n effeithio ar y Deyrnas Unedig. Byddai'n datblygu ac yn disodli'r rhannau perthnasol presennol o'r Canllawiau Cenedlaethol Cynllunio ac Ymateb i Argyfwng Niwclear presennol. Bydd hyn yn sicrhau ein bod yn dal ar flaen y gad ymysg gwladwriaethau ynni niwclear cyfrifol, a'n bod yn arwain o ran rhoi arferion gorau diweddaraf yr IAEA ar waith.

The consultation and the responses we received

42. BEIS, MOD and HSE held a joint consultation³ between 5 October and 15 November 2017. We consulted on the Government's policy intent for transposing the emergency preparedness and response provisions of BSSD 2013 into UK law. We proposed to do this through repealing and replacing REPIR 2001, and by amending the CDGs. As part of this, the transport provisions currently contained in REPIR would be removed.

43. We consulted on proposals around the following principles, and have considered consultation responses in line with these principles:

- Outcome focused planning;
- Commensurate planning;
- A graded approach;
- Transparency and consistent decisions about planning;
- Flexibility;
- Continuous improvement.

44. We received a total of 71 responses to our consultation, not all respondents answered all questions. Responses were received from a wide range of stakeholders from across Great Britain, and an international stakeholder. A number of the domestic respondents were Great Britain wide, others were England, Scotland or Wales only. Respondents fell into the following categories:

Group	Number of respondents
Local authorities	22
Members of the public	5
Radiological	1
Health	2
Emergency services	6
Civil nuclear sector and industry	16
Defence	7
Government agencies / public bodies	2
Professional bodies	4
Pressure groups	2
Research / education institutions	3
International organisation	1

³ <https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-emergency-preparedness-and-response>

45. We would like to extend our thanks to every respondent for their input and the time they have taken to help shape the future approach to emergency preparedness and response.
46. We have analysed and assessed the responses to the questions and any supporting evidence that was provided to support the response made. Based on this evidential analysis, we have reached the conclusions set out below.
47. The key themes set out to us in response to our consultation included:
- Broad support for the proposals, noting they were logical and kept the UK in step with international standards and guidance.
 - Strong support for a consistent approach across the civil nuclear, defence nuclear, and radiological sectors.
 - Requests for further detail on the mechanics of the proposals, ideally through definitions and guidance.
 - Comments around the removal of 'reasonably foreseeable' and the introduction of 'unforeseen consequences'.
 - Broad support for removing transport requirements from REPIR.
 - Concerns that a draft set of regulations was not available alongside the consultation document for comment.

Next steps

48. We intend to take forward the draft regulations published alongside this document. The new regulations replacing REPIR will come into force shortly after they are made. Businesses that start working with ionising radiations for the first time will have to comply with the new regulations from the outset. However, we are proposing to incorporate a 12 month transitional period into the regulations from the date they come into force for existing duty holders to ensure that they have sufficient time to comply with their revised legal obligations. This would mean that the current regulatory regime would continue to apply for existing duty holders for 12 months after the new regulations came into force. The precise timing of laying and making the regulations will be subject to the availability of parliamentary time. We anticipate that they will be made and then laid in parliament in early 2019.
49. The development of a supporting Approved Code of Practice (ACOP) made under the Health and Safety at Work etc. Act 1974 (HSWA) and additional guidance is being led by ONR. This will provide further practical advice to duty holders on complying with their obligations. There will be a public consultation on the ACOP led by HSE in due course. ONR intend to complete the ACOP so that it is ready for use shortly after the regulations are laid in parliament.
50. The draft regulations amending the CDGs published alongside this document will also be taken forward by BEIS. The precise timing of the laying in draft and making of the regulations will again be subject to the availability of parliamentary time, but we anticipate that they will be laid in early December and made by the end of January 2019. We are again proposing to incorporate a 12 month transitional period into the regulations to ensure that existing duty holders have

sufficient time to comply with their revised legal obligations, meaning the amending regulations would take effect in full 12 months after the date they come into force.

Analysis of consultation responses

51. The next sections of this document set out our evidential analysis of the responses to our consultation. The areas contained in the consultation document are taken in turn, setting out:

- A summary of what proposals we made in that area in our consultation.
- Any questions we asked in relation to those proposals.
- What respondents said to us in relation to our proposals and any questions we asked, and our evidential analysis of the points made to us.
- Our conclusion in that area in light of the evidential analysis of consultation responses.

Definition of emergency

Consultation proposals

52. We proposed to replace the current definitions of “radiation accident” and “radiation emergency” from REPIR 2001 with a new definition of emergency. It would be equivalent in scope to the BSSD 2013 definition of emergency⁴ and also reflect the clarity set out in the IAEA General Safety Requirements, part 7 (GSR7) definition⁵. We proposed that the new definition of emergency would no longer be linked to a dose of radiation.

What we asked and who responded

With regards to the transposition of the definitions of Emergency and Emergency Worker and the concept of reference levels into GB law, do you have any views or suggested improvements? If yes, please provide further detail.

53. 60 responses were provided to this question. We have, for ease of reference in this document, split the definitions of emergency and emergency worker, and the concept of reference levels, into separate sections. Respondents broadly welcomed the consultation proposals around the definitions of emergency and emergency worker, and concept of reference levels. Some respondents provided

⁴ Article 4 - <https://ec.europa.eu/energy/sites/ener/files/documents/CELEX-32013L0059-EN-TXT.pdf>

⁵ Page 80 - https://www-pub.iaea.org/MTCD/Publications/PDF/P_1708_web.pdf

constructive feedback on how the proposals could be refined. A small number of respondents were unsupportive of the consultation proposals. Key themes from these responses and analysis of them are set out below, and in the following sections on 'emergency worker' and 'reference levels'.

Scope of definition, and international standards

54. Respondents agreed that despite operator design, safety features and procedures, significant events can happen, such as in Chernobyl, Fukushima and Three Mile Island. Respondents therefore agreed there was a need to consider less likely more severe events, stating that it is therefore right to reflect this in the emergency planning and response provisions of BSSD 2013 and its transposition into UK law.
55. As our consultation document set out, the definition of emergency needs to be broadened beyond the dose threshold (5mSv) in current regulations to encompass the wider impacts of a radiation emergency. This will also change how planning is determined.
56. Our proposed definition makes clear that the declaration of an emergency is no longer linked to an actual or potential release of radiation but an event arising from work with radiation that requires prompt action.
57. Respondents welcomed the decision to broaden the definition of emergency to include serious adverse consequences to quality of life, property or the environment which could be widespread. Respondents agreed with the proposal to remove the 5mSv trigger dose currently associated with an emergency in REPPiR 2001 (and the link it has to requiring emergency planning). Respondents welcomed the move to align the definitions of emergency in CCA and BSSD 2013 as far as possible. Respondents noted that the current REPPiR 2001 definition is too narrow and restrictive, so welcomed the change to address this.
58. The Government welcomes this acknowledgement and the support for the proposed approach. The Government notes that planners are already required to consider how to reduce the transfer of radioactive substances to individuals from the environment under Schedule 8 Part II of REPPiR 2001. As such, the Government considers that the reference to the environment that will be included in the new definition of a radiation emergency should in practice be more a clarification of existing emergency preparedness obligations, rather than the introduction of a new planning obligation that did not previously exist. Expanding the definition of an emergency to include non-health impacts should also shift the focus of planning from medical protective actions towards other protective actions, in effect driving a more holistic approach to emergency preparedness.

59. Respondents welcomed that this change would keep Great Britain in step with international standards and guidance, such as that from the IAEA. The Government welcomes this support. We have been clear that as a world leader in nuclear energy we are committed to strengthening UK arrangements to ensure, where appropriate, closer alignment with international standards. We will continue to work on developing and implementing those standards following the implementation of BSSD 2013.

60. A small number of respondents stated that any definition should be narrower and not include the environment, property or prompt action. These respondents were concerned about an increase of planning burdens for duty holders, and how it could be practically applied. However, no further information was provided to support this view. The Government also note that it is a legal requirement to transpose the Directive, and a definition which did not include the elements objected to would fail to do this.

Clarification

61. Respondents requested further detail on how the need for planning will be determined without the 5mSv threshold. We have designed the new regulations to be commensurate and focus the most planning on those sites with the greatest potential hazard. This means that:

- **The lowest hazard sites will continue to be excluded on the basis of their inventories.** These are listed in a schedule of the new REPPIR regulations (previously schedule 2 and 3). The numbers have been updated by Public Health England (PHE) to reflect the removal of the 5mSv dose limit (on which the current Schedule is based), align with the policy intent and reflect the latest scientific evidence. It is not expected that the updated values will significantly impact on duty holders.
- **Sites over the inventory thresholds will need to identify all hazards with the potential to cause a radiation emergency, carry out an assessment of the consequences of a full range of possible radiation emergencies and recommend, based on this, whether offsite planning should be considered by their host local authority.** The site operator can recommend:
 - Detailed and outline emergency planning;
 - Outline emergency planning; or,
 - No off-site emergency planning.

62. The difference between outline and detailed emergency planning is set out in the section below on a commensurate emergency management system.

63. The ACOP and guidance will provide practical information for duty holders on what it means and how to comply. This will maximise understanding and consistency in application, bring reassurance to duty holders, and help ensure effectiveness. The ACOP will be consulted on in due course.
64. One respondent believed that the Government was proposing a continued use of the 5mSv trigger as a threshold for taking action to protect the public / classifying a current event as an emergency. The Government clarifies that we do not propose to keep any dose limit or trigger dose in the definition of emergency. Doses would, however, continue to play a part in determining what it is proportionate to plan for following an assessment of the risks and the completion of a consequences report (further information on the consequences report is set out in the hazard evaluation section of this document).
65. Some respondents argued that the Government was proposing to reduce the trigger dose for requiring a hazard assessment to 1mSv, which would bring more sites into the scope of REPIR. Consequently, they noted that this would incur administrative burden and resource requirements. The Government clarifies that where the new regulations that will replace REPIR apply, a site will require an assessment of the risks. The 1mSv trigger dose relates to where that assessment shows that an offsite radiation release of 1mSv or more is possible (with 1mSv being equivalent to the public dose limit). Commensurate planning will require duty holders to consider whether planning is needed for offsite releases of 1mSv or more and if so, what is proportionate to plan for. Our consultation acknowledged the potential for more sites to have to consider offsite planning due to this change, however we believe this will be very a small number as records show only 60 or so duty holders have potential releases in the 1 – 5mSv range. The Government considers that any additional burden on sites will be proportionate to the risks posed and commensurate with the hazard, and so justified to protect the public.
66. Some respondents noted that the 5mSv effective dose has been interpreted not only as the ‘trigger’ for detailed planning but also used to provide a ‘dose contour’ i.e. set the extent of planning zones. These respondents were concerned that removing this dose could lead to planning zones that were too large and would be prohibitively expensive. In transposing BSSD 2013, the policy objective is for emergency planning to be commensurate. Detailed emergency planning zones (DEPZs) will therefore only increase where this is appropriate given the particular circumstances of that site. The size of the DEPZ at some sites may change depending upon the planning assumptions that were considered when the current DEPZ was set. The Government is proposing more consistent standards in relation to how planning zones are determined in our new regulations. Some DEPZs may therefore increase or decrease as a result, but as this will be

commensurate to the risk that they pose, there will be no reduction in the standard of public protection provided under the plan.

67. The extent of planning will be informed by Emergency Reference Levels (see separate section) rather than a trigger dose. This is an improvement because these allow consideration of both the benefits and limitations of a protective action⁶.

Consistency

68. Respondents noted the need for consistency across regulatory frameworks which have similar terms, to ensure there is a clear regulatory picture that duty holders can readily follow. For example, the IRR definition of ‘radiation accident’, ‘reference levels’ in the ICRP documents, ‘emergency’ in the CCA and linking across to the IRRs on dose limits. The Government agrees with the need for consistency; our drafting approach to the regulations has included reviews across the relevant regulatory documents to ensure the regulations are appropriately aligned as far as is possible. We acknowledge that the definition of ‘radiation emergency’ in the draft regulations attached is not completely consistent with the definition of ‘radiation accident’ in the IRR’s. This is due to the need to fully transpose the definition of radiation emergency in BSSD 2013 into domestic law, and also reflects the fact that the regulatory regimes in the IRRs and REPIR have different functions.

Government conclusion

69. Overall, having considered the responses we have received and the broad support they gave for our proposals, we intend to continue with the proposals we consulted upon. The draft regulations published alongside this document give effect to these proposals.

⁶ An action that can be taken which does more good than harm to protect the health of the public by reducing the risk of additional radiation exposure in a radiation emergency. Not all protective actions apply to all sites. National guidance on the use of short term or urgent health protection actions is provided through the “Emergency Reference Levels” (ERLs) defined by Public Health England (PHE). The short term health protection actions are shelter, evacuation and stable iodine – food control can also be introduced very rapidly as a precaution. Longer term protective actions include food and drink controls, relocation and decontamination.

Definition of emergency worker

Consultation proposals

70. There is currently no specific definition of an emergency worker in REPPiR, CCA or any other relevant UK law. We therefore proposed to incorporate a definition of an emergency worker with a meaning broadly aligned with the current understanding of intervention personnel into the regulations that will replace REPPiR. A key requirement associated with the emergency worker definition in BSSD 2013 is the requirement for training for these people. We proposed that information and training for emergency workers included in emergency plans should be proportionate to their role.
71. We proposed to clarify that in the event of an emergency and to prevent an emergency, exposure to levels of radiation in excess of the dose limits in the IRRs, but not exceeding the levels set for an emergency worker (500mSv) in BSSD 2013, is lawful.
72. What we asked and the responses received is as set out for the definition of emergency section above.

Clarification

73. Respondents asked for clarity about who could be an emergency worker, at what location, how volunteers would fit in, what on the day training means and how it should be achieved. A respondent noted that the current REPPiR reference to intervention personnel does not include those people who may be exposed to radiation as a result of needing to enter an affected area, but who are not doing so in direct response to the emergency (for example provision of care in the community). We engaged further with stakeholders to refine our proposals and provide the clarity sought.
74. An emergency worker will be:
- a Category 1 responder as defined in CCA who has a defined role in an operator or local authority off-site emergency plan.
 - a person employed by the operator of a site who has a defined role in the operator's emergency plan.
 - a person employed, whether or not by an operator, to assist in the transition of that operator's site from an emergency state.
 - any other person or organisation who, whether on an employed or a voluntary basis, assists in the handling of an emergency.
75. The definition and training requirements set out in the regulations published alongside this document reflects these distinctions. Further practical advice, such

as in relation to providing care in the community, will be for the ACOP and guidance to set out.

76. Respondents asked whether emergency workers include healthcare professionals and, if so, in what circumstances. They were unsure current indemnity arrangements would cover radiation exposure. Healthcare professionals would fall into the categories of emergency worker set out above. Healthcare professionals are required to hold appropriate indemnity for their scope of practice under EU Directive 2011/24/EU. This is reflected in the transposed UK legislation⁷ such as the Nursing and Midwifery Order 2001, and the Medical Act 1983. Healthcare workers working for the NHS already have an appropriate indemnity arrangement. The NHS insures its employees for work carried out on its behalf⁸.
77. Volunteers could also be included in categories of emergency worker set out above. Volunteers could be employees of a duty holder who volunteer to carry out certain tasks in an emergency, persons who are members of a largely voluntary organisation such as drivers for the British Red Cross or St John's Ambulance, or those who simply volunteer their services on the day. How the law applies, and the various roles of emergency workers will be set out in the supporting ACOP and guidance publication.
78. The regulations published alongside this document require proportionate information and training for the different kinds of emergency worker. The training requirements for those involved in direct intervention close to any source of radiation during an emergency are intended to be significant, detailed and on-going. The training that it is practical to provide to the last kind of emergency worker set out above is intended to be different, and most likely to be an on-the-day briefing, orally or via some pre-prepared written information. The ACOP and guidance that will support the regulations will contain further information on training and information requirements for emergency workers.

Disapplication of dose limits

79. One respondent asked for clarity about what situations emergency workers can be exposed to levels of radiation in excess of the IRR dose limits. Currently, regulation 14 of REPIR 2001 sets out that employees are permitted to receive doses in excess of the IRR limits as a result of their response to a radiation emergency. Regulation 15 currently sets out the formal disapplication of dose limits in the event of a radiation emergency. Neither mentions the possibility of disapplying dose limits in order to prevent a radiation emergency. This could be interpreted as requiring duty holders to wait until a radiation emergency to actually occur before dose limits can be disappplied in order to comply with the law, even if they could prevent a radiation emergency from occurring by disapplying the dose limits for certain emergency workers at an earlier time.

⁷ SI 2014/1887 - The Health Care and Associated Professions (Indemnity Arrangements) Order 2014

⁸ <http://www.nhsemployers.org/your-workforce/retain-and-improve/standards-and-assurance/professional-regulation/role-of-the-employer>

80. The regulations published alongside this document have removed this ambiguity, and make clear that dose limits are disapplied to allow an appropriate emergency worker to receive higher doses (up to 500mSv) to prevent an emergency. The supporting ACOP and guidance will explain how emergency exposures should be interpreted and managed.

CBRN trained emergency responders

81. One respondent noted that there are too few CBRN (chemical, biological, radiological and nuclear) trained emergency responders in a particular area, coupled with budgetary restraint, so they would need to rely on support from neighbouring areas. In addition, it may be beyond the control of a site operator to ensure all potential emergency workers received prior information and training. The responder recognised the need to do so however.

82. The Government notes that the CCA, and accompanying non-legislative measures, delivers a single framework for civil protection in the UK. Part 1 of the CCA, its supporting Regulations and the statutory guidance '*Emergency preparedness*' establish a clear set of roles and responsibilities for those involved in emergency preparation and response at the local level. This includes assessing the risk of emergencies occurring, putting emergency plans in place, sharing information with other local responders to enhance co-ordination, and co-operating with other local responders to enhance co-ordination and efficiency. REPPIR currently contains arrangements which require radiation emergency assessment, planning, response and co-operation amongst local responders. The replacement REPPIR will build on these arrangements.

83. Emergency planning, including capabilities to bring to bear, should be proportionate. Where it is proportionate for co-operation amongst areas to provide capabilities under an emergency plan, this would be in line with current and future legal obligations. Breaching REPPIR obligations is, and will continue to be, a criminal offence.

84. The Government reiterates that the requirement for training for emergency workers is proportionate (on a sliding scale) to the worker and their role. CBRN emergency responders have extensive specialist training, whilst responders on the day may get an oral briefing and a demonstration on site relevant to their role. The draft regulations published alongside this document provides for this.

85. In addition to local responder requirements and obligations, the Government notes that the fire and rescue authorities are expressly required by the Fire and Rescue Services (Emergencies) Order 2007 and the Fire (Additional Function) (Scotland) Order 2005, to maintain resources to respond to nuclear or radiological transport emergencies. Fire and rescue authorities are also required

to respond to requests for specialist personnel or equipment in the event of an emergency from another fire and rescue authority. The fire and rescue authorities provide a general CBRN decontamination capability, and specialist CBRN trained units of the police and ambulance services also exist. This is a key national capability. Operational guidance has been provided by the Ministry of Housing, Communities and Local Government (MHCLG) to support fire and rescue authorities in meeting their requirements. PHE has also published guidance for frontline and primary healthcare professionals, emergency planners and emergency services on recognising and responding to CBRN incidents⁹.

Government conclusion

86. Having considered the responses we have received, and following additional stakeholder engagement since the consultation, we have built on our initial proposals. The draft regulations published alongside this document reflect the revised definition of emergency workers and the associated training requirements.

Reference levels

Consultation proposals

87. Reference levels are a new concept in the UK's regulatory framework for nuclear and radiological emergencies. They set out the residual dose of radiation over a year from the point of exposure. BSSD 2013 requires that a national reference level between 20 and 100mSv is set in the event of an emergency, and that plans to optimise protection should take these levels into account. We proposed to draft the new regulations to allow flexibility, i.e. to allow local authorities, after discussion with relevant bodies such as the regulator or PHE, to set reference levels within the 20 to 100mSv range on a local level in addition to having a national reference level. We also proposed to set a national reference level of 100mSv.

88. What we asked and the responses received is as set out for the definition of emergency section above.

89. Most respondents were neutral about the proposal but requested further detail.

⁹ <https://www.gov.uk/government/publications/chemical-biological-radiological-and-nuclear-incidents-recognise-and-respond>

Clarification

90. Clarity about how reference levels interacted with Emergency Reference Levels (ERLs), Maximum Permitted Levels (MPLs), and emergency planning zones was requested.

Emergency Reference Levels (ERLs):

91. An ERL is a criterion to apply to the optimisation and justification of protective actions; it is based on the dose expected to be averted following a radiation exposure. An ERL considers the balance between the benefit from reducing the dose against the other consequences of implementing the early protective action (e.g. cost, disruption). ERLs are provided in pairs; the lower level is the smallest quantity of averted dose that would justify a protective action. The upper level of averted dose is where a protective action is almost always justified, i.e. the potential benefit of dose reduction outweighs the harm of implementing the protective action. ERLs are therefore a key tool for emergency planning. PHE publishes the recommended ERLs.

Reference levels:

92. Reference levels are the individual annual residual effective dose, i.e. the dose expected to be received over the course of a year from the point of exposure, including following the implementation of the protection strategy. Reference levels consider all significant exposure pathways and can be applied during the response, transition to recovery and recovery phases. Importantly, unlike dose limits which are values that cannot be exceeded, reference levels are values to inform protection strategies such as protective actions over a year following exposure; they are a guide tool in emergency planning for supporting the practical implementation of optimisation of protection and to aid recovery. The reference level can be taken as an indicator of the level of exposure considered as tolerable, given the prevailing circumstances.

93. In considering the potential consequences of a release of radiation, developing an emergency plan and considering protective actions, the operator of a site should compare the projected annual residual dose from the implementation of the protection strategy with the reference level for each scenario considered. This will be required by the assumptions for risk assessment in the regulations published alongside this document. The results would be captured in drafting the consequences report for the local authority.

94. There may be situations where it might not be possible to keep all doses below a 100mSv national reference level e.g. low probability, high consequence accidents. For these situations, proportionate actions should be taken to reduce

the probability or severity of these exposures. For such events, it is important to focus on the doses that can be controlled or influenced and to plan for protective actions to be implemented to reduce doses as low as reasonably achievable through the optimisation of protection. During an emergency through to recovery, we would expect the local authority to discuss minimising exposures with the aim of keeping residual doses below the reference level with relevant experts such as PHE and the regulator.

95. ERLs and reference levels apply to both DEPZs and outline planning zones (OPZs). Reference levels therefore complement ERLs. They will fit into and complement an already well established hierarchy of protective actions and advice to enhance current arrangements and support more effective emergency planning, and the optimisation of protective strategies.
96. In the event of a radiation emergency, it will be for a local authority or appropriate body defined in the emergency plan to monitor the effectiveness of protective actions deployed in the context of ERLs and reference levels, i.e. what the dose is. This would better inform the protective actions being taken and any need to take further action. The Secretary of State can also set a reference level if required.

Maximum Permitted Levels (MPLs):

97. MPLs, by contrast, are concentrations of radionuclides in marketed food and feedstuffs that cannot be exceeded. Where values do exceed the Maximum Permitted Levels, food and feedstuffs cannot enter the food chain and must be restricted. They are therefore a complementary criterion to ERLs and reference levels. BSSD 2013, and therefore our proposals, make no requirements around MPLs, so existing approaches should stand. Nothing in BSSD 2013 transposition overrides MPL requirements. MPLs have no impact on emergency planning zones under BSSD 2013. But there is nothing to stop MPL protective actions for food production systems forming part of the same emergency plan as that which contains BSSD 2013 emergency planning and response arrangements.

Government Conclusion

98. Overall, having considered the responses we have received, we intend to implement the proposals we consulted upon, having provided the further details requested. The draft regulations published alongside this document give effect to these proposals. The Government has worked closely with PHE in calculating and defining the approach to reference levels. We recognise the need for additional supporting guidance on the introduction of reference levels; the ACOP will set out this additional information. The ACOP will be consulted on in due course.

Hazard evaluation

Consultation proposals

99. In the consultation document, we proposed a way of bringing greater consistency and transparency to what is currently the HIRE (Hazard Identification and Risk Evaluation) process. This is because risk assessment, and a clear link to preparedness, is central to demonstrating we have a commensurate emergency planning system.
100. To improve consistency, we proposed standardising the methodology for calculating offsite consequences of an emergency. We have worked with PHE, ONR and representative stakeholders to codify key assumptions while allowing sites to draw on their wider risk assessment work.
101. To improve transparency we proposed that the operator would recommend an offsite planning zone or zones (rather than the ONR determining this). We proposed that this recommendation would be made in an easy to understand document provided to the local authority (a 'consequences report').
102. This report would enable the local authorities to determine appropriate emergency planning zones. They would apply local practical and geographical considerations to a technical distance provided by the operator, so that the technical distance is workable and can enable effective planning. The local authority would then be responsible for making commensurate emergency arrangements within those zones through an offsite emergency plan.
103. It would remain the role of the relevant regulator to ensure relevant duties in the regulations have been complied with, inspecting and enforcing as appropriate; this is the case for the regulations as a whole.

What we asked and who responded

Do you have views on how the HIRE process could be made more consistent and transparent (Article 98.1)? If yes, please provide further detail.

104. We received 43 responses to this question. Respondents broadly welcomed the consultation proposals. Some respondents provided constructive feedback on how the proposals could be refined. A small number of respondents were unsupportive of the consultation proposals.

Consistency and transparency

105. Respondents welcomed greater standardisation of calculating offsite consequences, stating it would reduce current inconsistencies in planning distances between sites of the same design.
106. A number of respondents welcomed the move to providing local authorities with a less technical and more easily understandable document as it could lead to more effective emergency planning and be more transparent. The Government welcomes this support.

Proportionate risk assessment and evaluation

107. A number of respondents pointed out that there was an opportunity to reduce duplication. This could be achieved by making it clear that assessments of radiological consequences could build on existing risk assessments carried out for safe operation as required by other health and safety regulations (such as the IRRs) and nuclear licensing requirements. They noted that at civil nuclear sites extensive consideration is given to risk assessment through safety cases and severe accident analysis. It would seem sensible that the results of these assessments are not recreated for emergency planning and response. Instead, where the assessments show there is potential for an offsite release, this information could inform emergency planning arrangements. Respondents stated this would maximise the benefit from generic assessments of a design and, therefore, reduce the cost of production of assessments for regulators, authorities and licensees.
108. Similarly, at lower hazard sites the radiation risk assessment required by the IRRs could inform or be sufficient to meet the requirements of the new REPPiR regulations. All radiological, civil nuclear and defence nuclear sites covered by the IRRs have to complete a radiation risk assessment before they can work with ionising radiation.
109. The Government has explored these points further with stakeholders and agrees that there is scope for improving regulatory expectations. Whilst the IRRs are focussed on worker protection and the expectation is that only those risks it is reasonable to foresee are considered, many of the risk scenarios will be the same as those considered under REPPiR. This existing risk assessment work therefore may inform to a large extent, or perhaps even be sufficient for, emergency planning purposes. Where such work isn't sufficient to identify the full range of risks for a site with the potential to cause a radiation emergency however, further work would then be needed to ensure that emergency planning is based on an appropriate risk assessment. Further information on how this will work will be set out in the ACOP and guidance.

110. This also means that the requirement to carry out a HIRE, which has been interpreted as a specific and unique process or document, has been replaced in the new regulations. The HIRE is replaced with a requirement to identify all hazards that have the potential to cause a radiation emergency, consider and evaluate the range of possible offsite consequences for the site through a risk assessment framework and standardised offsite consequences methodology, and set the key outcomes of this in a consequences report to the local authority. Operators will still be required to retain records to evidence their risk assessment work for the purpose of emergency planning. The regulator may require this evidence to be supplied by the operator. The outcomes expected to be achieved and demonstrated from any such assessment are also clearly set out in the regulations. Where existing assessments do not fully meet these outcomes, further assessment will need to be undertaken.

Standardised offsite consequences methodology

111. A number of respondents asked for further details on a consistent methodology for assessing offsite consequences following risk assessment. The new regulations published alongside this document contain a set of the assumptions and criteria that sites must use. These have been developed by PHE with input from stakeholders and will standardise the way in which offsite consequences are calculated. PHE have also developed a methodology (other models can be used) that meets the criteria required in the regulations and the assumptions that will be set out in the supporting ACOP and guidance.

112. In addition, ONR and PHE have worked closely to develop a risk assessment framework. This will determine a consistent approach for how source terms¹⁰, reflecting the range of potential radiation emergencies for a site, should be selected to be input into the standardised assessment of offsite consequences, and then which outputs from that process should be contained or reflected in the consequences report to a local authority. Further details on the risk assessment framework and how it ensures the policy intent of assessing the full range of risks for a site and planning commensurately will be provided in the ACOP when it is consulted on in due course.

113. As set out in our consultation document, for risk assessment the key change required by BSSD 2013 is that the likelihood of an event occurring is no longer the sole criterion for determining what planning is undertaken. Impacts, even of events of extremely low probability not considered in the design, also need to be taken into account for preparedness to be commensurate with the risks of the

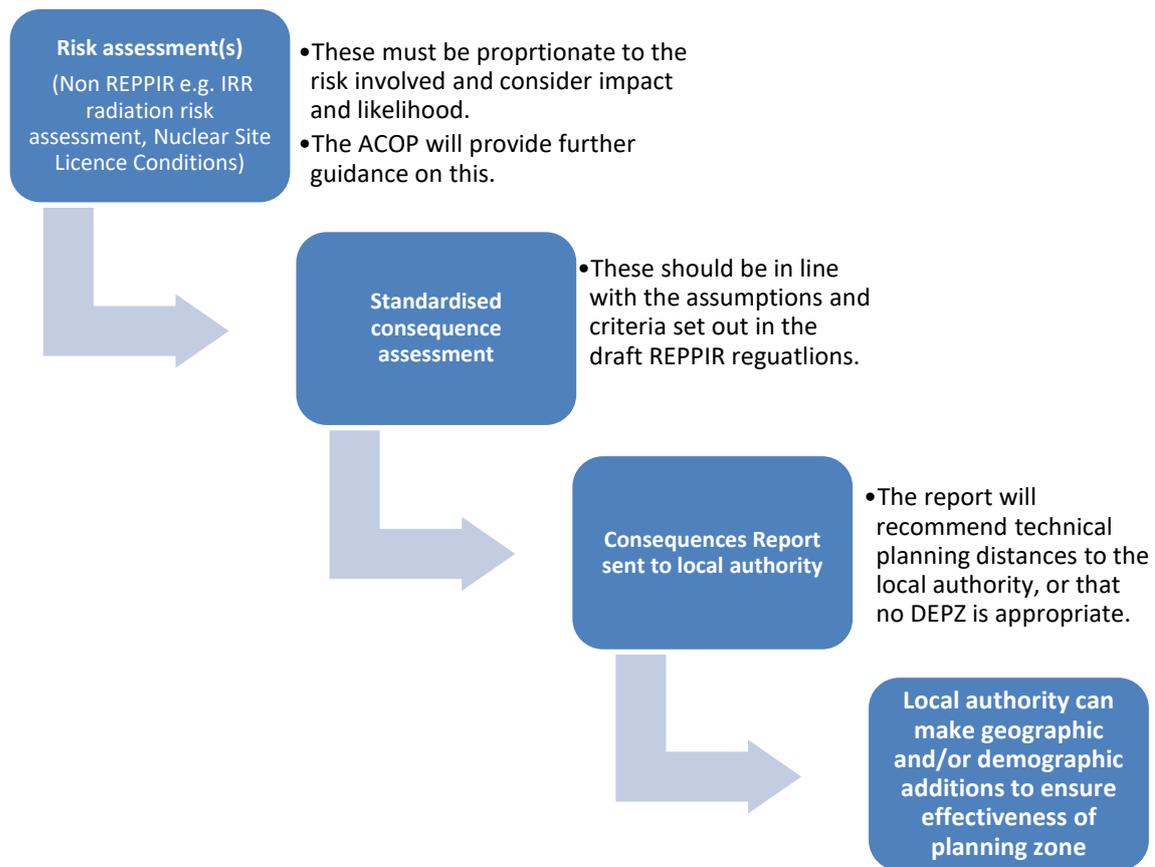
¹⁰ The types, quantities, and physical and chemical forms of the radionuclides present in a facility that have the potential to give rise to exposure to radiation, radioactive waste or discharges.

site. The regulations therefore require that operators provide an accurate reflection of the range of risks from their sites, and that this would need to take account of both likelihood and impact to meet the requirements of commensurate planning.

Consequences report

114. A number of respondents asked for further details on a consistent means of producing a consequences report. We have worked closely with stakeholders to develop a consequences report template for this purpose, which will be considered for inclusion in the supporting ACOP and guidance being led by ONR. The requirements for completing a consequences report, including what must be covered, are set out clearly in the regulations. It will be a high level report that accurately provides the range of hazards for a site with the potential to cause a radiation emergency, and their potential offsite consequences: doses, distances, times and relevant protective actions. Based on this, a minimum technical distance for a DEPZ will be recommended to the local authority with details of appropriate protective actions and when they should be applied. Or, an operator might conclude that no DEPZ is appropriate. The consequences report will not contain any information that is sensitive, or which impacts on or risks the compromise of the security and economic well being of the UK or our allies. The regulator would provide oversight to ensure this approach was followed and the results are able to be taken at face value by the local authority.
115. These sequential proposals flow from one to another to simplify and bring consistency to the risk assessment process, while ensuring it is robust and effective:

Figure 1: Flow diagram of risk assessment to consequences report



The determination of detailed offsite planning

116. In the consultation, we proposed that the need for and extent of offsite planning would be a decision for the local authority as owner of the offsite plan. However, several responses highlighted issues with this approach; the burden it would place on local authorities and the need for expertise in those organisations which either was not in place, or could be costly. Based on this feedback and further engagement with stakeholders, we have developed a revised approach with a clear division of responsibility between the operator and the local authority.

117. The operator will, in the consequences report, recommend to the local authority whether detailed and/or outline emergency planning should be undertaken, what protective action(s) this could require, its timeliness and to what distance(s). This represents the minimum technical distances and information based on scientific analysis. This is the trigger for the local authority to consider this advice (which should be prepared according to relevant ACOP materials and guidance), decide the final shape of the DEPZ according to its knowledge of local conditions and begin the process of preparing an offsite plan. For example, to ensure that a local road is not split in two, and natural barriers or boundaries such as rivers are taken account of to ensure the plan is effective. This two part process reflects the different responsibilities of the duty holders involved and will

be publicly available and transparent. Any additional distances made by the local authority to the technical distance provided by the operator to set a DEPZ would be appropriately bounded. This would be to ensure the planning zone is commensurate to the assessed potential offsite consequences for a site which are required for the development of an effective emergency plan. The ACOP will set out further details on this.

118. In further engagement following our consultation, a number of stakeholders asked for clarity on the implementation approach to ensure that sufficient time was available to step through this process by different parties at different stages. We have discussed this further with stakeholders and have included timeframes in the draft regulations which reflect this. This will ensure that each stakeholder has a fair timeframe to fulfil their requirements and not leave too little time at the end of the process for another. The implementation period (12 months from the date the regulations are made) allows sufficient time for all these timeframes.

119. A key point raised in discussion with local authorities after consultation was the potential impact of the 'key decision' process on implementation timeframes when the local authority sets the final shape of the DEPZ. The Local Authorities (Functions and Responsibilities) Regulations 2000 specify functions that must be exercised by the full Council. Entry C ("Functions relating to health and safety at work") in Schedule 1 to the Regulations requires a Council, rather than an executive, decision to be taken on any health and safety functions placed on the local authority.

120. As REPPIR 2001 and the draft regulations to replace REPPIR published alongside this document are made under powers in HSWA, the REPPIR functions of local authorities which will continue (e.g. information in the event of an emergency, offsite emergency plans), and any new or adjusted functions (e.g. planning zones confirmation, prior information) placed on them by the replacement REPPIR regulations, will continue to require a Council, rather than an executive, decision as is the case now. There is therefore no reason why modifying the current function of preparing an offsite plan by adding the function of adding local considerations to a technical distance (based on scientific analysis) provided by the operator to set the DEPZ, as is proposed, should cause the LA to make significant changes to their current practices. The decision can be made by a full Council or a committee of the full council.

121. A small number of respondents stated that the absence of a PHE methodology set out in the consultation, or the availability of ACOP and guidance to review, means that assessing the implications of the proposals or suggesting how greater consistency or transparency could be achieved was not possible. The Government believes that the policy intent has been clearly communicated, and this is reflected in the comments that have otherwise been returned.

Government conclusion

122. Since publishing the consultation, we have worked with stakeholders to refine the proposals we consulted upon in line with the feedback we received. We have done so by replacing the HIRE requirement, allowing for risk assessments from the wider regulatory picture such as the IRRs or nuclear licensing regime. This should minimise burden on stakeholders. The regulations published alongside this document give effect to these refined proposals. Local authorities can call upon PHE to support them for the provision of independent radiological protection expertise in relation to protective action planning in the DEPZ.

Commensurate emergency management system

Consultation proposals

123. Article 97(2) of BSSD 2013 requires the emergency management system to be commensurate with the results of an assessment of potential emergency exposure situations. And, to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events.

124. In the consultation document, we identified some barriers in the interpretation of the existing regulatory framework to achieving this. First, in line with the current supporting guidance it has become, in some cases, custom and practice to consider only 'reasonably foreseeable' radiation emergencies based on a likelihood of 1 in 10^{-5} , irrespective of consequences. Second, the use of the 5mSv trigger dose in determining the need for an offsite emergency plan. We proposed removing these thresholds and trigger doses and instead requiring commensurate planning informed by operator risk assessment at the site. We consulted on the introduction of new OPZs for less likely but more severe emergencies, in addition to DEPZs.

What we asked and who responded

In relation to transposition of Article 97(2):

Do you have any information about, or views on, the impact of the proposed changes?

Are there any opportunities, as part of this modification of planning arrangements, to make detailed planning around sites less burdensome to operators or local authorities (while maintaining the standards of public protection)?

If yes, please provide further detail.

125. 58 responses were provided to this question. Respondents broadly welcomed the consultation proposals. Some respondents provided constructive feedback on how the proposals could be refined. A small number of respondents were unsupportive of the consultation proposals. Key themes from these responses and analysis of them are set out below.

Clarity, proportionality and building on safeguards

126. A number of respondents fully supported planning for unforeseen events and welcomed greater transparency from the operators. One operator noted that the regulatory interpretation of the 5mSv and reasonably foreseeable accident has caused considerable confusion. Some respondents cited more common approaches to emergency preparedness and risk assessment which use impact and likelihood (not just likelihood) to inform decisions on what preparedness is commensurate.

127. Respondents welcomed proposals that would further strengthen our emergency preparedness and response arrangements for radiological emergencies. The Government welcomes this support.

128. Respondents welcomed the move to focussing on the impacts of where an emergency is most likely to be felt, the impacts are most severe, or where the benefits are greatest, as a sensible approach. Targeting hospitals, care homes, schools and other facilities where vulnerable people may reside and our proposal for DEPZ pockets within an OPZ was also welcomed as common sense.

129. The proposal to replace Reports of Assessment (RoA's) with a consequences report was welcomed as likely being much more easily understood and therefore having an improved impact on appropriate planning by local authorities.

130. The Government welcomes this acknowledgement and the support for the approach taken.

Extendibility and risk likelihood

131. A number of respondents who took part in the recent extendibility exercises did not wish to revisit planning zones so recently after reviewing them as part of the extendibility exercise. They viewed it as an unnecessary use of time and resources which would add little to the lessons already achieved. The Government acknowledges the value the extendibility exercises added in progressing emergency planning and response arrangements. However, whilst it was a useful exercise and provided invaluable information for policy development, it falls short of BSSD 2013 requirements as it is an assessment, not a plan. The Government hopes that lessons learned by stakeholders from the extendibility exercise will be used in implementing any additional planning required by new regulations.

132. Some respondents made comparisons to the National Risk Register and the relatively lower likelihood of risks being considered for outline emergency planning. We acknowledge this difference but consider that it is in line with the UK's historically lower tolerance of radiological risk and its ongoing commitment to the highest international standards of nuclear safety. We are clear that these changes are in no way driven by any change in risk at the UK's nuclear and radiological sites, rather they are for continuous development and improvement in emergency preparedness, building on the already robust arrangements that are in place.

Defining the unforeseen and the OPZ

133. Some respondents noted that the term 'unforeseen' would need careful definition and could be misunderstood. The Government agrees that it is a challenging concept to convey but in developing policy has used the IAEA definition of 'events of very low probability not considered in the design [of sites]'.

134. To support civil nuclear operators and local authorities in preparing for unforeseen emergencies, BEIS has worked with PHE, ONR and site operators to model the impact of very severe, very unlikely emergencies at civil nuclear sites. This applied the standardised approach to risk assessment for DEPZs set out in the sections above to a full range of scenarios for sites, including unforeseen scenarios (i.e. including events with more severe consequences; this includes emergencies that site operators may believe to be very unlikely, such as those that involve multiple/total barrier failures and are not considered in the design). As set out in the consultation document, this scientific analysis has informed the

“default distances” for OPZs which will be included in regulation for civil nuclear sites.

135. As well as this scientific analysis, in determining the default OPZ distances for the civil nuclear sector, we considered other factors. This included:

- international comparisons for outline planning, including best practice advice from the IAEA;
- the practical ability for a site and local authority to plan, respond effectively and where that could extend to;
- the potential for costs to outweigh benefits and for costs to be justified; and,
- the overriding need for commensurate planning effort, given the extreme unlikelihood of such an event coming to pass.

136. In the draft regulations published alongside this document, civil nuclear sector OPZ default distances are categorised by type of site, with the highest potential risk site(s) having larger outline planning distances. Sites will be able to move between categories subject to ONR approval; for example if the site is decommissioned and the risk is therefore reduced, allowing the site to move category will change the default OPZ required so it continues to be commensurate. For further flexibility and to ensure that outline planning zones remain commensurate, we intend for variation from the default distances set in regulations to be allowed for a site. Any increase or decrease in the default distance for a site will require both ONR Chief Nuclear Inspector and Secretary of State approval in consultation with each other. This will act as an appropriate safeguard to ensure public protection is maintained. Any variation to the default distances for an individual site will require evidence to an equivalent standard of the approach set out above in order to be considered.

137. In addition, to further mitigate against unforeseen emergencies, in due course the Government will be developing a national plan for radiation emergencies which could extend beyond outline emergency planning zones. It would also cover transport emergencies and international events which affected the UK. It would build on and replace appropriate parts of the current National Nuclear Emergency Planning and Response Guidance in due course.

138. For defence nuclear sites and operational berths a similar approach to assessing the impacts of very low likelihood, severe emergencies has been adopted. MOD reviewed the current outline planning arrangements in place by undertaking internal modelling and analysis. This analysis concluded that existing defence planning distances are proportionate, and that for the majority of defence sites no changes are proposed. Defence OPZ distances will not be set out in regulations.

139. For the radiological sector overseen by HSE (hospitals, universities, transit hubs and defence non-nuclear sites for example), the intention is that no default OPZ distance(s) will be set by HSE. The reason for this approach is as follows.
140. The introduction of outline planning to transpose the requirement in BSSD 2013 to plan for the very rare yet very severe consequence scenario is a reflection of inherent hazard. HSE is adopting a goal-setting rather than prescriptive approach for the non-nuclear sector, which is consistent with the well-established approaches to management of work-related hazard and risk established in HSWA under which the regulations that replace REPPiR will be made. This goal-setting approach puts the duty to plan in outline firmly on the duty holders, who are best placed to think about, understand and actively develop arrangements for planning that are both proportionate to the risk and commensurate with the hazard.
141. Setting default distances would only be in line with this goal-setting approach if the sector were uniform and one assessment would accurately reflect a commensurate level of planning. However, the non-nuclear sector is diverse. HSE as the regulator has received HIREs under REPPiR 2001 from duty holders in around 15 different industry sectors. Setting one default distance when even within sectors there are differences in the operating environment would be hard to justify and arguably disproportionate. The sector is not static, with technical development(s), advances in research and changes in inventory levels in storage all potentially altering radionuclide holdings. Therefore setting default distances risk imposing disproportionate, impractical requirements on this diverse and dynamic sector, and would not future-proof regulations.
142. But importantly this does not mean that there is no need for the non-nuclear sector to consider outline planning, as this will be a requirement in the regulations. The intention is for supporting ACOP and guidance publication to assist duty holders in determining both the need for and the size of their OPZ.
143. Very simply, non-nuclear operators will, as appropriate, need to discuss with their local authority whether outline planning for a less likely, but (relatively) severe, radiological emergency in a non-nuclear facility is covered by generic planning arrangements that already exist or whether these are a baseline from which more information-type planning activity is considered.
144. These assessments are therefore commensurate to the hazard potential of the different sectors covered by the new REPPiR. Each approach to outline planning has the standardised approach to risk assessment that has been developed at its centre and has resulted in setting the following categories of site and any default OPZ distances:

Category / site:	Default OPZ distance:
Sites involved in the processing of High Level Waste and/ or storing in excess of 100 tonnes of Plutonium	50km.
Operating nuclear power plants and decommissioning nuclear power plants with a presence of irradiated fuels	30km.
Sites with a significant presence of enriched uranium and decommissioning nuclear sites (other than power plants) with a significant presence of irradiated fuels	5km.
Decommissioned sites without a significant presence of irradiated fuels	1km.
Sites involved in the production of radiopharmaceuticals	0km.
Defence authorised and licensed nuclear sites, and operational berths.	As may be determined by MOD (will not be set in regulations).
Radiological sector sites (including Defence non-nuclear sites).	Case by case assessment informed by application of the standardised risk approach to outline planning (will not be set in regulations).

145. One response to the consultation noted that the maximum distance for outline emergency planning should be 30km. However, we have proposed that 50km is the maximum distance for one category of site; this has been informed by modelling we have jointly undertaken and the unique nature of the category of site. We have confirmed that this is in line with IAEA guidance (accounting for the differences between the UK approach and the IAEA's different emergency planning zones) as the OPZ is a blend between the IAEA's 'Urgent Protective Action Zone' and 'Extended Planning Distance'.

Clarifications

146. There were a number of requests for more detail on the difference between DEPZs and OPZs. The Government anticipates that, to assist the operator and local authority, the ACOP and guidance supporting the regulations will contain detailed, practical information about the different kinds of arrangements expected by the regulator in DEPZs and OPZs.

147. The outline planning zone is a new regulatory concept designed to deliver commensurate planning for very low likelihood more severe emergencies. The central aim of the outline planning zone is to support the decision-making of emergency responders in the event that detailed or generic arrangements for

nuclear emergencies are not sufficient. It is similar to the approach taken for reservoir flooding. Plans should contain as a minimum:

- pre-prepared information that can be provided to the public immediately to limit high risk behaviours (e.g. self-evacuation);
- relevant information about population demographics (e.g. location of schools, hospitals, care homes, vulnerable groups); and,
- an assessment of where regional (e.g. a neighbouring local authority) or national support would be needed and how that could be requested.

148. This new formal outline emergency planning should build on the voluntary extendibility assessments undertaken post Fukushima. As with detailed emergency planning, local authorities will create and be responsible for outline emergency plans; where a detailed nuclear emergency plan already exists this should simply be an additional section.

149. Outline emergency planning differs from detailed emergency planning (currently carried out around nuclear sites) in the following key ways:

- **Outline emergency planning does not aim to implement protective actions like evacuation or sheltering immediately.** Because the population in question is largely further away from the site (unless there is no DEPZ) and therefore any release, and outline emergency plans are made on the basis that emergencies are much less likely, it is proportionate to allow for a greater time to implement protective actions and/or take decisions about further actions.
- **It assumes that the residents in question have no prior knowledge of the emergency arrangements;** given the large areas and significant populations involved, we assessed that it would be counterproductive for outline emergency planning to attempt to warn and inform people in advance of incidents. The churn rate alone would make prior information ineffective and it could have significant disadvantages.
- **It is higher level and therefore requires less resource;** much of the cost associated with current detailed emergency planning is driven by the need to be able to implement protective actions immediately. For example, for some emergencies stable iodine tablets are pre-distributed and sites set up automatic phone systems. Given the low likelihoods involved this kind of investment would not be proportionate and it could well prove ineffective in the event of an unforeseen emergency. It is therefore about identifying and making high level provision for how capabilities could be extended from the DEPZ (where one exists) or where, how and what

protective actions could be obtained from and implemented, rather than having them in place ready to mobilise immediately.

150. The above description reflects an important amendment we have made to our approach on informing the public. Respondents highlighted that if prior information for the public was the same in DEPZs and OPZs then this could be disproportionate and lead to unintended consequences, such as confusion and decreased public confidence. We are grateful for these responses and we have amended our policy approach accordingly. The draft regulations published alongside this document give effect to this approach. In short, prior information would be provided proactively to populations in DEPZs. Appropriate information would be available when requested by those in OPZs, and there would be a requirement for planning zones to be shown on a local authority website for transparency (however, there is no bar on local authorities providing prior information proactively in the OPZ).

151. Requirements around the provision of information to the public in the event of a radiation emergency will be retained from current regulations, but with the addition that this should cover events in Great Britain or internationally which may affect Great Britain. We have also updated the communication channels by which information can be provided to ensure it is up to date.

152. In addition to the concept of outline emergency planning, the Government intends in due course to develop a national plan for radiation emergencies which could extend beyond outline emergency planning zones. It would also cover transport emergencies and international events which affected the UK. It would build on and replace appropriate parts of the current National Nuclear Emergency Planning and Response Guidance in due course. This will ensure we remain at the forefront of responsible nuclear energy states. This is in line with the latest guidance from the IAEA and will provide a framework for responding to the most severe and least likely emergencies.

Government conclusion

153. Overall, having considered the responses we have received, we intend to amend our approach to prior information to the public, and the determination of offsite plans as discussed above, but otherwise continue with the other proposals we consulted upon. The draft regulations published alongside this document give effect to these proposals. The ACOP and guidance being taken forward by ONR will provide further information for duty holders and practical advice for duty holders on how to comply with their obligations. This will help to ensure consistency in approach.

Stable iodine

Consultation proposals

154. We proposed that there should be revised arrangements for the timely administration of stable iodine in the event of a radiation emergency involving radioactive iodine. These changes should provide local responders with flexibility to determine how they pre-distribute, or store and distribute from a local hub / hubs in an emergency. This will enable them to best take account of local circumstances and ensure they protect the health and well-being of the public. We proposed to do this by removing the legal barriers preventing stable iodine distribution without supervision from a pharmacist in an emergency. We proposed to develop guidance with others to support this.

Responses we received

155. 12 respondents provided a view on our stable iodine proposals. Responses offered support for a flexible system that includes the ability to store and then distribute stable iodine, as well as pre-distribute it. Respondents set out different preferences for how they could use a more flexible model to supply stable iodine, demonstrating the need for flexibility and the Government proposals around flexibility which would accommodate this. One suggested reclassifying stable iodine as a general sales list drug to further increase flexibility and negate any need for a wholesale dealers licence. The Government welcomes this support, but notes that drug classification is out of scope for these changes and would be a matter for MHRA (Medicines and Healthcare products Regulatory Agency). In addition, reclassification of stable iodine would not remove the need for a wholesale dealer's licence which may be required in order to distribute stocks of the medicine.

New legislation in effect

156. Given that respondents welcomed the proposals set out in response to our consultation and the availability of parliamentary time, we have worked closely with MHRA and DHSC (Department of Health and Social Care) to make changes to the Human Medicines Regulations. They took effect from 1 April 2018¹¹. The changes allow stable iodine provision in a radiation emergency (or where one is likely) by a person named in an emergency plan under REPPiR, or by a Category 1 responder as defined under the CCA, without supervision from a pharmacist. A local authority could choose to pre-distribute stable iodine or store locally in a hub/hubs to distribute from. Those which pre-distribute now could continue to do so if they wished. This means stable iodine could be lawfully obtained and

¹¹ SI 2018/199 – Regulation 12 of The Human Medicines (Amendment) Regulations 2018

distributed in an emergency, whether at a site or following a transport emergency. Therefore, it is a substantially more flexible framework of options for local responders than the previous approach of requiring pharmacist supervision which may not always be available during the extreme time pressures of a radiation emergency.

Using the flexible framework

157. One respondent asked whether existing pre-distribution in the DEPZ will change following the amendments to the Regulations. The Government notes that duty holders who are currently pre-distributing in the DEPZ can continue to do so if they wish. This framework provides flexibility for local authorities and responders to decide how best to protect the public based on local circumstances. It would be for the local authority to determine appropriate stable iodine arrangements in their DEPZ(s) having considered the consequences report. In determining whether stable iodine should form a part of emergency planning, and the form it should take (for example pre-distribution, local hubs to distribute from in an emergency, or a combination), local authorities would consider the commensurate need for it.
158. In considering the best means of distribution, local authorities should base this on advice from, and working in partnership with, relevant public health bodies. However, they must satisfy the regulator that these arrangements are adequate and proportionately protect the public. Each method of distribution has advantages and disadvantages, for example pre-distribution has low retention rates in large populations, but is likely to be more practical in low and sparsely populated areas.
159. We intend to work with PHE, DHSC and other key stakeholders to develop further guidance on stable iodine provision in due course. This would also cover advice on stable iodine provision in OPZ's.
160. It should be noted that there may be a need to acquire a wholesale dealer's license by local authorities or other entities depending on how they chose to use the flexible framework. It is required where there is any supply of stable iodine (other than supply to the public) between separate legal entities. Therefore if the local authorities need to be able to share stocks between one another then they will need to hold a wholesale dealer's licence to enable them to do so.
161. The same will go for moving stock between different legal entities within infrastructure on a local authority's territory – such as between schools, hospitals, fire stations, police stations, a site operator etc. A wholesale licence would not be required, however, if those organisations were simply acting as agents on behalf of the local authority so that it is the local authority that retains responsibility for

the medicine at all times (hence there would be no change in ownership of the product and only a change in where the local authority is storing it). As set out in our consultation, a single organisation would need to ensure the stable iodine is procured in a correctly packaged manner, i.e. it can be distributed to households without further need for breaking down the pack into smaller quantities (this would be considered medicine assembly, requiring a manufacturer's licence). Members of the armed forces would continue to be exempt from the restriction on supply of prescription only medicines under the conditions set out in Schedule 17, part 2, paragraph 10 of the Human Medicines Regulations.

162. One respondent noted that pre-distribution of stable iodine in recent decades was largely adopted because of the difficulties encountered in determining who would be responsible for distributing stable iodine reactively and to ensure that administration would take place promptly. Pre-distribution also supports administration in combination with sheltering advice, rather than stable iodine being a "stand alone" protective action. The respondent asked what the evidence base was for the statement regarding "low retention rates in large populations" in the UK?

163. The statement in our consultation document on low retention for pre-distributed stable iodine is supported in several studies. For example, Zwolinski et al 2013¹²; Rosselli, et. al. 2013¹³; and J Astbury et al 1999¹⁴.

Transition to recovery

164. Article 98.3 of BSSD 2013 requires that the transition to recovery is planned for as part of an effective emergency management system. The draft regulations published alongside this document set out that the consequences report will set out when and to whom the premises are to be handed over in order to transition to recovery. This should therefore include considering how an emergency is terminated. The ACOP and guidance being taken forward by ONR will provide further information for duty holders and practical advice for duty holders on how to comply with their obligations. This will help to ensure consistency in approach.

165. Some respondents felt that our proposed changes did not go far enough because they did not require emergency plans to consider recovery in detail. This is a deliberate decision; the emergency plans should consider how the recovery phase actors and governance will take over from the responders. Requiring recovery planning would go beyond BSSD 2013. We are clear that the focus of

¹² <https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/article/nuclear-power-plant-emergency-preparedness-results-from-an-evaluation-of-michigans-potassium-iodide-distribution-program/2398876E39ABBCF70BD860F42F9F8D79>

¹³ <http://www.ijmed.org/articles/622/download/>

¹⁴ <https://www.ncbi.nlm.nih.gov/pubmed/11469363>

emergency plans required by the regulations that will replace REPIR should remain the response phase, in particular the first few hours after the emergency. As the process of transitioning from an emergency situation to a recovery situation is not specific to nuclear or radiological emergencies, the Government is of the view that most local authorities will be able to draw on non-radiological processes to plan for the transition from an emergency exposure situation to an existing exposure situation.

166. Nonetheless, there is recovery guidance available from PHE¹⁵; planning for recovery after a radiological emergency is best practice but not a legal requirement.

Co-ordinated planning

Consultation proposals

167. Under our proposals, the duty for offsite emergency planning falls to local authorities. With the introduction of outline planning zones more local authorities have the potential to be within an emergency planning zone. It is important that the lead local authority can plan for and lead an effective response, especially where a plan crosses the boundaries of local authorities.

168. It is important for sites to consider the range of risks and consequences associated with their activities and how this impacts on preparedness and response. We proposed that this should not be limited to just the single site but extended to include adjacent sites and consider the sum of the parts. To reflect this, our consultation offered two proposals:

- Continue current arrangements under REPIR 2001. Within a given emergency planning zone, the lead local authority would coordinate emergency planning and response across local authorities within that area.
- Develop a new strengthened approach whereby the lead local authority would have a duty to work with local authorities to develop a single, coherent offsite plan. Where sites are located adjacent to each other, multiple duty holders, where appropriate, should seek to develop off site plans that encompass those sites, given the proximity and potential impacts of an emergency within the same area, cross over in offsite plan boundaries and benefits of mutual support arrangements

¹⁵ <https://www.gov.uk/government/publications/uk-recovery-handbooks-for-radiation-incidents-2015>

What we asked and who responded

Do you have views on the proposal to require coordinated planning between multiple duty holders (where they are in close proximity)?

If yes, in particular, please share your suggestions for how this could work in practice.

169. 43 responses were provided to this question. Respondents broadly welcomed the consultation proposals. Some respondents provided constructive feedback on how the proposals could be refined. A small number of respondents were unsupportive of the consultation proposals. Key themes from these responses and analysis of them are set out below.

Reducing burden and strengthening safeguards

170. Respondents welcomed proposals that would further strengthen our emergency preparedness and response arrangements for radiological emergencies. And that they would keep us in step with the latest relevant international standards and guidance, such as that from the IAEA.

171. Respondents also welcomed the second proposal as a sensible and logical requirement. A number saw the potential for this requirement to reduce the burden on duty holders who could develop a single plan for adjacent sites. This would remove duplication and help with effective use of resources to enhance emergency preparedness and response. Some saw this as a formalisation of existing processes, that it is already implicit in the current regulatory regime via national, local forums, committee meetings and under the Control of Major Accident Hazards (COMAH) Regulations.

172. For example, Dounreay Site Restoration Limited and the Naval Reactor Test Establishment (NRTE) Vulcan are two adjacent sites. They work closely with the local authority to develop their plans through a local liaison meeting with other responders, participation in each other's annual emergency exercises and the preparation of a joint local residents' emergency handbook. In Lancashire and across the North West region, coordinated planning and sharing of best practise is already in place and effective. In the Argyll and Bute area, duty holders work closely with all partners in order to ensure effective co-ordinated planning – collectively preparing and reviewing plans whilst ensuring lessons identified in exercise debriefs are actioned.

173. Other respondents highlighted that this was a proportionate proposal, strengthening arrangements and bringing consistency. One respondent considered it vital to effective emergency planning and response. The Government welcomes this support.

Guidance

174. Respondents stated that the proposals were useful and necessary. There were a small number of requests to provide further detail on the mechanics of the proposals, including the roles and responsibilities of duty holders ideally through definitions and guidance. One respondent suggested setting up a national forum to support duty holders with implementation. One respondent asked who would have decision making power if there is a dispute between duty holders. The Government agrees that any definitions, terms or roles used will need to be clear and not open to wide interpretation. The ACOP and guidance being taken forward will provide further information and practical advice for duty holders on how to comply with their obligations. This will ensure consistency in approach.

Existing regulations

175. One respondent believed this proposal was already covered by COMAH and CCA, and that BSSD 2013 makes no mention of it. Therefore the focus should be on getting the risk assessment right. Another respondent saw no reason why a decommissioned / decommissioning site should co-ordinate with a neighbouring active site since the risk of an emergency occurring was so low. There were also comments about difficulties in obtaining information to understand the radiation sources, risks and hazards associated with adjacent sites.

176. BSSD 2013 requires that the UK's emergency management system to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events. The Government considers that a lack of coordination where a plan crosses the boundaries of local authorities could compromise the effectiveness of the UK's emergency management system. We do not think that the CCA, which is a high level, generalised set of emergency procedures, is itself sufficient to overcome this potential lack of coordination.

Government conclusion

177. Coordinated planning is a relatively new area. There are barriers to implementation (commercial and security) that limit the ability to apply a consistent and straightforward approach. Although some sites already undertake this, many do not. This is especially difficult where clusters of sites with low quantities of low hazard material that pose a low level of risk exist. Based on the

consultation responses, further discussions with duty holders and current practices we are implementing the following arrangements.

Offsite emergency plans

178. We intend to continue with the proposal to strengthen the role of the lead local authority and place a requirement on other relevant local authorities and duty holders to work together with the lead local authority to develop the offsite emergency planning.

Onsite emergency plans

179. Duty holders must consider adjacent sites in their risk assessment and planning activities. We recognise the benefit in joint planning between sites where their planning boundaries are in close proximity or overlap, and mutual support arrangements. However, we recognise the difficulties in applying this. We would therefore encourage this as good practice, but will not mandate this requirement in regulation. The ACOP and supporting guidance will set out further details and advice on compliance.

180. The Government believes that the different level of requirements between onsite and offsite planning should reflect the commensurate and graded approach intended by the policy.

181. The draft regulations published alongside this document give effect to this proposal, while the ACOP and guidance being developed will provide support to duty holders to enable them to put them into practice.

Testing arrangements

Consultation proposals

182. Testing is critical to understanding whether our emergency response plans will deliver public protection in an emergency. It is important that when revising these plans they take account of lessons learned to maintain improvement in the sector. Our consultation proposed that a similar provision to the current requirement that emergency response plans are tested, reviewed and, as appropriate, revised at regular intervals not exceeding three years, should be retained.

183. We considered, and sought views on:

- Adding an explicit requirement that plans take account of lessons learned from past emergency exposure situations, participation in emergency exercises at national and international level;
- A requirement to demonstrate an adequate test of any offsite plan to the relevant regulator; and,
- The ability for local authorities to request from operators the recovery of reasonable costs incurred by all responders required to participate in the preparation and testing of an offsite emergency plan, not just costs incurred in arranging for the emergency services to participate in the testing (as is currently the case).

What we asked and who responded

Do you have any views or suggested improvements on the proposed amendments to testing arrangements (Article 98.4)? If yes, please provide further detail.

184. 48 responses were provided to this question. Respondents broadly welcomed the consultation proposals. Some respondents provided constructive feedback on how the proposals could be refined. A small number of respondents were unsupportive of the consultation proposals. Key themes from these responses and analysis of them are set out below.

Strengthening arrangements

185. Respondents welcomed proposals that would further strengthen our emergency preparedness and response arrangements for radiological emergencies. They felt this would bring us a step closer to meeting the latest relevant international standards and guidance, such as that from the IAEA. Respondents saw the proposals as logical, and a number stated that the proposals would formalise the current best practice approach that they operate, while being in line with CCA requirements. Others stated there was no adequate testing at present, so this was a welcome development. The Government welcomes this support.

Guidance

186. There were a number of requests to provide further detail on what this would mean in practice. Questions included: What the frequency of testing would be? What would happen if the offsite plan demonstration exercise consistently failed and what would the cost and operational implications would be? What the mechanism and system of enforcement and dispute resolution would be? How lessons would be identified and taken into account? Whether all agencies would

be required to participate in exercises? How different protective actions e.g. evacuation would be tested? The difference between testing offsite emergency plans and emergency response plans. Respondents also questioned the current recharge arrangements where local authorities were the central contact point, indicating a preference to recover costs directly from the operator. We understand the need for clarity in this area given the importance of, and the number of elements involved in, testing the emergency plan.

Cost recovery

187. There were a number of responses provided on cost recovery with a focus on ensuring relevant and reasonable costs would be recovered with some wanting precise details on the actual costs allowed and amounts. The majority of respondents were supportive of the proposal to be able to recover reasonable costs from the operator. However operators were concerned about the potential implications and wanted clear boundaries for what was reasonable. One respondent also highlighted that while cost recovery is welcome, it should not hinder the arranging of large scale live-play exercises.
188. One respondent stated that they did not support the proposal to introduce the ability of local authorities to request the recovery of reasonable costs incurred by all responders required to participate in the preparation and testing offsite emergency plan.

Frequency and approach to testing

189. One respondent stated that retaining the current frequency of a test at least every three years was unsustainable. The planning for such an exercise takes approximately 18 months, the debrief 3 months, and the re-write of the plan a further 3-4 months, meaning that there will only be 12 months to resolve any lessons learned. Three respondents commented that they would prefer a move from the three year full testing to a modular approach with more frequent testing. Another suggestion was to allow flexibility in exceptional circumstances to the requirement for a full test every 3 years.
190. On cost recovery from testing one respondent suggested that each agency should be able to recover its own costs directly from the operator rather than going through the local authority, which was putting additional burdens on the local authority to coordinate.

Government conclusion

Testing

191. We remain committed to ensuring that duty holders demonstrate an adequate test of any offsite plan to the relevant regulator. The ACOP and guidance will set out what an adequate demonstration would look like in practice.
192. We understand changes in the planning requirements under the new regulations will put requirements on duty holders to consider and plan for DEPZs and OPZs. The two zones both have different planning and therefore testing needs; it is important that this is reflected in our testing arrangements. We therefore propose to implement a graded approach to testing that is commensurate in detail and scale to the potential emergency.

Detailed Emergency Planning Zones

193. We intend to continue with a three year testing cycle as currently operated to ensure emergency response arrangements remain up to date. The three year cycle offers sufficient time to implement and learn any lessons while providing both the flexibility required and reassurance that the plans are regularly tested. We agree that there may be exceptional circumstances which, subject to the regulator's agreement, *could* justify a need to extend the three year limit. This could include, for example, military deployment or in the event of a radiation emergency. The regulations published alongside this document provide for this should the regulator determine it is appropriate. The ACOP and guidance will play a role in articulating what the exact criteria for exceptional circumstances could be and the procedures to obtain such a consent from the regulator.

Outline Emergency Planning Zones

194. We want to maintain our outcome focused, commensurate and flexible principles. We understand the benefits of a modular testing arrangement for some operators and how this could apply in particular in OPZs. Modular testing or using aspects from other types of large scale emergency response situations, could prove useful ways to demonstrate capability in OPZs. However, it will be for the ACOP and guidance to provide practical advice to duty holders as to how to demonstrate an adequate test.

Lessons Learned

195. We are aware that lessons learned from past emergency exposure situations are already adopted and incorporated into a number of emergency plans. We want to strengthen this arrangement and make it a requirement for all those

involved to ensure best practice applies across the whole sector. We will maintain our consultation commitment to including the requirement that plans take account of lessons learned from past emergency exposure situations or the results of the participation in emergency exercises at national and international level.

196. The national Lessons Learned Working Group will continue to play a key role in supporting the sector to develop and apply this learning and, where appropriate, tackling the higher level, cross cutting issues through escalating to the National Nuclear Resilience Coordination Committee (NRCC) or through the ability to translate these into local practice.

Cost recovery

197. A number of responses were provided on cost recovery. The Government consultation set out that reasonable costs should be recovered from operators in emergency plan testing. We did not consult on the type and amount of costs that could be recovered but further information will be included in the ACOP and guidance.

198. We understand the need for costs to be fair, reasonable, affordable and specific to the costs actually incurred. We believe that the local authority should remain as the single contact point for operators for cost recovery for simplicity, providing clear oversight and reducing duplication. Reasonable costs should be recoverable from the operator by participants in emergency plan testing. Costs need to be set out in a detailed statement and agreed. These costs are recoverable as a civil debt. It will be for the ACOP and guidance to provide practical advice to duty holders on meeting these outcomes in a consistent manner. The relevant regulator will continue to play a central role in ensuring compliance with the requirements. We note that there are a number of routes that could be used to resolve disputes before pursuing recovery as a civil debt, for example raising as a compliance issue to the regulator, or the use of mediators.

Transport

Consultation proposals

199. As set out in our consultation, BSSD 2013 applies equally to radiological transport as it does to fixed sites. BEIS is the lead policy department for all radiological transport by road, rail and inland waterway. MOD is the lead policy department, and is responsible, for Defence nuclear movements. ONR is the regulator for civil transport. Regulation 24 and Schedule 2 of the CDG sets out the requirements for preparing for and responding to nuclear and radiological emergencies which occur during the carriage of radioactive material.

200. We proposed the following key changes to the regulations to transpose BSSD 2013:

Definitions

- *'emergency'*: The previous definition of emergency was broadly in line with BSSD 2013, but did not mention the environment or property. The Government proposed to amend the CDG so that the definition of a radiological emergency explicitly includes risks to quality of life, property and the environment.
- *'emergency worker'*: As previously stated, there is currently no specific definition of an emergency worker in the CDG, the CCA or any other relevant UK law. We proposed to include one in line with the new REPPIR definition discussed above.

Reference levels

- Paragraph 4 of Schedule 2 to the CDG already requires emergency plans to have regard to dose limits set by PHE (referred to as the Health Protection Agency), so we proposed to build on this so that plans also have regard to any national reference level.

Transition to recovery

- Carriers and consignors will be required to support the transition from an emergency exposure situation to an existing exposure situation.

Risk assessment requirement

- We will make explicit the requirement for duty holders to carry out a risk assessment as specified under Regulation 8 of the Ionising Radiation Regulations 2017.

Removing references to transport from REPPIR

201. Amendments to REPPIR mean that all normal forms of transport are excluded from the application of the regulations. We proposed to make this clearer by removing all references to transport from REPPIR. There are no real-world impacts and the improved clarity has been welcomed by stakeholders.

202. For the avoidance of doubt, transit sheds (in-transit storage facilities) – despite their link to transport - will be subject to the requirements of the regulations that replace REPPIR where they exceed the inventory limits, just as they are currently subject to the requirements of REPPIR.

Giving ONR enforcement powers for IRRs

203. We have amended the Health and Safety (Enforcing Authority) Regulations 1998 by the IRRs so that ONR can enforce the IRRs in those situations where they also enforce CDG i.e. in relation to the transport of radioactive material as a practice for the purposes of the IRRs. For transport in particular it has the benefit of ensuring that ONR can regulate relevant risk assessment requirements of the IRRs which we have proposed will be incorporated into emergency planning aspects of the CDG. In addition, HSE and ONR are sharing information gathered from the notification, registration and licencing regime in the IRRs so that ONR are better able to specifically identify those companies involved in the transport of radioactive substances.

Provision of Prior Information to the Public

204. We received several responses expressing dissatisfaction with the BSSD 2013 requirement that members of the public deemed likely to be affected by a radiological emergency must be proactively supplied with certain information prior to a potential emergency. Respondents said the requirement would be problematic from a practical and regulatory sense; this has been echoed by other stakeholders and transport operators. As such, we propose to place a duty on the transport competent authority (ONR) to publish generic information relating to transport emergency preparedness to fulfil this requirement.

What we asked and who responded

With regard to the proposed amendments to the CDG and accompanying Regulatory Triage Assessment, do you have any views or suggested improvements? If so, please use evidence to support your answer.

205. We received 31 responses to this question. Respondents broadly welcomed the consultation proposals. A small number of respondents provided constructive feedback on how the proposals could be refined. A small number of respondents were unsupportive of the consultation proposals.

Strengthening arrangements

206. Most respondents welcomed the proposed changes to the CDG as a means of strengthening Great Britain's emergency preparedness and response arrangements for radiological emergencies. They welcomed that the proposals aligned with the latest IAEA best practice in terms of safety standards. Respondents agreed it was logical to remove transport requirements from REPPiR, which will clarify the situation to duty holders.

Guidance

207. A small number of respondents requested that supporting guidance was developed for the CDG proposals, expressing the view that current ONR guidance was insufficient. Those respondents stated that the same rationale for guidance supporting REPPIR applied for transport. The Government notes that no formal guidance currently exists for transport, unlike for REPPIR. As the changes to the CDG are relatively minor, the Government and ONR have taken the view that a formal ACOP for the CDG is unnecessary. ONR have committed to publishing supporting guidance as is appropriate.

Definitions

208. Several respondents supported the alignment of the definitions of 'emergency' and 'emergency worker' for transport with the BSSD 2013 and REPPIR definitions. They noted this would bring greater consistency and a simpler understanding for duty holders.

209. A number of respondents emphasised the need for clarity around the definitions of 'emergency' and 'emergency worker'. While the definition of 'emergency' in CDG was broadly in line with BSSD 2013, it did not mention property or the environment. The Government will resolve this by specifically mentioning property and the environment in the new definition.

Reference levels

210. We received queries on how reference levels would be implemented. As set out above in relation non-transport emergency planning, we proposed the introduction of a national reference level of no greater than 100mSv. CDG already requires emergency plans to have regard to dose limits set by PHE, so plans also having regard to any national reference level would build on this. We did not consider that there needs to be an addition made to the CDG requiring the carrier and/or consignor to play a role in determining reference levels in an emergency or optimising the response in light of them. It would be for the agencies leading the response to establish reference levels.

Transition to recovery

211. Local authorities sought clarity around their role during the transition to recovery. Article 98(3) of BSSD 2013 introduces the requirement for emergency plans to include a provision for the transition from an emergency exposure situation to an existing exposure situation. This information is already required under CDG. However there is currently no requirement in the CDG for any of this

information to be shared with the authority responsible for the recovery phase of an emergency.

212. We therefore propose to amend CDG to ensure that carriers and consignors support the transition to recovery. The value they can add to this transition is in their knowledge of the load and the nature of the emergency.

213. The knowledge transfer will be achieved through a handover report. This report should be produced by the consignor in collaboration with the carrier, and be submitted to the relevant local authority. The purpose of this report will be to document any contamination and radiation assessments that have been conducted, detail the intervention actions taken by the driver, carrier and consignor to date, and any other relevant information that may be helpful in facilitating this transition process.

Prior risk assessment requirement

214. The current emergency management system for transport consists of several layers of risk assessment and response capabilities. The government considers that these capabilities largely ensure that provision is made for appropriate protective measures as required by Article 69(3) and (4). To provide clarity, we are strengthening the link to the risk assessment requirement as set out in Regulation 8 of the IRRs.

Provision of prior information to the public

215. Since publishing the consultation, and in light of further stakeholder engagement, we have changed our approach to prior information for the transport of radioactive material.

216. BSSD 2013 contains a requirement whereby members of the public deemed likely to be affected by a radiological emergency must be proactively supplied with certain information prior to a potential emergency (e.g. about health protection measures). The CDG appears to meet this requirement. The regulations make ONR, as the Great Britain competent authority, responsible for identifying those members of the public. The carrier, consignor and consignee are required to make this information available to those members of the public identified by ONR, including endeavouring to make arrangements with the relevant local authorities for its dissemination.

217. However, further discussion with stakeholders has highlighted challenges with the current provisions in the CDG. The nature of transport makes identification of members of the public likely to be affected by an emergency very difficult or impracticable. Carriers and consignors are able to select any available route to

transport the radioactive material. Hence, a member of the public could be in the vicinity of, or travelling on a road or railway, at any time during the transport operation. Identification by ONR of those members of the public likely to be affected in the event of a transport emergency is therefore virtually impossible.

218. Historically ONR has taken the view that stringent packaging requirements and the low incidence of significant events result in it being unlikely that any member of the public might be affected by a radiological emergency. As a consequence, the CDG's prior information requirement is not enforced in practice. ONR's own regulatory experience and intelligence from events overseas has now prompted a review of this position.

219. Following consultation with ONR, we propose to remove this regulation from the CDG completely. It will be replaced by a requirement for ONR (or the competent authority) to publish generic information on their websites. For example, ONR as competent authority for Great Britain, could highlight the presence of this information on their website along with other guidance relevant to emergencies arising during the transport operation. This would align with ONR's role as the competent authority for the transport of radioactive material.

220. This will be in addition to the requirement in REPIR that requires all local authorities (whether or not they host a radiological site) to prepare information for members of the public about the effects of radiation. This information could be deployed in the event of a transport emergency.

221. In addition, in due course the Government intends to develop a national plan for radiation emergencies which could extend beyond outline emergency planning zones. It would also cover transport emergencies and international events which affected the UK. It would build on and replace relevant parts of the current National Nuclear Emergency Planning and Response Guidance¹⁶ in due course. This will ensure we remain at the forefront of responsible nuclear energy states, and are leading in the implementation of the latest IAEA best practice.

Direct costs to business

222. We published a detailed Regulatory Triage Assessment (RTA) which set out that the proposed CDG changes will affect the approximately 1,300 carriers and consignors involved with the transport of radioactive materials in Great Britain. The main regulatory burden of this measure is the cost to businesses of familiarising themselves with the CDG amendments. Familiarisation costs will include reading and understanding the legislative changes; providing advice to

¹⁶ <https://www.gov.uk/government/publications/national-nuclear-emergency-planning-and-response-guidance>

others in the organisation where necessary; assessing compliance against new arrangements; and making necessary revisions to emergency arrangements. The only other potential costs to business are fees for hiring a Dangerous Goods Safety Advisor (DGSA), if the business chooses to do so. Some duty holders may engage a DGSA to advise on changes to regulations and update the organisation's emergency arrangements and plans.

223. Costs to other parties (such as first responders) will be negligible, because this measure will only place duties on carriers and consignors. Furthermore, we do not expect any costs on these businesses to have any significant indirect impact on other parties, particularly as the bulk of costs relate to familiarisation.

224. CDG 2009 states that emergency plans should be tested at suitable intervals, with ONR supporting guidance recommending that this testing is carried out annually. This guidance also suggests that training should be delivered to ensure that each person with a role in the emergency plan understands their duties, that the plans are revised as necessary, and that all relevant people should be made aware of changes as and when they occur. ONR may choose to issue supplementary or updated guidance in addition to the changes to CDG. It is assumed that any costs associated with updating guidance will be borne by ONR, as it would be in line with their core purposes. We also expect that duty holders are currently complying with ONR's existing guidance. As such, there should not be any further costs associated with training because any additional requirements arising from these changes would be subsumed in duty holders' existing budgets.

225. The findings of our RTA remain unchanged following our consultation and the responses received.

Government conclusion

226. Overall, having considered the responses we have received, we intend to revise our approach to providing prior information, but continue with the other proposals as consulted upon. The draft regulations published alongside this document give effect to these proposals.

Other responses

227. We received responses outside of the consultation questions but still within the scope of the consultation. Key themes from these responses and analysis of them are set out below.

Public reassurance

228. A number of respondents took the opportunity to welcome the proposed changes as a whole package. One noted that the changes should enhance public reassurance over UK nuclear emergency arrangements, but noted this would require clear public messaging. The Government welcomes the support.

Timeframes

229. A number of respondents asked for clarity on the timeframes for regulatory changes, and details of whether there would be any transitional period for duty holders to come up to speed with new arrangements and comply with them. We have explored a number of options for when the new regulations published alongside this document should take effect for duty holders. The new regulations replacing REPPiR will come into force shortly after they are made. Businesses that start working with ionising radiations for the first time will have to comply with the new regulations from the outset. However, we are proposing to incorporate a 12 month transitional period into the regulations for existing duty holders from the date they come into force to ensure that they have sufficient time to comply with their revised legal obligations. This would mean that the current regulatory regime would continue to apply for existing duty holders for 12 months after the new regulations come into force. The precise timing of making and laying the regulations will be subject to the availability of parliamentary time. We anticipate that they will be made and then laid in parliament in early 2019. Again, subject to the availability of parliamentary time, the regulations that will amend CDG will be laid before Parliament in draft separately by the end of 2018. Again we are proposing to incorporate into the new regulations a 12 month transitional period, so the amendments would also take effect for existing duty holders 12 months after they came into force.

230. We make clear that the planned programme of emergency exercises overseen by the relevant regulator, which have substantial lead in times, would not be affected. They would continue as planned until the current programme of work closes at the end of 2020.

Lessons from past emergencies

231. One respondent noted that the right lessons should be drawn from Chernobyl and Fukushima Daiichi; prescriptive exclusion zones and dose limits did not work well and did not lead to good decisions for the people they were supposed to protect. In addition the mass relocation of people is likely to be the wrong policy even if a significant radioactive release occurs.

232. The Government believes that the lessons of Fukushima Daiichi are incorporated into the requirements within BSSD 2013. The emergency planning and response requirements of BSSD 2013 were drafted in response to those events. The proposals we are taking forward to transpose it, and to capture learning set out in international best practice, will build on the robust safeguards we have in place to further protect the public in the event of a radiation emergency.

Defence

233. A number of respondents welcomed the applicability of arrangements to defence in a single set of requirements. A number of respondents asked for general clarity on the application of the proposals to defence, and any exemptions that will be applied. The Government welcomes the support and clarifies that existing exemptions for the MOD in REPIR and CDG would remain in place. This is set out in the draft regulations published alongside this document.

Updating existing guidance

234. One respondent noted that existing guidance would need to be updated as a result of BSSD 2013 implementation, such as the National Nuclear Emergency Planning and Response Guidance¹⁷ and Radiation Monitoring Units: planning and operational guidance¹⁸. The Government agrees, and will work with stakeholders to update appropriate guidance in due course.

Security incidents

235. A small number of respondents asked about security incidents and how they fit in with BSSD 2013 transposition. Security incidents are outside of the scope of BSSD 2013 transposition and so are not covered by the proposals we take forward here. Separate arrangements exist for security incidents.

Draft regulations, ACOP and guidance

236. A very small number of respondents stated that as the draft regulations and draft ACOP and guidance were not available with the consultation, they were unable to assess the proposals or have the opportunity to influence the revised regulatory arrangements. The Government disagrees; there is no general requirement to consult on draft regulations. We have held an open public

¹⁷ <https://www.gov.uk/government/publications/national-nuclear-emergency-planning-and-response-guidance>

¹⁸ <https://www.gov.uk/government/publications/radiation-monitoring-units-planning-and-operational-guidance>

consultation during the formative stage of policy development. Consultees have had the opportunity to influence the policy proposals put forward, and have done so as set out through the document above. The regulations are a vehicle used to deliver the policy outcomes arrived at. Consultation responses have been considered by the Government and helped to shape the policy outcomes we intend to take forward. Respondent views have therefore been carefully considered and reflected where appropriate in the draft regulations published alongside this document. An ACOP and supporting guidance will be consulted on by the regulator in due course to support the regulations which will replace REPPIR. ONR have committed to publishing supporting guidance for the CDGs as is appropriate.

237. The draft regulations published alongside this document have been subjected to robust legal scrutiny to ensure they deliver the policy intent consulted upon (taking account of the consultation responses we received). We have shared drafts with ONR to enable them to develop an ACOP and guidance to support the regulations. We have engaged closely with stakeholders who have been involved in the development of the ACOP and guidance to ensure it will provide practical advice for duty holders in how they can comply with the legal obligations set out in the regulations. The ACOP will be consulted on in due course.

Land use planning

238. Two respondents noted that the proposals did not take account of land use planning, notably how they interact with the DEPZs and OPZs. The respondents set out that the DEPZs and OPZs could have a negative impact on land use planning applications already granted, underway and in the future. This could affect the number of properties that could be built in a local authority area.

239. We have given careful consideration to the potential impact these regulations may have on land use planning. The Government does not envisage that nuclear emergency planning arrangements relating to an OPZ will be material to the determination of planning applications within those zones. And, the introduction of OPZs does not alter existing consultation arrangements for relevant planning applications under the Town and Country Planning Act 1990 regime.

Cost analysis for REPPIR changes

240. BEIS and HSE published a consultation stage impact assessment (IA) alongside our Government consultation that considered the costs associated with the transposition of the emergency preparedness and response elements of BSSD 2013. The assumptions in the IA were informed by input from stakeholder engagement and extendibility assessments carried out during 2016. The

assessment considered both the nuclear and non-nuclear sectors but did not include the impact on defence facilities; this was considered in a separate assessment undertaken by MOD and their stakeholders.

241. With the increased pressures placed on Government departments as a result of EU exit, the Government recognised that it needed a more proportionate better regulation framework that focused on those policies with the greatest potential impact on business. A new system - the De Minimis Self Certification assessment - was introduced. If a regulatory measure has a net direct additional impact on private business or civil society organisations of less than £5 million annually it qualifies as De Minimis.

242. The annual final cost analysis for the new REPPIR follows this new system as our cost analysis indicates the impact on private business falls below the additional costs of £5 million per year threshold. Therefore, the IA has been replaced with a De Minimis Self Certification assessment. Given we had initially undertaken an IA, for transparency, we have decided to include our cost analysis in the chapter below.

What we asked and who responded

The following questions relate to some of the cost estimates in the Impact Assessment that accompanies this consultation document:

Are you able to provide further information about current costs associated with radiological and nuclear emergency preparedness? In particular the costs of risk assessment, planning, costs of countermeasures and communicating to the public?

Are you able to provide further information about future costs associated with radiological and nuclear emergency preparedness? In particular, information about the numbers of sites in scope of Option 1 or 2 and the costs of outline planning?

Do you have any other comments on the assumptions or the cost estimates in the Impact Assessment? If yes, please provide further detail.

243. We received 41 responses to our question on current costs; 44 responses to our question on future costs; and 31 responses to our request for further information.

244. Most respondents provided high-level, qualitative evidence in response to our questions but did not provide significant quantitative evidence of the costs

associated with the various aspects of emergency preparedness. Some responses suggested the IA had underestimated the impact of the proposed regulatory changes. Therefore BEIS, HSE and MOD engaged in a post-consultation dialogue with stakeholders who would be most impacted to gain a better estimate of the likely costs.

245. Through further discussion with respondents, we identified seven cost categories where most duty holders will incur costs to some degree. These areas became the cost categories which we used to focus our analysis. These are:

- Familiarisation;
- Preparation of information for the local authority;
- Engagements with the local authority;
- Enhancing existing off-site planning capabilities;
- Introducing off-site planning capabilities at sites with no existing off-site plans;
- On-site planning; and
- Testing and exercising.

246. Responses to the consultation and our subsequent engagement with selected stakeholders has enabled us to refine the costings analysis. In areas where uncertainty remains due to lack of evidence, we have used several assumptions to help with our analysis. We adopted a conservative approach (i.e. assumed higher ranges of costs and higher numbers of businesses impacted) in the absence of this significant quantitative data.

Summary of cost analysis

247. Total additional cost of the policy change is estimated to have an overall impact across all sectors of £7.8 million in year one, with additional on-going costs (across years 2-10) of £3.1 million thereafter. This covers both additional costs to private business (£4.6 million year one additional costs and £1.7 million ongoing additional annual costs) which are in scope for de minimis, and additional costs for public funds (£3.2 million year one additional costs and £1.5 million ongoing additional annual costs) which are out of scope for de minimis. We anticipate the highest costs to be associated with either enhancing existing off-site planning capabilities, and for developing new arrangements (e.g. introducing off-site planning capabilities at sites with no existing off-site plans) that were not required under REPPIR 2001. Our analysis indicates that the civil nuclear sector will be the most impacted sector across year one, and for additional on-going costs.

248. A breakdown of the overall costs can be found in the table below, with further information on each cost category and sector set out in the sections which follow.

Cost Category	Sector	Additional year one	Additional on-going costs (2-10) (per annum)
Familiarisation	Civil Nuclear	£0	£0
	Defence Nuclear and non Nuclear	£50,000	£0
	Radiological	£930,000	£0
	Total	£980,000	£0
Preparation of information for the local authority	Civil Nuclear	£210,000	£20,000
	Defence Nuclear and non Nuclear	£430,000	<£10,000
	Radiological	£460,000	£40,000
	Total	£1,100,000	£70,000
Engagements with the local authority	Civil Nuclear	£320,000	£40,000
	Defence Nuclear and non Nuclear	£20,000	£10,000
	Radiological	£200,000	£80,000
	Total	£540,000	£140,000
Enhancing existing Off-site Planning Capabilities at sites with existing off-site plans	Civil Nuclear	£1,680,000	£1,890,000
	Defence Nuclear and non Nuclear	£310,000	£30,000
	Radiological	£20,000	£20,000
	Total	£2,000,000	£1,930,000
Introducing Off-site planning capabilities at sites with no existing off-site plans	Civil Nuclear	£340,000	£250,000
	Defence Nuclear and non Nuclear	£130,000	£10,000
	Radiological	£960,000	£130,000
	Total	£1,430,000	£400,000
On-site planning	Civil Nuclear	£680,000	£0
	Defence Nuclear and non Nuclear	£380,000	<£10,000
	Radiological	£30,000	£30,000
	Total	£1,080,000	£30,000
Testing and Exercising	Civil Nuclear	£340,000	£250,000
	Defence Nuclear and non Nuclear	£40,000	£40,000
	Radiological	£270,000	£270,000
	Total	£650,000	£560,000
Total Costs	Civil Nuclear	£3,570,000	£2,450,000
	Defence Nuclear and non Nuclear	£1,350,000	£100,000
	Radiological	£2,870,000	£580,000
	Total	£7,780,000	£3,130,000

Who the regulations will impact

249. The regulations will impact operators differently depending on whether they currently plan for offsite emergencies. These include:

- Civil nuclear and defence nuclear sites and operational berths which already have offsite plans as required by REPPiR 2001. These operators will enhance their existing arrangements to comply with the new regulations that will replace REPPiR.
- Sites which hold inventories of radionuclides that exceed the current REPPiR 2001 schedule quantities, but do not currently have off-site planning as their HIREs do not postulate a dose that exceeds the current threshold. Some of these sites may require some form of offsite planning under the new regulations. Historically, records show around 60 duty-holders across the civil nuclear, radiological, and defence nuclear sectors fall into this group. We do not expect this number to be exceeded under the new regulations that will replace REPPiR.
- Sites which will hold inventories of radionuclides that do not exceed the schedule quantities in the new regulations that will replace REPPiR. These sites will compare their inventory quantities against the quantities outlined in the new schedules in the new regulations that will replace REPPiR. For the purposes of this assessment, these only include operators from the radiological sector and are estimated to number 2,500 sites.

Assumptions used for cost analysis

250. The following assumptions have been used when producing cost estimates:

- Cost estimates in the tables below consider the impact on both the private and public sectors.
- All costs represent the additional costs faced by all sectors.
- All cost estimates have been rounded to the nearest £10,000. Total figures may not sum due to rounding.
- The cost estimates in this document is based on evidence provided by key industry and local authority stakeholders. All stakeholders were asked to provide transitional costs of implementing the new regulations (year 1 costs) and the additional on-going costs to their business.

- Where returns were incomplete, the most appropriate proxy has been used. In most of cases the proxy was a stakeholder with similar responsibilities or experience(s).
- Of the 60 sites that have produced a HIRE, but do not have off-site plans under REPPIR 2001, we estimate 6 to be MOD non-nuclear sites. For the purposes of this analysis, and due to limited evidence, we have used information from the radiological sector as a proxy. These costs have been included in the defence nuclear sector category.
- Where costs are uncertain we have used pessimistic assumptions (either in magnitude of impact or number of sites affected) to ensure costs are not underestimated.
- Any costs incurred by a local authority will be passed on to the operator of the site. Similarly, BEIS assumes that all additional costs associated with the Nuclear Decommissioning Authority (NDA) estates are borne directly by BEIS. (These are public sector, not private business costs, and therefore out of scope of de minimis).
- MOD assumes that all additional Defence sites and Operational Berth costs associated with the new REPPIR are borne directly by MOD. (These are public sector, not private business costs, and therefore out of scope of de minimis). This is because:
 - Defence sites and Operational Berths will pass their additional costs onto MOD directly;
 - MOD industry partners will seek to recover their additional costs associated with the new REPPIR from Defence directly through extant commercial arrangements; and
 - MOD has also assumed that, where local authorities incur additional costs, they will seek to pass reasonable costs onto MOD directly.

Familiarisation costs

251. Operators will face some degree of familiarisation costs associated with developing an understanding of the new regulations and an associated ACOP and guidance publication. This is a one-off cost, only applicable in year one.
252. Rather than detailing familiarisation as a separate cost category, civil nuclear and defence nuclear site operators considered familiarisation costs within the year 1 costs for each of the other cost categories. Therefore, the familiarisation

cost category reflects the costs faced by operators who currently do not have off-site emergency planning arrangements in place.

253. For sites which hold inventories of radionuclides that exceed the current REPPIR 2001 schedule quantities, but do not currently have off-site planning, year one costs are estimated as £600,000, and £50,000 for radiological and defence nuclear sites, respectively. This is based on an average familiarisation cost for the 60 operators of just over £10,000 per site based on evidence provided by operators. These costs account for the operator's radiation protection advisors' need to familiarise themselves with the entirety of the new regulations, and to update arrangements as necessary with the relevant emergency planners.

254. It is expected that very few, if any, sites which hold inventories of radionuclides that do not exceed the schedule quantities in the new regulations that will replace REPPIR, will be required to make any changes to their existing arrangements. The familiarisation time and costs are therefore assumed to be minimal. It is estimated this will take approximately an hour and a half per organisation, at a fee of £90 per hour. We assume these to be one-off, with year one costs amounting to £330,000. These are the only costs associated with these sites in this assessment.

Additional costs for preparation of information for the local authority

255. Costs in this category are associated with operators undertaking the risk evaluation process and production of the initial consequences report.

256. Under the new regulations that will replace REPPIR, operators will be required to submit a consequences report to the local authority. Respondents who have offsite emergency plans suggested that the new consequences report process will be comparable to the current REPPIR 2001 RoA process.

257. Sites which hold inventories of radionuclides that exceed the current REPPIR 2001 schedule quantities, but do not currently have off-site emergency planning, will also have to follow this new consequences report process. These sites already produce a HIRE assessment under REPPIR 2001. Under the new regulations they will be required to produce a report of these assessments (the consequences report) and review these in accordance with the regulations. As these operators will have no previous experience of this stage in the process, we estimate year one costs to be higher than those associated with sites that already have REPPIR 2001 emergency plans.

Sector	Current emergency planning arrangements under REPPiR 2001	Additional year one	Additional on-going costs (2-10) (per annum)
Civil Nuclear	Has REPPiR 2001 plans	£110,000	£0
	No REPPiR 2001 plans	£100,000	£20,000
Defence Nuclear and non Nuclear	Has REPPiR 2001 plans	£380,000	£0
	No REPPiR 2001 plans	£50,000	<£10,000*
Radiological	No REPPiR 2001 plans	£460,000	£40,000
Total		£1,100,000	£70,000

*Values rounded to nearest £10,000 as there is a cost, but these would have otherwise been rounded down to £0.

Additional costs of engagement with the local authority

258. Costs are associated with the time and resource needed for the local authority to determine the final DEPZ, and revision of documentation, such as in the event of a material change to the DEPZ.

259. Local authorities will have a new duty to determine the DEPZ. We have calculated the costs for engagement between the operator and local authority to discuss the initial consequences report and determine the need for, and scale of, a final DEPZ. Local authorities will recover reasonable costs from the operators of civil nuclear, defence sites and operational berths, and radiological sites.

Sector	Current emergency planning arrangements under REPPiR 2001	Additional year one	Additional on-going costs (2-10) (per annum)
Civil Nuclear	Has REPPiR 2001 plans	£260,000	£40,000
	No REPPiR 2001 plans	£60,000	£60,000
Defence Nuclear and non Nuclear	Has REPPiR 2001 plans	N/A*	N/A*
	No REPPiR 2001 plans	£20,000	£10,000
Radiological	No REPPiR 2001 plans	£200,000	£80,000
Total		£540,000	£140,000

* For the defence nuclear sector, the operators of sites that already have off-site plans, incorporated their engagement costs within the evidence supplied against the preparation of information for the local authority.

260. Radiological sector costs are very conservative, i.e. based on the most pessimistic scenario where all 60 sites require some detailed planning.

Consistent with the policy intent, we expect only in exceptional circumstances will such sites need a DEPZ.

Additional costs of enhancing existing planning capabilities at sites with existing off-site plans

261. The revised regulations require that plans can respond to more severe emergencies i.e. can be extended through the implementation of OPZs. For sites that already have off-site planning arrangements for their DEPZs, the policy intent is for DEPZ planning arrangements to remain broadly the same, and so future costs related to these zones are expected to be comparable to those at present.

262. Costs are associated with (but not limited to) the need for additional resources for operators and local authorities; collaboration with relevant services and personnel such as those that play a role in offsite emergency planning; the update and revision of off-site emergency plans in the event of material changes; provision of information to the local authorities; maintenance of emergency capabilities such as monitoring vehicles; and familiarisation of new regulatory concepts such as reference levels.

263. For the radiological sector, a handful of respondents suggested that they have communications arrangements in place with local communities in their immediate vicinity, and so we have included these in our estimates.

Sector	Additional year one	Additional on-going costs (2-10) (per annum)
Civil Nuclear	£1,680,000	£1,890,000
Defence Nuclear and non Nuclear	£310,000	£30,000
Radiological	£20,000	£20,000
Total	£2,000,000	£1,930,000

264. The availability of stable iodine tablets in the OPZ is the largest contributor to costs in the civil nuclear sector. Stable iodine is only used as a protective action around sites with operating nuclear reactors and off-site emergency plans. Costs could amount to an additional £720,000 in year one, and £720,000 per year thereafter. We have adopted a conservative approach to our calculation to ensure costs are not underestimated. We have assumed that operators purchase enough tablets to pre-distribute to the entire population in the OPZs. There is no policy intention to pre-distribute stable iodine tables to the entire population in the OPZs. Annual costs associated with stable iodine tablets relate to their limited shelf life and maintenance of the stockpiles around sites.

Additional costs of introducing off-site planning capabilities at sites with no existing off-site emergency plans

265. The new regulations that will replace REPIR introduce the concept of commensurate planning, which requires more sites to consider the need for off-site emergency planning.
266. Information obtained from stakeholders does not allow for separation between DEPZ and OPZ planning costs. As such, this cost category only considers off-site emergency planning in its entirety. The costs in this category are attributed to the same aspects as those in the previous cost category.
267. HSE consider that a radiological site will only require a DEPZ in exceptional circumstances. Any planning is likely to be outline planning and then only if generic arrangements are deemed insufficient. Therefore, it is worth understanding that the estimates in this category for this sector are extremely conservative (i.e. assumed higher ranges of costs and higher numbers of businesses impacted).

Sector	Additional year one	Additional on-going costs (2-10) (per annum)
Civil Nuclear	£340,000	£250,000
Defence Nuclear and non Nuclear	£130,000	£10,000
Radiological	£960,000	£130,000
Total	£1,430,000	£400,000

268. In some instances, the local authority may decide that no off-site plan is necessary outside of their existing arrangements; conversely, more might be needed. The final decision will be based on an agreement between the operator and local authority. Some operators and local authorities may not have the available expertise to prepare emergency arrangements at first and may require either additional resource or certain services and expertise being bought in to meet the requirements; where possible, we have factored this into the analysis.

Additional costs of on-site emergency planning

269. On-site emergency plans are owned by the site operators. Operators have suggested there will be costs associated with the revision of documentation (internal use and public information documents) and training material for new concepts introduced by BSSD 2013. This would include the introduction of reference levels and the interaction between on-site and off-site arrangements. The staff costs required to review and update this documentation, and then the subsequent training of relevant staff will account for most of these costs.

270. Once any relevant documentation has been revised and staff members have been trained in accordance with the new regulations, operators will resume business as usual processes. For sites that have current emergency planning arrangements under REPPIR 2001, operators have suggested that these processes will be comparable to current costs, and so we assume there will be no additional on-going costs thereafter.

271. Sites that do not have planning arrangements under REPPIR 2001 will have to consider on-site arrangements for the first time under the new regulations. Currently, the Ionising Radiation Regulations 2017 require duty holders to control, so far as is reasonably practicable, the risks to all those who might be affected by a radiological accident on-site; therefore, some on-site planning for events is already considered. The arrangements under IRR 2017 will inform the on-site planning arrangements for REPPIR 2019. Where these are not sufficient to meet the requirements of REPPIR, some planning will need to be undertaken, resulting in some additional costs.

Sector	Current emergency planning arrangements under REPPIR 2001	Additional year one	Additional on-going costs (2-10) (per annum)
Civil Nuclear	Has REPPIR 2001 plans	£620,000	£0
	No REPPIR 2001 plans	£60,000	£0
Defence Nuclear and non Nuclear	Has REPPIR 2001 plans	£380,000	£0
	No REPPIR 2001 plans	<£10,000*	<£10,000*
Radiological	No REPPIR 2001 plans	£30,000	£30,000
Total		£1,080,000	£30,000

*Values rounded to nearest £10,000 as there is a cost, but these would have otherwise been rounded down to £0.

Additional costs of testing and exercising

272. Year one additional costs are attributed with the revision of all relevant documentation such as the review and update of training and material to be in accordance with the new regulations that will replace REPPIR. Costs also include the preparation for emergency exercises for OPZs such as modular or table top exercising, and recovery of reasonable costs by local authorities.

273. With regard to on-going costs, evidence from local authorities suggests that annual costs will increase because of the requirement for all responders named in a plan to prepare and participate in emergency exercises. Local authorities have experienced a similar increase working with the COMAH 2015 regulations which introduced a similar provision.

274. For sites that do not currently have off-site plans, respondents with little to no experience of the regulations found this aspect difficult to provide evidence for any associated costs. As such, we have used a proxy derived from operators and local authorities that undertake these arrangements.

275. Again, for the radiological sector this is a very pessimistic estimate, assuming all sites would need to undertake testing and exercising.

Sector	Current emergency planning arrangements under REPPIR 2001	Additional year one	Additional on-going costs (2-10) (per annum)
Civil Nuclear	Has REPPIR 2001 plans	£280,000	£220,000
	No REPPIR 2001 plans	£60,000	£30,000
Defence Nuclear and non Nuclear	Has REPPIR 2001 plans	£10,000	£10,000
	No REPPIR 2001 plans	£30,000	£30,000
Radiological	No REPPIR 2001 plans	£270,000	£270,000
Total		£650,000	£560,000

Government conclusion and next steps

276. The Government intends to take forward the draft regulations published alongside this document to transpose the emergency planning and response elements of BSSD 2013. The new regulations replacing REPPIR will come into force shortly after they are made. Businesses that start working with ionising radiations for the first time will have to comply with the new regulations from the outset. However, we are proposing to incorporate a 12 month transitional period into the regulations for existing duty holders from the date they come into force to ensure that they have sufficient time to comply with their revised legal obligations. This would mean that the current regulatory regime would continue to apply for existing duty holders for 12 months after the new regulations come into force. The precise timing of making and laying the regulations will be subject to the availability of parliamentary time. We anticipate that they will be made and then laid in parliament in early 2019. Again, subject to the availability of parliamentary time, the regulations that will amend CDG will be laid before Parliament in draft separately by the end of 2018. Again we are proposing to incorporate a 12 month transitional period for existing duty holders into the new regulations, so the amendments would also take effect 12 months after they came into force.

277. To support the new regulations that will replace REPPiR, ONR are leading the development of an ACOP and guidance; consultation on this by HSE will follow in due course.

278. We would like to thank all respondents for taking the time to respond to our consultation and for helping to shape the future arrangements for emergency preparedness and response in the civil nuclear, defence nuclear and radiological sectors.

Glossary

Acronyms – organisations

BEIS:	Department for Business, Energy and Industrial Strategy
CRCE:	Public Health England's Centre for Radiation, Chemical and Environmental Hazards
DHSC:	Department of Health and Social Care
HPA:	Health Protection Agency (now Public Health England)
HSE:	Health and Safety Executive
HSWA:	Health and Safety at Work etc. Act 1974
IAEA:	International Atomic Energy Agency
ICRP:	International Commission on Radiological Protection
MOD:	Ministry of Defence
MHRA:	Medicines and Healthcare products Regulatory Agency
NHS:	National Health Service
ONR:	Office for Nuclear Regulation
PHE:	Public Health England

Acronyms – other

ACOP:	Approved Code of Practice
BSSD 2013:	Basic Safety Standards Directive 2013
CCA:	Civil Contingencies Act 2004
CDG:	Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (2009)
DEPZ:	Detailed emergency planning zones (http://www.onr.org.uk/depz.htm)
ERL:	Emergency Reference Level (https://www.gov.uk/government/publications/radiation-emergency-reference-levels)
HIRE:	Hazard Identification and Risk Evaluation
IRRs:	Ionising Radiations Regulations 2017
mSv:	Millisievert (measure of radiation dose)
NEPRG:	Nuclear Emergency Planning and Response Guidance
OPZ:	Outline Planning Zone
REPIR:	Radiation (Emergency Preparedness and Public Information) Regulations 2001
RTA:	Regulatory Triage Assessment

Annex 1: List of respondents

The following organisations provided a response to our consultation. Some organisations provided a joint response. Individuals are excluded for data protection reasons:

- Amec Foster Wheeler
- Argyll and Bute Council
- Atomic Weapons Establishment
- Ayrshire Civil Contingencies Team
- Babcock International Group
- BAE Systems plc
- Cumbria County Council
- Cyclife UK Ltd
- Defence Nuclear Safety Regulator (DSNR)
- Devon County Council and South Hams District Council
- Dounreay
- East Lothian Council
- EDF
- Food Standards Agency, and Food Standards Scotland
- Gartnavel Royal Hospital
- GE Healthcare
- Gloucestershire County Council
- Gwynedd Council, Conwy County Borough Council, Denbighshire County Council, Flintshire County Council, Wrexham County Borough Council
- Her Majesty's Naval Base Clyde
- Her Majesty's Naval Base Devonport
- Highland Council
- Horizon Nuclear Power
- International Atomic Energy Agency (IAEA)
- Imperial College Reactor Centre
- Institute of Physics and Engineering in Medicine
- Isle of Anglesey County Council
- Kent Fire and Rescue HQ
- Lancashire County Council
- London Resilience Group
- Low Level Waste Repository Limited
- Magnox
- National Fire Chiefs Council
- NHS Ayrshire and Arran
- North Somerset Council
- Nuclear Emergency Arrangements Forum (NEAF)
- Oil and Gas UK
- Pharmacy Leads Emergency Planning Network
- Plymouth City Council
- Police Scotland
- Portsmouth City Council and Southampton City Council

- Public Health England
- Radioactive Waste Management
- Reading Borough Council
- Rolls Royce plc
- Scottish Ambulance Service
- Scottish Fire and Rescue Service
- Sefton Council
- Sellafield Limited
- Shut down Sizewell Campaign
- Sizewell Site Stakeholder Group
- Society for Radiological Protection
- South Ribble Borough Council
- Suffolk Constabulary
- Suffolk County Council
- Transport Container Standardisation Committee
- UK & Ireland Nuclear Free Local Authorities Secretariat
- University of Bristol, Safety Systems Research Centre
- West Berkshire Council
- West Suffolk Councils
- Westingate Electric Company
- Westinghouse Springfields Fuels Ltd
- Wiltshire Council
- Wokingham Borough Council