

Last Energy UK Ltd

The Justification of Practices Involving Ionising Radiation Regulations 2004

OPINION

1. I am instructed to provide this opinion to Last Energy UK Ltd in respect of the Justification of Practices Involving Ionising Radiation Regulations 2004 (the 2004 Regulations), As my Instructions point out, the 2004 Regulations transpose requirements of the Euratom Treaty, and in particular the requirements of the European Directive 2013/59/Euratom on radiological Basis Safety Standards (the 2013 Directive), and are unaffected by the withdrawal of the United Kingdom from the European Union. Indeed by reg. 3(2) expressions and words in the 2004 Regulations have the same meaning as in the 2013 Directive.
2. Last Energy is the prospective developer in the UK of a type of small modular nuclear reactor (SMR) known as the PWR-20. The PWR-20 will generate electricity from nuclear energy using oxide fuel of low enrichment (less than 4.95%) in fissile content in a light water cooled, light water moderated thermal reactor. It has a thermal capacity per reactor of 20MW electric. The fuel is uranium dioxide industry standard pellets in a 17x17 square array. This advice relates not just to the PWR-20, but to the generation of electricity from nuclear energy using oxide fuel of low enrichment in fissile content in a light water cooled, light water moderated thermal reactor.
3. The issue which arises is the application of the 2004 Regulations to this practice. The 2004 Regulations provide a procedure for the Secretary of State as justifying authority to make justification decisions determining whether the class or type of practice is justified (reg. 4(3)). "Justified" in relation to a class or type of practice means that the individual or societal benefit resulting from the class or type of practice outweighs the health detriment

that it may cause (reg. 4(2)). “Practice” is defined in the 2013 Directive at article 4(65) and means “a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation”.

4. By reg. 4(5) no person shall carry out a practice, resulting in exposure to ionising radiation, belonging to a new class or type of practice. Breach of this provision may be the subject of enforcement procedures by service of a contravention notice under reg. 22, failure to comply with which is a criminal offence under reg. 24.
5. By reg. 4(1) a class or type of practice is “new” for the purposes of the 2004 Regulations if either:
 - (a) no practice in that class or type was carried out in the UK before 6 February 2018;
or
 - (b) a practice in that class or type was carried out in the UK before 6 February 2018 but was in breach of a requirement not to carry out a practice unless justified and in either case the class or type of practice has not been found to be justified.
6. By reg. 5(3) a class or type of practice is “an existing class or type of practice” if either:
 - (a) a practice in that class or type was carried out in the UK before 6 February 2018 without breaching any requirement not to carry out a practice in that class or type until that class or type had been found to be justified; or
 - (b) it has been found to be justified; or both.
7. A person may carry out a practice resulting in exposure to ionising radiation belonging to an existing class or type of practice: reg. 5(2).
8. The requirement for justification of new practices has its origin in article 19(1) of the 2013 Directive (and before that Directive 96/29/Euratom Article 6) which provides that “Member States shall ensure that new classes or types of practices resulting in exposure to ionising radiation are justified before being adopted.” Article 19(2) provides: “Member States shall consider a review of existing classes or types of practices with regard to their justification whenever there is new and important evidence about their efficacy or

potential consequences or new and important information about other techniques and technologies.” The 2013 Directive therefore distinguishes between new and existing practices but does not define them, thus the definition of “new” and “existing” are matters of domestic law.

9. A person may therefore rely on reg. 5(2) and will not be in breach of reg. 4(5) if either their practice is of a class or type which was already being carried out in the UK before 6 February 2018, or it is of a class or type which has already been the subject of a positive justification decision.

10. The term “class or type” is not defined in either the 2013 Directive or the 2004 Regulations. Nor so far as I am aware is there any case at UK or EU level which defines or discusses these terms.¹ As pointed out in recent guidance from the Irish Health Information and Quality Authority, *“the Directive does not provide a definition of a type or class of practice and for this reason, member states differ in how they define new ‘classes or types of practice”*.² Whilst the principle of justification derives from ICRP Recommendations (currently ICRP Publication 103 of 2007) this does not provide any assistance on how a class or type of practice is to be defined.

11. By reg. 12(1) the Secretary of State may, and at the request of any other person must, determine whether a practice belongs to a new or existing class or type of practice for the purposes of the 2004 Regulations.

12. I am asked to give my opinion on the following matters:
 - (a) Whether the generation of electricity from nuclear energy using oxide fuel of low enrichment in fissile content in a light water cooled, light water

¹ There was an unsuccessful challenge to justification of the AP-1000 and EPR in *R (Rory Walker) v. Secretary of State for Energy and Climate Change* [2011] EWHC 2048 (Admin) (permission was refused at first instance and on appeal) but the case does not address the issue of existing practices.

² Methods of generic justification of new practices in ionising radiation – February 2023 page 9. <https://www.hiqa.ie/sites/default/files/2023-08/Methods-for-Generic-Justification-of-New-Practices-in-Ionising-Radiation.pdf>

moderated thermal reactor (whether Last Energy's or other developer's SMR technology) is an existing practice;

- (b) Whether it would be lawful for Defra, as the justifying authority, to make a determination to that effect under regulation 12 of the 2004 Regulations; and
- (c) Whether Defra could do this on the basis of either information which has been used in recent applications for regulatory justification and/or other information readily and publicly available to them.

Existing practice

13. As noted above, there are two routes by which a practice could be an existing practice.

14. The first is by reason of it having been carried out in the UK before 6 February 2018 without breaching any requirement not to carry out a practice in that class or type until that class or type had been found to be justified. This is addressed in the current Guidance on the 2004 Regulations issued by Defra in May 2019 (revised March 2023). The relevant passage is at para. 26 of the Guidance (my emphasis):

"In the context of the nuclear industry, nuclear power generation represents a very broad generic class or type of practice.

However, the benefits and detriments arising from the operation of different designs of nuclear power plants could differ substantially. Where there are such substantial differences, it is unlikely that a single Justification decision could be made. Rather, a decision may need to be made in respect of a particular type of nuclear power plant and the conditions attached to the justification decision would ensure that it applied only to plants of similar designs and having broadly similar benefits and detriments. However, it may be possible to make a single decision in relation to a number of similar reactor designs, each employing particular processes, provided the evidence indicates that the technical differences do not result in major disparities between the scale and balance of the benefits and detriments."

15. Annex 2 of the Guidance provides a non-exhaustive list of classes or types of practice existing prior to 6 February 2018. These include under item 3, “*the generation of electricity by nuclear reactors*”, referring to (1) operation of Magnox power stations; (2) operation of advanced gas-cooled reactor power stations and (3) operation of pressurised and boiling water power stations. The Lead Department for this category is given as DESNZ. Note 2 to the Annex states (again, my emphasis):

“If in doubt as to whether a particular practice belongs to one of the types or classes above, clarification should be sought from the lead Department responsible for the class or type of practice which you consider applicable to your practice. It may be that the balance of detriments and benefits are not considered similar to those in the class or type in which case the practice may not be of the same class or type and a justification application for a new practice will need to be made. If necessary, a determination from the Secretary of State can be sought as to whether the practice is new.”

16. The second route is that the class or type of practice has already been found to be justified. As appears from the register of justification decisions maintained by Defra there have been justification decisions in 2010 in favour of the light water reactor designs known as EPR and AP1000, and in 2015 in favour of the light water reactor known as the ABWR. The thinking of Defra behind the approach of individual decisions for these three reactor models is discussed further below, but the statutory instruments which constitute the justification decisions make clear that the scope of what is being justified is specific. In respect of the AP1000, SI 2010 No. 2845 reg. 3 states that what is justified are:

- (a) the AP1000 practice; and*
- (b) any class or type of practice which is—*
 - (i) a development of the AP1000 practice; and*
 - (ii) so similar to the AP1000 practice that the balance of benefits and detriments from that class or type of practice does not materially differ from the balance of benefits and detriments from the AP1000 practice.*

Essentially the same wording appears in the Regulations justifying the EPR (SI 2010 No. 2844) and ABWR (SI 2015 No. 209).

17. The basis on which these decisions were made was explained in the determinations made by the Secretary of State for Energy and Climate Change in November 2009.³ The background is that the Nuclear Industry Association (NIA) had applied for justification in

³ New Nuclear Power Station Designs: Determinations on Class or Type of Practice.

respect of four reactor designs; the ACR-100, the AP1000, the EPR and the ESBWR. The NIA had sought justification on a generic basis for *“The generation of electricity from nuclear energy using oxide fuel of low enrichment in fissile content in light water cooled, water moderated thermal reactors using evolutionary designs”*, the four designs being examples of this class or type of practice. However, in its application the NIA had recognised that it would be for the Justifying Authority to decide whether the proposed class or type of practice constituted a single new class or type of practice or a number of different classes of types of practice and stated that if the Justifying Authority decided that the application comprises more than one class or type of practice the NIA would ask that the application be treated as an application for justification of each of such new classes or types of practice.

18. The Government expressed a preliminary view in public consultation that the Secretary of State should treat the Application as an application for a regulatory justification decision on the basis of four different classes or types of practice, each based on one of the reactor designs specified in the Application. It also took the view that what was relevant were the technical characteristics of the designs, not (as had been suggested by NIA) some further *“attributes”* of a design which could be achieved by small or moderate modifications to existing designs; a design currently available for assessment by UK regulators; and a design commercially available in the UK. Such attributes might be weighed in the balance of benefits and detriments, but not used as criteria for defining a class or type of practice (para. 3.6).

19. The reasoning behind treating each design as a separate class or type of practice was stated as being that a single regulatory justification decision could be made in respect of similar designs *“having broadly similar benefits and detriments”* (para. 3.12). However, where there were *“substantial differences”* between designs in terms of benefits and detriments it was unlikely that a single regulatory justification decision could be made (para. 3.12). The Government’s preliminary view was that if the decision covered multiple designs it would need to identify sufficient relevant information to ensure that it was aware of the benefits and detriments arising from all of the designs falling within the defined class or type of practice (para. 3.13). This would involve assessing information in

relation to designs other than those included in the application, which “*could differ quite significantly from that contained in the Application and could require the Secretary of State to acquire significant further information*” (para 3.14).

20. Importantly, the Government acknowledged that this involved a more narrowly defined class or type of practice than is necessarily required for regulatory justification and that it would in principle be legitimate to justify a much broader class or type of practice under the Regulations (para. 3.16). Responses on the consultation generally supported this narrow approach, but some respondents said that they preferred the single class or type of practice proposed by the Applicant, on the grounds that the benefits of new nuclear power stations are broadly independent of specific reactor designs and that the detriments are broadly similar between all four designs (para. 3.19).
21. However, consideration of these arguments did not lead the Secretary of State in that case to reconsider the preliminary view that a class or type of practice is best defined by reference to a common set of technical characteristics in so far as they affect the benefits and detriments of the class or type of practice and that he should make regulatory justification decisions based on four classes or types of practice (paras. 3.29-3.30).
22. The Decision went on to consider whether the four classes or types of practice to be assessed were new or existing. At that date, before amendment of the 2004 Regulations, the threshold for existing practices was those of a class or type carried out in the UK before 13 May 2000. These existing practices included the PWR at Sizewell B. In the consultation on the Application, the Government had expressed its preliminary view that the four classes or types of practice it had proposed qualified as new classes or types of practice. This preliminary view was on the basis that it was arguable that there are material differences between each of the proposed classes or types of practice and the existing practices, and that the decision in relation to Sizewell B was made under a previous version of the Directive 96/29/Euratom (para. 4.6).
23. Comments received during the consultation on the Application generally accepted the preliminary view that the four classes or types of practice proposed by the Government qualified as new classes or types of practice. Others felt that the EPR was not a new class

or type of practice because it differs little from the existing PWR at Sizewell B. Some respondents argued that, although the proposed classes or types of practice might not be entirely new, a fresh Regulatory Justification decision was advisable in view of the time which had passed since the previous Justification decisions on nuclear power Stations (paras. 4.7-4.8).

24. Having considered the responses to the consultation on the Application, the Secretary of State concluded that each of the four reactor designs was a new class or type of practice and therefore required a Regulatory Justification decision (para. 4.9)

Discussion

25. With the benefit of hindsight, it is probably regrettable that the Secretary of State in 2009 took the approach he did. In reality he probably simply opted for the easier and less controversial approach, which was offered as an alternative in the NIA's application, of considering each design separately. The Decision did not rule out other possibilities of a wider approach (and, as set out below, such a decision is in principle lawful), but rather regarded the individual design approach as preferable on that application. I discuss below the considerations which would apply in taking a wider approach.

26. In order to rely on reg. 5(2) and 5(1)(a), it is necessary to show that the PWR-20 and other light water fission reactors belongs to the same existing type or class as the Sizewell PWR. So far as I am aware, no formal regulatory justification decision was made in respect of the generation of electricity from Sizewell B,⁴ though benefits and detriments were weighed as part of the public inquiry chaired by Sir Frank Layfield QC into the application for a generating licence.⁵

⁴ There was however a justification decision in respect of the disposal of wastes from Sizewell B PWR in February 1996: see https://assets.publishing.service.gov.uk/media/61dd3be2e90e070372b3a8ff/Decisions_determined_before_Jo_PIIRR_2004_-_Updated_November_2021.csv/preview

⁵ See Hansard HL Deb 02 March 1987 vol 485 cc455-506, where the following conclusion from Sir Frank Layfield's report is quoted: *"In forming my recommendations on whether consent and deemed planning permission should be granted for Sizewell B, I have weighed the advantages and disadvantages of the proposed station. The disadvantages are of two principal kinds: risks to health and safety, and environmental damage to the locality. If consent is to be given, these disadvantages must be outweighed by anticipated economic benefits"*

27. In the 2009 determination the Secretary of State made a determination that the AP-1000, EPR and AWBR did not fall within the existing type or class of practice derived from the Sizewell B PWR, apparently for two reasons: (1) it was arguable that there were material differences between each of the proposed classes or types of practice and the existing practices, and (2) that the decision in relation to Sizewell B PWR was made under a previous version of the Directive 96/29/Euratom.
28. Of these, reason (2) does not seem a compelling one. The existing practice rests on its being in operation in the UK before the relevant date: the Sizewell B PWR plainly was in such operation, and the regulatory regime in force at the time does not seem relevant. In any event there was no material difference between the earlier and later versions of the Directive so far as the process of justification is concerned.
29. The other reason is that it was “*arguable that there were material differences*” between Sizewell B and the designs of nuclear power stations being considered. However, there was no real consideration of what those differences might be and whether they were material. Clearly, a finding that the PWR-20 and other light water fission reactors belong to the same broad type or class as Sizewell B would involve the Secretary of State taking a different approach to that adopted in 2009.
30. In principle the Secretary of State could lawfully take a different approach. He or she is not bound by the previous determination of their predecessor, on what is essentially an exercise of regulatory discretion. However, as a matter of public law, the reasons for departing from the previous approach would need to be explained and might well need to be consulted on.
31. The guiding principle for the Secretary of State seems to me to be that derived from the current Guidance on the 2004 Regulations issued by Defra in May 2019 (revised March 2023), quoted at para. 14 above, which is whether the characteristics of the reactor design

for the nation”. “*In my judgment the expected national economic benefits are sufficient to justify the risks that would be incurred*”. <https://api.parliament.uk/historic-hansard/lords/1987/mar/02/sizewell-power-station-inquiry-report>

being considered do not have significant differences from the existing reactor design such that the balance of detriments and benefits are not considered similar. If there are no such differences then the generic and high level nature of the regulatory justification exercise would suggest that the reactor design being considered can properly be regarded as belonging to the same existing class. This appears to me the test which should be applied.

32. In that regard, I note that the 2009 determination did not identify any such differences. It merely speculated that they might arguably exist.

33. I also note that when reviewing the actual regulatory justification decision for the EPR,⁶ very little weight was placed on any design-specific characteristics of the EPR. The determination was made, it appears to me, based predominantly on generic information and considerations, namely the general benefits of nuclear generation of electricity in terms of zero carbon emissions, reliability and security of supply, set against the very small health risks.⁷ Plainly great emphasis was placed on the fact that the regulatory systems for permitting and licensing the EPR would ensure control of the risks and high standards of security and safety. The regulatory systems which the Secretary of State was satisfied would ensure that the health risks from the EPR, AP-1000 and ABWR would be very small are the same as those which would apply to the PWR-20 or other designs of light water fission reactors,⁸ and would accordingly support the same conclusion in respect of such reactors.

34. Further, it was clear that there were no significant differences to the balance resulting from possibly different fuel burn up rates,⁹ or the types of spent fuel and intermediate

⁶ <https://assets.publishing.service.gov.uk/media/5a78afc0ed915d04220648cd/666-decision-EPR-nuclear-reactor.pdf>. October 2010.

⁷ Para. 6.122.

⁸ These include standards of nuclear safety, safeguards and security, funding for decommissioning and waste management, and assessment and control of environmental impacts depending on where reactors are eventually sited.

⁹ Para. 6.68.

level waste which the EPR would produce.¹⁰ I am not aware of any significant differences in the spent fuel arising from the PWR-20 or other light water reactor designs relative to that which has arisen from the designs of such reactors which are already in operation or have been subject to a positive regulatory justification decision.¹¹

35. The benefits of generating electricity from nuclear fission as identified for these designs of light fission reactors would seem to be no different in principle from the benefits which would result from the PWR-20 or other light water fission reactor designs.

36. I have reproduced for ease of reference in an Annex the relevant passages from the introduction to the justification decision for the EPR. I struggle to find much in there which is not generic to light water fission reactors generally and which turns on the specific technical characteristics of the EPR.

Conclusions on the questions asked

37. On the first question, whether the generation of electricity from nuclear energy using oxide fuel of low enrichment in fissile content in a light water cooled, light water moderated thermal reactor (whether Last Energy's or other developer's SMR technology) is an existing practice, this would clearly turn on whether it belongs to the same class or type of practice as the Sizewell B PWR, which could it seems to me be properly described as *"The generation of electricity from nuclear energy using oxide fuel of low enrichment in fissile content in a light water cooled, light water moderated thermal reactor."* It would for the reasons above in principle be possible to regard the PWR-20 and other light water fission reactors as belonging to the same existing practice as Sizewell B PWR.

¹⁰ Para. 6.71

¹¹ The Committee on Radioactive Waste Management in its February 2024 Position Paper on *Development of Small Modular Reactors and Advanced Modular Reactors* acknowledges at page 26 that any such differences are not likely to require new storage or disposal routes: *"According to the IAEA, for countries with established nuclear power programmes, management of SF arising from SMRs should not pose a challenge, particularly if SMRs based on current technologies are deployed. Proposed technologies that do not deviate significantly from current light water reactor (LWR) designs are likely to be able to utilise waste management, storage and disposal routes currently in use, albeit potentially with some modifications to accommodate subtle differences in the characteristics and volume of waste"* See <https://assets.publishing.service.gov.uk/media/65c26c9ca6838e000d49d589/corwm-smr-and-amr-position-paper.pdf> The IAEA material referred to is at <https://www.iaea.org/newscenter/news/small-modular-reactors-a-challenge-for-spent-fuel-management>

38. The second question is whether it would be lawful for Defra, as the justifying authority, to make a determination to that effect under regulation 12 of the 2004 Regulations. In principle, this can be answered in the affirmative. As discussed above, such a determination would differ from that made in 2009, but that does not mean it would be unlawful, provided it is properly reasoned and explained why the approach has changed. The fact that the 2009 determination was not based on any identified differences is helpful in that respect.
39. The third question is whether Defra could do this on the basis of either information which has been used in recent applications for regulatory justification and/or other information readily and publicly available to them.
40. It seems to me that Defra can rely on the information and reasoning contained in the aforementioned determinations for the ACR-100, the AP1000, the EPR and the ESBWR (unless of course anything material has changed since the determinations were made, and I am not aware that it has). These in my view are helpful in showing that the issue does not materially turn on details of an individual design but rather on generic issues, including the required standards of safety which would apply equally to the PWR-20 and other light water fission reactors and should not be affected by the specific design.

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ANNEX

EPR Justification Decision October 2010

<https://assets.publishing.service.gov.uk/media/5a78afc0ed915d04220648cd/666-decision-EPR-nuclear-reactor.pdf>

1.5 An EPR will be able to produce large quantities of low carbon electricity over an extended period, giving it the capacity to make a significant contribution to a secure, low carbon electricity supply in the UK

1.6 The Secretary of State is confident that there will be important economic benefits for the UK in the event that companies decide to invest in new nuclear power stations. Beyond the direct investment and employment necessary for the construction and operation of any EPR, the Secretary of State is satisfied that the UK economy can benefit through the development of a globally competitive nuclear supply chain and improvement in the quality of a skilled UK workforce.

1.7 Against this, although there is potential detriment to health, safety and the environment from the EPR, this potential is small, well understood and guarded against by an established regulatory regime, which actively and effectively works to keep detriments within acceptable limits. The Secretary of State considers that the risk of health detriment from the building and operation of EPRs in the UK is very low. As a proportion of the overall radiation to which members of the public are exposed from all sources, including natural sources, the evidence he has reviewed suggests that the contribution from any EPR would be very small. The radiation dose which members of the public would receive from the normal operation of an EPR on an annual basis would be below detectable risk levels in the context of overall radiation exposure. The inherent safety features of the design combined with the UK's strong and effective regulatory regime will ensure that gaseous and aqueous emissions will be kept to a minimum and the risk of accidental release of radioactive or other harmful material will be reduced and mitigated. Any potential detriment to health which the EPR could cause would therefore be very small, and satisfactorily minimised.

1.8 The Secretary of State is satisfied that the licensing and planning regime would ensure that potential environmental detriment caused by any proposed EPR would be prevented or mitigated. The Secretary of State also considers that radioactive waste and spent fuel arising from any EPR built in the UK could be effectively managed to ensure that the potential risks or detriments from its handling, storage, transport or disposal are within acceptable limits.

1.16 The EPR is capable of producing 1,600 – 1,660 MWe for a high proportion of its operating lifespan. Modern Pressurised Water Reactors (PWRs) have a strong reliability record and the

EPR is expected to be capable of generating a large quantity of low carbon electricity at a high load factor over the course of its lifespan.

1.20 The Government has made specific arrangements for the storage and disposal of nuclear waste, under which owners and operators of new nuclear power stations will be required to have an approved Funded Decommissioning Programme in place before construction of a new nuclear power station can begin. The Secretary of State is satisfied that these measures will ensure that the owners and operators of new nuclear power stations will set aside funds over the operating life of a nuclear power station to cover the full costs of decommissioning and their full share of waste management and disposal costs. The Secretary of State is satisfied that these costs will not become a burden on UK taxpayers.

1.21 Beyond the direct investment and employment created by the nuclear power stations themselves, the Secretary of State is satisfied that the UK economy will benefit from any investment in new nuclear power stations which companies decide to make, through the development of a globally competitive nuclear supply chain and an increasingly skilled UK workforce. The Secretary of State is satisfied that the actions being taken by the Government and industry mean that the UK is well placed to take the best possible advantage of this opportunity. 1.22 The Secretary of State accepts that there is a potential economic detriment that could arise as a result of an accident at a new nuclear power station, including costs to be met from public funds. However, the risk of this is minimised through the robust regulatory regime in place. Any economic impacts will be mitigated through well established arrangements for third party compensation. The Secretary of State is satisfied that arrangements are and will continue to be in place to provide the insurance or other financial security required under the arrangements for third party compensation.

1.23 An important risk associated with the EPR, as with all nuclear power stations, is the potential for detriment caused by the release of ionising radiation. However, this needs to be set in the context of overall levels of radiation. The overall average annual dose to a member of the public from all sources of radioactivity is 2.7 millisieverts (a measure of dose and abbreviated as mSv) per year. Of this, about 84% is from natural sources, about 15% from medical procedures and about 1% from all other sources, including existing nuclear power stations.

1.24 Release of radioactivity from nuclear power stations is strictly limited by regulation. By law, the radiation to which members of the public are exposed from all sources, excluding natural sources and medical procedures, is limited to 1 mSv per year.

1.25 But the regulatory regime goes further than the legal 1 mSv limit. It requires operators to use BAT (Best Available Techniques) and ensure that the resulting exposures are below the statutory limits and as low as reasonably achievable (ALARA). A recommendation from the Health Protection Agency (HPA) that the radiation to which members of the public are exposed from a proposed controlled source, such as a new nuclear power station, should be no more than 0.3 mSv per year, is given effect by a Direction to the environment regulators. HPA further recommends that dose constraints lower than this should be set where this is appropriate.

1.26 HPA has said that a dose of 1 mSv per year is equivalent to an additional risk of fatal cancer of one in twenty thousand (0.005%) per year, and that a risk at this level is not detectable among normal background levels of cancer risk.

1.27 The annual 'Radioactivity in Food and the Environment (RIFE)' report produced jointly by the Environment Agency, Food Standards Agency and others, confirms that radiation doses received by members of the public are below the statutory dose limit of 1 mSv per year.

1.28 Under UK law, all employers are responsible for protecting their employees, as well as the public, against exposure to ionising radiations. The maximum occupational dose limit which applies to people at work is 20 mSv per year. The UK nuclear industry monitors and regularly reports exposure levels for its employees which show that it works well within the legal dose limits, and applies additional stricter constraints on dose. The Secretary of State is satisfied that employees of the nuclear industry are adequately protected.

1.29 The Secretary of State is aware of concerns about the findings of studies suggesting a link between nuclear power stations and a higher incidence of cancer. However, he is satisfied that the best evidence suggests that no such linkage has been demonstrated. In coming to this view he has given particular attention to the reports of the Committee on Medical Aspects of Radiation in the Environment (COMARE), a scientific advisory committee providing independent advice on all aspects of health risk to people exposed to natural and man-made radiation. In particular, its view is that there is no evidence for unusual aggregations of childhood cancers in populations living near nuclear power stations in the UK.

1.30 The Secretary of State is therefore satisfied that the regulatory regime will effectively limit and minimise the radiation dose and release of radioactivity from the EPR to very low levels. He is also satisfied that because the regime applies during and beyond the operational life of the nuclear power station, effective limits on radiological emissions will remain in place until the EPR has been fully decommissioned. He therefore considers that the health detriments associated with the operation of an EPR will be very low.

1.32 The generation of electricity by any EPR built in the UK would give rise to spent fuel, intermediate level waste (ILW), low level waste (LLW) and liquid and gaseous discharges, all of which contain differing levels of radioactivity. The Secretary of State recognises that the unnecessary introduction of ionising radiation into the environment is undesirable, and has considered the steps taken to limit the exposure of individuals to radiation from these sources.

1.33 Higher activity waste (spent fuel and ILW) will be managed in the long term through geological disposal. This will be preceded by safe and secure interim storage until a geological disposal facility (GDF) can receive waste.

1.34 The Secretary of State considers, based on scientific consensus and international experience, that despite some differences in characteristics, waste and spent fuel from EPRs would not raise such different technical issues compared with nuclear waste from legacy programmes as to require a different technical solution. 1.35 The disposability assessment for the EPR conducted by the Nuclear Decommissioning Authority (NDA) as part of the generic design assessment (GDA) process supports that conclusion and concludes that compared with legacy wastes and existing spent fuel, no new issues arise that challenge the fundamental disposability of the spent fuel and ILW expected to arise from operation of the EPR. Given a disposal site with suitable characteristics, the spent fuel and ILW from the EPR is expected to be disposable.

1.36 The Secretary of State has noted that the length of time for the safe and secure on-site interim storage of spent fuel is contingent on a number of factors, but remains satisfied that

interim storage of spent fuel and also ILW can and will be carried out in a way which causes a very low level of health detriment.

1.37 The Secretary of State is satisfied that a GDF would be able to, and would be required to, meet the strict dose limits and risk guidance level required by the UK regulatory regime. He has taken into account the fact that the Government is considering steps to ensure that any GDF built in the UK would be introduced into the regulatory regime in a staged manner with the involvement of the relevant regulators at an early stage. The Secretary of State is conscious that no GDF for spent fuel is yet operational anywhere in the world. However, in light of the findings of the disposability assessments and the progress being made in the implementation of geological disposal abroad, the Secretary of State is satisfied that it is technologically feasible to build a GDF which could contain both higher activity wastes arising from existing nuclear power stations and from any EPR which might be built in the future, with only very low levels of health detriment.

1.38 The Secretary of State, having considered the Government's approach to the selection of a site for the implementation of geological disposal, is satisfied that there is a robust process in place to identify a suitable site and is confident that one will be identified and that a GDF (or more than one if necessary) will be built.

1.39 The Secretary of State is satisfied that the LLW originating from any new nuclear power stations would not vary greatly from that of existing nuclear power stations, and expects that LLW from new nuclear power stations would be handled in a manner similar to current practice and in line with Government policy on LLW.

1.40 Liquid and gaseous discharges from nuclear power stations give rise to emissions of radioactivity into the environment. In relation to these discharges the Secretary of State is satisfied that the regulatory regime is sufficiently robust to ensure that doses arising from such discharges will remain within limits and will be as low as reasonably achievable (ALARA).

1.41 The existing regulatory regime, which limits by law the radiation to which people can be exposed from nuclear installations, would apply to the management and disposal of radioactive waste from any EPR and from its decommissioning, as well as to activities during its operation. The Secretary of State is confident that this will ensure that the management and disposal of radioactive waste will give rise to only very low levels of health detriment.

1.42 The Secretary of State is satisfied that the regulatory regime will act to ensure that the release of radiation from the radioactive waste from any EPR remains within regulatory dose limits. In coming to this conclusion, the Secretary of State has given particular weight to the arrangements already in place to deal with waste from existing nuclear power stations, the effectiveness and transparency of the existing regulatory regime, and to the extensive powers that the regulators have to enforce compliance.

1.43 The Secretary of State is of the opinion that, whilst there would be a potential health detriment from the management and disposal of radioactive waste arising from the generation of electricity from any EPR built in the UK, the health detriment from such radioactive waste would be very small and would remain very small up to and beyond disposal.

1.44 The Secretary of State recognises that the construction, operation and decommissioning of an EPR, as a significant infrastructure project, will involve potential detriment to the environment which must be addressed.

1.45 In making his Regulatory Justification decision, the Secretary of State has considered in detail some of the issues covered in the Appraisal of Sustainability (AoS) and Habitats Regulations Assessment (HRA) of the Revised Draft Nuclear National Policy Statement (NPS) published for consultation in October 2010, including radiological health detriment, radioactive waste, security of supply and climate change. In the case of other issues covered in the Revised Draft Nuclear NPS, including biodiversity, landscape and visual impact, air quality, water quality and flood risk, these can by their nature only be fully addressed at a site-specific level in connection with individual applications to build nuclear power stations and not as part of the high-level Regulatory Justification decision-making process.

1.46 The Secretary of State has considered the arrangements for processing applications for development consents for new nuclear power stations. In granting development consent, the Infrastructure Planning Commission (IPC) must generally act in accordance with the NPS and its supporting documents. These contain policy aimed at minimising and mitigating harm to the environment that could arise from the construction and operation of an EPR. When considering an application, the IPC will also have the benefit of an Environmental Statement which details all the potential impacts of the development on the environment. The IPC will be able to attach conditions to a decision to mitigate damage to the environment from developments or aspects of developments which might otherwise not be environmentally acceptable.

1.47 The IPC can also decide not to grant consent where it judges that the adverse impact of a development, which could include the adverse environmental impact, outweighs its benefits. In cases where a development might cause environmental harm which could not be fully mitigated or avoided, this allows the IPC to take a decision, in light of the particular circumstances of the application, about whether the benefits of that development justify the environmental detriment it would cause.

1.48 The examination of an application for new nuclear development and the decisions as to whether or not to grant development consent will be taken in consultation with the Environment Agency and other regulatory bodies (including the Department for Transport, the Nuclear Installations Inspectorate and the Office for Civil Nuclear Security). The nuclear regulators will be responsible for the site licence and environmental permits for the project and ongoing regulation in the event that development consent is granted. The Secretary of State believes that this will provide effective regulation of the environmental impact of any development. The Secretary of State is satisfied that the new planning regime for nationally significant infrastructure set up under the Planning Act 2008 and the proposed changes to this system announced by the Government in June 2010, will allow environmental considerations to be identified and addressed at an early state of the planning process, including through consultation with the regulators and the public, so that unsuitable proposals can be prevented and potential adverse impacts mitigated to the extent possible.

1.49 On balance, the Secretary of State considers that potential environmental detriments arising from the construction, operation and decommissioning of the EPR are likely to be avoided or adequately mitigated and that a decision to allow environmental detriment that

cannot be avoided or mitigated will include a consideration of whether the benefits of the development outweigh the harm.

1.50 The risk of detriment from an accident or terrorist incident at an infrastructure project is something that must be taken into account, including for nuclear power stations. The Secretary of State acknowledges that the release of large quantities of radioactive material into the environment from such incidents could lead to significant adverse health detriment.

1.51 However, this potential detriment already exists for current nuclear power stations, and the risk of such incidents should be seen in the context of the regulatory regime which is intended to prevent accidents and protect against terrorist attack. The Secretary of State has therefore considered the advice of regulators and other advisory bodies on the measures in place. In particular, the Secretary of State notes that no events have occurred relating to a civil nuclear power station in the UK with off-site consequences or where all the safety barriers inherent in the design were breached.

1.52 The Secretary of State also notes the regulators' assessments under the GDA process that there are at this stage no safety or security shortfalls that would rule out the construction of the EPR on UK licensed sites.

1.53 The Secretary of State further notes that the regulators are undertaking a more detailed assessment of the EPR as part of the GDA process and that before permitting the start of construction the HSE would have to be satisfied that the operators have taken all reasonably practicable steps to reduce the risk of accidents and their radiological consequences.

1.54 Under the security regime, nuclear licensed sites are required to have a security plan in place. This plan must be approved by the civil nuclear security regulator, the Office for Civil Nuclear Security (OCNS), which has the power to direct at any time that the site adopt specific standards, procedures or arrangements or submit for approval a new or amended security plan; and has the power to compel the licence holder to take certain action. Under directions issued by OCNS, the Civil Nuclear Constabulary (a dedicated police force responsible for providing an on-site armed response force) carries out the roles and responsibilities assigned to it in the approved security plan.

1.55 The Secretary of State has confidence that the GDA and licensing processes will ensure that the regulators are satisfied with the safety and environmental implications of the EPR before site-specific proposals are approved for construction and operation in the UK. The Secretary of State is satisfied that the UK's effective and robust regulatory framework will ensure that industry minimises and manages safety and security risks during and beyond the operational life of any EPR, and that this is supported by the nuclear industry's strong safety and security record in the UK. The effectiveness and efficiency of the regulatory regime is kept under continuous review and improvements are made where necessary. 1.56 The Secretary of State also notes that the Government and industry have an emergency preparedness framework in place to mitigate health effects in the unlikely event of any accidental release of radiation into the environment.

1.57 The Secretary of State acknowledges concerns about the possibility of diversion of nuclear material and the proliferation of nuclear weapons. The UK Safeguards Office (UKSO), part of the HSE's Nuclear Directorate, ensures that the UK complies with its international

safeguards obligations, including those under the Euratom Treaty and the UK/Euratom/International Atomic Energy Agency (IAEA) safeguards agreement.

1.58 Under this regime, the operator of any EPR would be subject to the same stringent safeguards provisions as existing operators, including inspection and verification by the international safeguards inspectorates of the European Commission and the IAEA. The Secretary of State believes that there is therefore no reason to think that the building of EPRs in the UK would result in any significant rise in proliferation risk from the current low levels.

1.59 In summary, the Secretary of State is conscious of the extent of damage and health detriment that a release of radioactive material from an EPR would have. However, he has confidence in the regulatory regimes for safety and security of civil nuclear installations and materials in the UK. The regulatory bodies are all independent, experienced and held in high regard around the world. He is also conscious that the EPR includes inherent safety and security features, based on years of international experience with nuclear power stations and which will be subject to approval by the UK regulators. He therefore considers that the likelihood of an accident or other incident occurring at an EPR giving rise to a release of radioactive material is very small.

Last Energy UK Ltd

**The Justification of Practices Involving
Ionising Radiation Regulations 2004**

OPINION

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