The Justification of Practices Involving Ionising Radiation Regulations 2004

Guidance on their application and administration

June 2015
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Foreword

1.1. The Justification of Practices Involving Ionising Radiation Regulations 2004\(^1\) came into force in August 2004. The Regulations, which implement European Directive obligations, provide a framework in which justification decisions will be made. The purpose of this document is to provide applicants and other interested parties with guidance on the application of the Regulations and to explain the administrative procedures that will be used by Government in reaching justification decisions.

1.2. European Union Council Directive 96/29/Euratom (known as the Basic Safety Standards Directive)\(^2\) lays down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The Directive requires Member States to ensure that all new classes or types of practice resulting in exposure to ionising radiation are justified by the economic, social or other benefits in relation to the health detriment they may cause, in advance of being first adopted or first approved. In addition, existing classes or types of practice may be reviewed as to justification whenever new and important evidence about their efficacy or consequences is acquired.

1.3. The Basic Safety Standards Directive has been revised by Directive (2013/59/Euratom)\(^3\) which must come into force in the UK by 6 February 2018. The new Directive does not change the requirement for all new classes and types of practice to be justified before being adopted but Government is currently looking at how to update the Regulations in line with the new Directive. In addition a separate work stream will be undertaken to review how medical practices are listed both in the new regulations and the relevant guidance. If new UK Regulations require any change to this Guidance a further revision will be published.

1.4. It is important to note that, apart from any requirement for justification, practices that can result in increased exposure of individuals to ionising radiation are subject to additional controls under other regulatory provisions, including the Ionising Radiation Regulations (IRR99)\(^4\), Schedule 23 of the Environmental Permitting (England and Wales) Regulations 2010 (EPR10)\(^5\) (in England and Wales) and the Radioactive Substances Act 1993 (RSA93)\(^6\) (in Scotland and Northern Ireland). If you require further advice on these you should contact:

IRR99
- Health and Safety Executive

EPR10
- Environment Agency
- Natural Resources Wales

RSA93

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1.5. The 2004 Regulations do not affect any previous justification decisions made in the UK prior to their coming into force. Such decisions can be found on the justification register⁷. A list of classes or types of practice existing prior to 13 May 2000 can be found at Annex 2 of this guidance.

1.6. The Regulations also prohibit the deliberate addition of radioactive substances to certain goods, and the import and export of those goods.

1.7. This guidance is issued by the Department of Energy and Climate Change (DECC) in conjunction with the devolved administrations. Any enquiries about the guidance or the Regulations themselves should be addressed to the Justification Application Centre.⁸

What is Justification?

1.8. Justification is a process based on EU legislation which requires that before any new class or type of practice involving ionising radiation can be introduced in the UK, the Government must first assess it to determine whether the individual or societal benefit outweighs the health detriment it may cause. This principle of justification derives from the recommendations of the International Commission on Radiological Protection (ICRP). The ICRP principles which form the radiological protection framework can be found at Annex 1.

1.9. The process of justification requires that before a practice is introduced, it should be shown to give an overall benefit. It is also implicit in approach that all aspects of the practice should be considered. For example, where a practice generates radioactive wastes, the detriments arising from their management need to be taken into account in the justification of the practice.

1.10. Justification is relevant not only when a new practice is being introduced but also when an existing practice is being reviewed in the light of new information about its efficacy or consequences.

1.11. The process of justifying classes or types of practice and reviewing existing practices involves consideration not only of technical factors associated with the practice and its radiological detriment, but also of wider social and economic issues. Under the Regulations all justification decisions will be taken by the Government, either the relevant Secretary of State or the relevant devolved administration.

1.12. A decision that a class or type of practice is justified does not in itself allow practices of that class or type of practice to be operated. There are other regulatory provisions that need to be met (i.e. IRR99, EPR10, RSA93) and these control the manner in which a practice is operated in order to ensure compliance with the ICRP principles of optimisation and dose limitation (see Annex 1).

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⁷ Justification of Practices Involving Ionising Radiation Regulations Register

⁸ Justification Application Centre Justification_application_centre@decc.gsi.gov.uk
Why do we need the Regulations?

1.13. The Regulations are needed in order to comply with European Union (EU) law arising from the Basic Safety Standards Directive. The Directive lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

1.14. Article 6 of the Directive provides that:

“Member States shall ensure that all new classes or types of practice resulting in exposure to ionizing radiation are justified in advance of being first adopted or first approved by the economic, social or other benefits in relation to the health detriment they may cause.” (Article 6(1))

“Existing classes or types of practice may be reviewed as to justification whenever new and important evidence about their efficacy or consequences is acquired.” (Article 6 (2))

1.15. In addition, Article 6(5) of the Directive prohibits the addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, as well as the import and export of such goods. In other words, the addition of radioactive substances to any of these products is prohibited and no case for justification can be considered.

1.16. A further Directive, 97/43/Euratom, came into force in 1997 and supplements the Basic Safety Standards Directive by laying down the general principles for the health protection of individuals against ionising radiation in relation to medical exposure. It includes in Article 3(1)(a) similar requirements to those in the Basic Safety Standards Directive for justification. However, Article 3(1)(b) provides that if a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type could be justified in special circumstances to be evaluated on a case by case basis. Hence, medical practitioners may deviate from utilising only types of practices that have been justified where this would be beneficial to the health of a particular patient.

1.17. Apart from justification, much of the remaining requirements of the Basic Safety Standards Directive have been transposed by existing legislation including the IRR99, EPR10 and the RSA93, with minor amendments to these.

What are the main provisions of the Regulations?

1.18. Under the Regulations:

- It is forbidden to undertake any new practices resulting in exposure of workers or members of the public to ionising radiation unless the practice belongs to a class or type that has been determined to be justified;
- The deliberate addition of radioactive substances to personal ornaments and toys; and the import and export of these goods, and of cosmetics if radioactive substances have been added to them, is prohibited;
- The justification of existing classes or types of practices may be reviewed whenever new and important evidence as to their efficacy or consequences is acquired;

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- All justification decisions will be taken by the Government, either the relevant Secretary of State or the relevant devolved administration. For convenience a central contact point (the Justification Application Centre) has been established;
- A register containing details of applications and decisions is maintained in the Department of Energy and Climate Change.

What constitutes a practice?

1.19. The Basic Safety Standards Directive defines a “practice” as “a human activity that can increase the exposure of individuals to radiation from an artificial source, or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile, or fertile properties, except in the case of an emergency exposure”. The scope of the Directive is set out in Article 2 and applies to the following practices:
- The production, processing, handling, use, holding, storage, transport, import to and export from the Community and disposal of radioactive substances;
- The operation of any electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kV; and
- Any other practice specified by the Member State.

1.20. The Regulations have the same scope and application as the Directive. They apply only to activities covered by the above definition.

1.21. The term “practice” includes a wide range of activities including nuclear power generation and supporting activities, the use of radioactive materials or radiation sources for industrial applications such as radiography or process control, and the use of radioactive materials in various types of products, research and educational activities.

1.22. What constitutes the scope of any given practice is an important issue. Nuclear power plants need to be supported by facilities for fuel manufacture and for managing spent fuel and various categories of radioactive waste. The ICRP emphasises that waste management and disposal operations are an integral part of the practice generating the waste and that it is wrong to regard them as a free-standing practice that requires its own justification.

1.23. Similar considerations apply to the decommissioning of a practice and the subsequent release of the site from regulatory control. These activities are the inevitable consequences of the original practice and it is inappropriate to require separate justification. This is the case even where it is clear that these issues had not been considered in the initial justification decision for the practice or where the practice has been reviewed and found to be no longer justified.

1.24. This means that proposals concerning the management of radioactive wastes and the decommissioning and remediation of nuclear sites do not need a separate justification decision under the Regulations. However, strategies and operations will need to be fully assessed under other regulatory regimes, including the Nuclear Installations Act 1965, the IRR99, the EPR10 and the RSA93. It will have to be shown, among other things, that the approach adopted in a particular case is the best practicable environmental

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10 Justification Application Centre Justification_application_centre@decc.gsi.gov.uk
11 Justification Application Centre Justification_application_centre@decc.gsi.gov.uk
option, that the best practicable means are employed in its implementation and that all radiation exposures will be as low as reasonably practicable.

1.25. In order to ensure protection of workers and the public from the effects of radiation it may be necessary, depending on the circumstances, to consider transport either as part of a practice or as a practice in its own right. Where practices are entirely based within the UK it may be appropriate to consider transport when considering the practice. However, there are cases where only the transport of radioactive material occurs within the UK (and no other part of the practice) and it will therefore be considered a practice in its own right.

1.26. Medical procedures involving the use of radiation sources or radioactive materials should either:

- fall within one of the existing classes or types of practice (listed in Annex 2 of this guidance); or
- be justified as part of a new class or type of practice under the 2004 Regulations.

However, in individual cases and at the discretion of a clinician, a procedure that does not fall within an existing or newly-justified class or type may be applied where dictated by the needs of the patient. The safety of the individual patient is not compromised in any way as the Ionising Radiation (Medical Exposure) Regulations 2000 require justification of each individual exposure, whether or not it falls within an existing/newly-justified class or type of practice. The individual justification decision must be undertaken by the practitioner, a registered medical practitioner, dental practitioner or other health professional with adequate training who has been given that responsibility by those responsible for the use of radiation at the installation where the exposure will be carried out.

What are classes and types of practice?

1.27. The Basic Safety Standards Directive refers to classes and types of practice, rather than simply to practices. This emphasises the underlying principle that justification is to be applied generically rather than at the level of individual uses of a practice. There is no obvious intent in the Directive to differentiate between classes of practice and types of practice; they may be widely or narrowly defined in particular cases.

1.28. Under Regulation 4(2), “justified” in relation to a new class or type of practice means justified by its economic, social or other benefits in relation to the health detriment it may cause. The Directive defines health detriment as an estimate of the risk of reduction in length and quality of life in a population following exposure to ionising radiations. This includes loss arising from somatic effects, cancer and severe genetic disorder. If a justification decision is to apply to a class or type of practice the benefits and detriments of the different uses that make up the class or type are likely to be broadly similar. In the decision process the scope of a class or type of practice can be limited by making a decision subject to appropriate conditions, as permitted by Regulation 11(1).

1.29. An example of a broad class or type of practice would be the use of x-ray equipment or radioactive sources for the purpose of industrial radiography. Within this class or type of practice there are various narrower classes or types of application, some operating in fixed installations and others using portable equipment or sources for on-site use.

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1.30. 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 and so it is unlikely that a single justification decision could be made to cover all potential nuclear power plant designs. 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. It may well be, therefore, that a proposal for a new nuclear power plant of a significantly different design to those currently operating in the UK would require a new justification decision.

**What is a new class or type of practice?**

1.31. A new class or type of practice is one of a type or class that was not undertaken within the United Kingdom before 13 May 2000, the date on which the requirements of the Directive became effective.

1.32. No-one may carry out a practice of a new class or type of practice unless it has been the subject of a justification application and a decision has been made by the Justifying Authority confirming that the class or type of practice is justified.

**What is an existing practice?**

1.33. The Regulations define an existing class or type of practice as one in which a practice of that class or type was carried out in the United Kingdom before 13 May 2000. A list of these practices can be found at Annex 2. Practices defined under the 2004 Regulations are listed in the register.14

1.34. For the purpose of the 2004 Regulations a class or type of practice is also defined as existing if there has been an express justification decision made under previous arrangements or it has been found to be justified under these Regulations. A list of classes or types of practices that have been found to be justified can be found on the register.

**What is the Justifying Authority?**

1.35. Decisions on justification are taken by the Justifying Authority i.e. the devolved administrations for devolved subject areas, and the appropriate Secretary of State in relation to subject areas which have not been devolved.

1.36. Functions performed by the Justifying Authority in Scotland, Northern Ireland or Wales are exercised only in respect of their own countries whilst those performed by the Secretary of State may be applied to the whole of the UK. For example, determinations under Regulation 12 may only be made by the Secretary of State (see paragraph 1.39).

1.37. Formally, justification decisions, other than on matters that are reserved to the UK Government, are taken separately within the devolved administrations. However, the devolved administrations and the UK Government are agreed that there should be a single mechanism for deciding whether a particular class or type of practice is justified for the whole of the UK. In this context, Ministers would endeavour where possible to reach individual justification decisions which are consistent for the UK as a whole. A

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concordat\textsuperscript{15} sets out the administrative details and procedures that will be followed. Under the proposals of the concordat, a Justification Liaison Group (JLG) will assist the Justifying Authorities in their consideration of applications and will consist of officials from the devolved administrations and the relevant Whitehall departments.

1.38. Annex 2, which lists existing practices, also shows which Whitehall departments are responsible for justification decisions for classes or types of practice in different subject areas. However, on a case by case basis it may be agreed that a different Secretary of State will lead.

What types of application may be made?

1.39. There are three types of application that may be made by any person to the Justifying Authority. These are:

- For a justification decision in respect of a new class or type of practice (regulation 9);
- For a review of an existing class or type of practice in the light of new and important evidence about its efficacy or consequences (regulation 10);
- For a determination by the Secretary of State as to whether a practice belongs to a new or existing class or type of practice (regulation 12).

1.40. Any applications under regulations 9 or 10 will necessarily require a decision as to whether the class or type of practice is indeed new or existing and hence will also be considered under regulation 12.

1.41. It should be noted that for decisions and determinations under regulation 9 for a decision on a new class or type of practice, the onus is on an applicant to provide sufficient information to allow the Justifying Authority to reach a decision. There is no standard application form but the information required includes:

- The applicant’s name and contact details;
- A description of the class or type of practice, with drawings and diagrams, where appropriate;
- A full explanation of the radiation sources that will be used and the precautions that will be taken to ensure safety and minimise the radiological impact;
- An appraisal of the benefits and detriments of the class or type of practice. This appraisal should include the economic, social, environmental, health and safety, waste disposal and decommissioning benefits and detriments. Where appropriate, the appraisal should also cover the strategic, industrial, medical, transport, agricultural or other benefits and detriments;
- An assessment of the health detriment it may cause; this refers to the effects of the radiation on both employees and any other persons who might be affected and may include potential exposures as well as expected exposures;
- An indication of the expected extent of the practice.

No comparison needs to be made with alternative practices delivering the same or similar benefits.

1.42. There is nothing to prevent a person from making a new application in relation to a new class or type of practice which has previously been found not to be justified. However, in these circumstances, the applicant would clearly need to present evidence which had not been available at the time of the previous decision or whose significance had changed since that decision was made, in order to show why the class or type of practice in question ought to be reconsidered.

1.43. Under regulation 10, any person may apply to a Justifying Authority for review of the justification of an existing class or type of practice whenever new and important evidence about its efficacy or consequences is acquired, or a Justifying Authority may undertake a review without having received an application. An application for review should provide sufficient evidence to convince the Justifying Authority of the need for a review. In the context of this regulation, “new evidence” means evidence acquired since 13 May 2000 or, where there has been a published justification decision, since the date of the last decision. Broadly, “efficacy or consequences” will only be relevant if they affect the benefits or detriments associated with a class or type of practice. The Justifying Authority will interpret “important evidence” as meaning information that may significantly change its view of the balance of the benefits and detriments. The Justifying Authority will decide whether a review is needed. If it decides to proceed with a review, it will, where necessary, seek further information for its review from whichever persons seem most appropriate. The decision the Justifying Authority makes as a result of the review will be based on consideration of all the information it acquires during the review process.

1.44. Any review is therefore the result of a two stage process. Firstly there must be information acquired that is new and important evidence about the efficacy or consequences of a class or type of practice. If this is not acquired the review cannot take place. Secondly, a decision must be made as to whether or not to undertake a review in the light of this evidence.

1.45. For an application under regulation 12, the scope of information required may be less than or broadly the same as that for an application under regulation 9, as set out above depending on the circumstances. Applicants may be asked to provide an appraisal of the benefits and detriments of the practice because any determination as to whether a practice belongs to an existing or new class or type of practice may involve a detailed examination of the benefits and detriments of the practice and a comparison with those of existing classes or types.

Where should an application be sent?

1.46. Applications should be sent to the Justification Application Centre.¹⁶

1.47. The application will be acknowledged, logged onto the system, placed on the register and passed to the relevant Whitehall departments and devolved administrations forming the JLG, for processing.

When should an application be made?

1.48. For an application under regulation 9, it is in the interests of the applicant to make an application at the earliest practicable time and before significant expenditure has been made. Applications under regulations 10 or 12 can be made at any time.

¹⁶ Justification Application Centre justification_application_centre@decc.gsi.gov.uk
How will the decision be made?

1.49. In their examination of applications, the Justifying Authority and the JLG will initially focus on the information provided by the applicant. If the information provided by the applicant is insufficient, the first recourse will be to refer back to the applicant requesting more information. In some circumstances, for example, where there is an application from a member of the public for a review the JLG might consider that there is sufficient merit in the application to seek further information from other sources. This could be, for instance, an operator of the practice in question.

1.50. In advising the Justifying Authorities on a decision the JLG may:

- Review and examine the benefits claimed for the class or type of practice and where necessary seek independent expert advice;
- Review and examine the stated health and other detriments that are expected to arise from the class or type of practice and again, where necessary, seek further information and/or advice on the adequacy of the assessment of detriments;
- Consider the balance of benefits and detriments;
- Advise as to whether a public consultation or inquiry should be undertaken and the extent of any publicity;
- Consider evidence on the efficacy and consequences and whether this is new and important.

1.51. It should be recognised that the comparison of benefits and detriments is, in the majority of cases, likely to be subjective. In some cases, the benefits might be almost entirely economic and the detriments entirely radiological. Although mechanisms do exist for expressing radiation dose in monetary terms to assist such decisions, they are not universally accepted. In other cases, the benefits claimed might be mainly safety or environmental, and here the comparison could be more straightforward.

1.52. The Regulations fully recognise the independence of the devolved administrations and it is up to the Justifying Authority in each country (where applicable) to come to its own decision. However, from an applicant’s point of view, what is important is that the Justifying Authorities will strive to make a consistent decision for the whole of the UK. Decisions will be made in the form of secondary legislation (a Statutory Instrument (SI)). That legislation may be a single SI for something that is not devolved or transferred to any of the three devolved administrations, or it could be in the form of four SI’s for something that is devolved or transferred to the three devolved administrations. Where the latter is the case, the Justifying Authorities would endeavour to be consistent in terms of effect and timing of the decision.

1.53. For matters that are reserved to the UK Government, the Government will consult and take into account the views of the devolved administrations.

1.54. Any decision document accompanying a decision or determination will set out the considerations and the rationale for the decision.

1.55. It should be noted that justification decisions have to be made by individual countries. The UK cannot rely on a decision made elsewhere though such information may be relevant in a specific case and may be taken into account.

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17 For an example of a decision document see the ABWR document at https://www.gov.uk/government/publications/the-justification-of-practices-involving-ionising-radiation-regulations-2004
Who will the Justifying Authority seek information from?

1.56. The Justifying Authority has the power to require any person to provide relevant information in their possession by the serving of a notice. It can also undertake consultation and, where it considers appropriate, hold an inquiry or other form of hearing.

1.57. The Justifying Authority has the power to require information to be provided by any person within a certain time (not less than 28 days). However, this power is limited in that it may only seek information that a person possesses or which the person may reasonably be expected to furnish. The notice is required to invite the person to notify the Justifying Authority within 14 days of any grounds upon which the notice ought to be withdrawn or varied.

1.58. Before making a justification decision, a determination or serving a contravention notice, the Justifying Authority is required to consult:

- Health and Safety Executive
- Office for Nuclear Regulation
- Food Standards Agency
- Food Standards Scotland
- Public Health England
- Environment Agency
- Scottish Environment Protection Agency
- Natural Resources Wales
- Department of Environment Northern Ireland

1.59. The Justifying Authority may also consult with others, as it considers appropriate. It will ensure that the extent of any consultation is proportionate to the issues involved. In some cases, consultation would be a limited information gathering exercise. In other cases, it would involve a public consultation.

1.60. Where the Justifying Authority considers that any application is of sufficient importance and wide public interest, they may cause a public hearing or other inquiry to be held. It is expected that inquiries under the regulations would only be held in relation to major or contentious classes or types of practice.

How will the decision be communicated?

1.61. Having completed its considerations, the Justifying Authority is required to take steps to bring the proposed decision to the attention of those likely to be affected by it. The extent of such an exercise will be decided on a case by case basis and may include a public consultation on the draft decision where appropriate.

1.62. A decision that:

- determines that a class or type of practice is justified where it was not previously justified (that is a positive decision under regulation 9);
- determines that a class or type of practice is no longer justified (a negative decision under regulation 10); or
- introduces or changes the conditions attached to be justification of a class or type of practice under regulation 11;
1.63. For matters that are entirely reserved to the UK government, a single SI will be laid before the Westminster Parliament. For devolved matters, separate SIs would be laid before the Westminster Parliament, the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly, as appropriate.

1.64. All determinations, decisions, notices or inquiries made under the Regulations are required to be brought to the attention of any person likely to be affected by them in such manner as the Justifying Authority considers appropriate. The Register will be updated to reflect decisions made and notices of determinations will be given in the London, Edinburgh or Belfast Gazettes, as appropriate. The Justifying Authority also has the option of publicising decisions in the national or local press where it considers this appropriate. As in the case of consultation, the scale of any publicity will be proportionate to the issues raised by the particular case. For all determinations made under the Regulations, whether positive or negative, the Justifying Authority will produce a decision document, setting out the key evidence and basis for their decision.

1.65. Details of decisions, including either the decision document or a reference to it, will be available from the Justifying Authorities or the Justification Application Centre.

Is there a fee involved?
1.66. No fees are currently payable in respect of an application or copies of the register.

How long will an application take to process?
1.67. The time that it will take from receipt of an application to its determination and the issue of the decision will clearly be dependent on the complexity of the issues raised. The application will be acknowledged by the Justification Application Centre. The Justifying Authority will provide an indicative timetable to the applicant within one month of receipt of the application. If the timetable needs to be changed, the Justifying Authority will inform the applicant of the new timetable, and the reason for the change, as early as possible and in any event before the time expires within which the applicant was expecting a decision.

What information will be put on the register?
1.68. The register will contain details of all applications, decisions and determinations irrespective of where the decision is made and will be maintained on the Department of Energy and Climate Change (DECC) website. The requirement to publish information in the register does not in any way restrict the rights to information under existing freedom of information regimes or under Environmental Information Regulations.

1.69. The register does not provide details of where individual instances of the class or type of practice are undertaken.

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18 Justification of Practices Involving Ionising Radiation Regulations Register
How are the Regulations enforced?

1.70. The primary enforcement mechanism under the Regulations is the contravention notice. A notice will be issued by the Justifying Authority where:

- An unjustified practice is being carried out;
- Conditions attached to a justification decision are not being complied with;
- A person fails to supply information in his possession or which he may be reasonably expected to have;
- Radioactive substances have been added in the production of personal ornaments or toys; or
- Any personal ornament, toy or cosmetic to which any radioactive substance has been added in production has been imported or exported.

1.71. The contravention notice will specify the matters constituting the contravention, the steps to be taken to remedy the situation, the date within which the steps shall be taken and the date on which the notice takes effect.

1.72. The Regulations give the person on whom the notice is served 14 days to show why the notice should not have been served, and to delay the coming into effect of the enforcement notice for a further 14 days following this. However, there is a provision for the notice to have immediate effect if the Justifying Authority believes circumstances warrant it.

What offences do the Regulations create?

1.73. It is an offence for a person to:

- Fail to comply with any requirement imposed by a contravention notice;
- Make false statements or provide false information; or
- Obstruct the Justifying Authority or his lawful delegate in the exercise of their enforcement powers.

What are the penalties?

1.74. Persons convicted of offences under the regulations are liable to fines, to periods of imprisonment or to both. See regulation 24(3) for details.

Can the enforcement powers be delegated?

1.75. The enforcement powers exercisable under the regulations are broadly those of section 108 of the Environment Act 1995\(^\text{19}\). The Justifying Authority can delegate various powers, including the issue of contravention notices and other powers of enforcement. Other than in Scotland, the Justifying Authority may delegate the powers to institute prosecutions, although any such proceedings require the consent of the Justifying Authority.

What is the impact of justification on planning and other regulatory decisions?

1.76. It must be emphasised that the generic justification decisions made under the Regulations are only the first stage of the regulatory process. Further radiological protection issues, such as optimisation and ensuring compliance with dose limits will be addressed in individual authorisations, licensing and other existing measures. Similarly, planning and environmental impact questions related to specific sites, plans or projects will be addressed under those regimes. Although justification decisions and Environment Impact Assessments (EIA)\(^{20}\)/Strategic Environment Assessments (SEA)\(^{21}\) require some consideration of the same factors (environmental, economic, etc.) the consideration is for different purposes and factors might well have different weights. For these reasons, it would not be appropriate for a decision under one to be conclusive as to the outcome under the other.

Prohibition of radioactive substances in personal ornaments, toys and cosmetics

1.77. The prohibition relating to personal ornaments and their import and export is addressed in regulation 20. The term “personal ornament” is not defined in the Basic Safety Standards Directive or in other UK legislation. It is intended that the Regulations apply to articles to be worn on the person where the radioactivity has no function other than decoration.

1.78. The prohibition relating to toys and their import and export is also addressed in regulation 20. A toy, as defined by the Toys (Safety) Regulations 2011 means any product designed or intended (whether or not exclusively) for use in play by children under 14 years old.

1.79. The prohibition relating to the import or export of cosmetics is addressed in regulation 20. The prohibition on the deliberate addition of radioactive substances to cosmetics is incorporated into UK law by virtue of Regulation (EC) No. 1223/2009 and enforced through the Cosmetic Products Enforcement Regulations 2013. Under Regulation (EC) No. 1223/2009,”cosmetic product” means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

Department of Energy and Climate Change
June 2015


Annex 1

ICRP Principles

The system of radiological protection recommended by the Commission is contained in its most recent general recommendations, ICRP Publication 103 - These 2007 Recommendations provide revised principles on Radiological Protection:

- The justification of a practice which is the process of determining whether either (1) a planned activity involving radiation is, overall, beneficial, i.e. whether the benefits to individuals and to society from introducing or continuing the activity outweigh the harm (including radiation detriment) resulting from the activity; or (2) a proposed remedial action in an emergency or existing exposure situation is likely, overall, to be beneficial, i.e., whether the benefits to individuals and to society (including the reduction in radiation detriment) from introducing or continuing the remedial action outweigh its cost and any harm or damage it causes.

- The optimisation of protection which is the process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account.

- The dose constraint which is a prospective and source-related restriction on the individual dose from a source, which provides a basic level of protection for the most highly exposed individuals from a source, and serves as an upper bound on the dose in optimisation of protection for that source. For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source.

- The reference value which is the value of a parameter recommended by the Commission for use in a biokinetic model in the absence of more specific information, i.e., the exact value used to calculate the dose coefficients presented in the report. Reference values may be specified to a greater degree of precision than that which would be chosen to reflect the uncertainty with which an experimental value is known, in order to avoid the accumulation of rounding errors in a calculation.

- The dose limit which is the value of the effective dose or the equivalent dose to individuals from planned exposure situations that shall not be exceeded.
### Annex 2

**Classes or type of practice existing prior to 13 May 2000**

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Classes or type of practice</th>
<th>Lead Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Enrichment of uranium</td>
<td>Use of the centrifuge process</td>
<td>DECC</td>
</tr>
<tr>
<td>2. Production of nuclear fuel</td>
<td>Manufacture of uranium metal and oxide fuel for power reactors</td>
<td>DECC</td>
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<tr>
<td></td>
<td>Manufacture of mixed oxide fuel for power reactors</td>
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<tr>
<td></td>
<td>Manufacture of uranium fuel for research for materials testing reactors</td>
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<td></td>
<td>Manufacture of experimental nuclear fuel</td>
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<tr>
<td>3. Generation of electricity by nuclear reactors</td>
<td>Operation of Magnox power stations</td>
<td>DECC</td>
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<td></td>
<td>Operation of advanced gas-cooled power stations</td>
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<td></td>
<td>Operation of pressurised water power stations</td>
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<tr>
<td>4. Recovery of usable products from spent nuclear fuel</td>
<td>Reprocessing of uranium metal from power reactors</td>
<td>DECC</td>
</tr>
<tr>
<td></td>
<td>Reprocessing of uranium oxide fuel from power reactors</td>
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<tr>
<td></td>
<td>Reprocessing of fuel from research/materials testing/prototype reactors</td>
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<tr>
<td></td>
<td>Production of radioisotopes</td>
<td>Manufacture of radioisotopes using nuclear reactors and accelerators</td>
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<tr>
<td>6.</td>
<td>Production of radioactive products</td>
<td>Manufacture of radioactive sources, substances and radiopharmaceuticals</td>
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<tr>
<td>7.</td>
<td>Non-destructive testing</td>
<td>Use of radioactive sources, substances and radiation generators for radiography</td>
</tr>
<tr>
<td>8.</td>
<td>Radiation processing of food</td>
<td>Use of gamma or electron beam radiation sources to reduce bacterial levels, sterilise, disinfect or modify materials</td>
</tr>
<tr>
<td>9.</td>
<td>Radiation processing of products</td>
<td>Use of gamma or electron beam radiation sources to reduce bacterial levels, sterilise, disinfect or modify materials</td>
</tr>
<tr>
<td>10.</td>
<td>Substance measurement and process control</td>
<td>Use of sealed sources and x-ray generators for thickness gauging, density gauging, mass gauging, level gauging, flow measurement, borehole and well logging, control of pipeline crawlers</td>
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<td></td>
<td></td>
<td>Use of neutron sources for moisture gauging</td>
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<tr>
<td>11.</td>
<td>Detection and analysis</td>
<td>Use of sealed sources and x-ray generators for analysis</td>
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<td>Use of beta sources for gas chromatography detectors</td>
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<td></td>
<td></td>
<td>Use of radioactive sources for leak detection, chemical and explosives detection</td>
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<td></td>
<td></td>
<td>Use of neutron sources for activation analysis</td>
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<tr>
<td>12.</td>
<td>Elimination of static electricity</td>
<td>Use of radioactive sources to eliminate static electricity</td>
</tr>
<tr>
<td>13.</td>
<td>Illumination</td>
<td>Use and repair of gaseous tritium light sources for illumination, in safety signs and equipment, sighting and location markers, watches and instruments.</td>
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<td></td>
<td>Use of radioluminous paint (tritium and promethium-147) for the luminising of timepieces and the repair of radioluminised timepieces.</td>
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<tr>
<td>14.</td>
<td>Electronic apparatus</td>
<td>Use of electronic apparatus containing radioactive substances, e.g. tritium in spark gap devices</td>
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<tr>
<td>15.</td>
<td>Safety devices</td>
<td>Use of ionising radiation in smoke and fire detectors and other safety instruments</td>
</tr>
<tr>
<td>16.</td>
<td>Security screening</td>
<td>Use of x-rays, gamma rays or neutron apparatus to examine packages, baggage, containers or vehicles</td>
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<td></td>
<td></td>
<td>Use of x-rays to radiograph suspected smugglers</td>
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<td></td>
<td>Use of x-rays or gamma rays to detect people seeking illegal entry to the UK in vehicles or freight</td>
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<td>Use of back-scatter imaging for the detection of concealed items on the person</td>
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<td></td>
<td></td>
<td>Use of x-rays, gamma rays or neutron sources to detect concealed items in buildings</td>
</tr>
<tr>
<td>17.</td>
<td>Equipment producing ionising radiation incidentally</td>
<td>Use of electron beam welders, electron microscopes, radar, thermionic valves, cathode ray tubes, ion implantation machines and high voltage switchgear</td>
</tr>
<tr>
<td>18.</td>
<td>Radioactive tracers</td>
<td>Use of radioactive tracers in industrial process controls</td>
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<td>Use of radioactive tracers for medical or biological techniques</td>
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<td></td>
<td></td>
<td>Use of radioactive tracers for environmental tests</td>
</tr>
<tr>
<td>19.</td>
<td>Diagnosis - medical</td>
<td>Use of ionising radiation in radiography, fluoroscopy, computed</td>
</tr>
<tr>
<td>20. Treatment - medical</td>
<td>Use of ionising radiation in interventional radiology, in-vivo nuclear medicines, teletherapy, brachytherapy, radiography (for planning purposes) fluoroscopy (for planning purposes), computed tomography and neutron activation analysis</td>
<td>Department of Health</td>
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<tr>
<td>21. occupational health screening</td>
<td>Use of ionising radiation in radiography and in-vitro nuclear medicine</td>
<td>Department of Health</td>
</tr>
<tr>
<td>22. Health screening</td>
<td>Use of ionising radiation in radiography and in-vitro nuclear medicine</td>
<td>Department of Health</td>
</tr>
<tr>
<td>23. Medical and biomedical research</td>
<td>Use of ionising radiation in radiography, fluoroscopy, interventional radiography, computed tomography, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy, brachytherapy and neutron analysis</td>
<td>Department of Health</td>
</tr>
<tr>
<td>24. Medico-legal procedures</td>
<td>Use of ionising radiation in radiography, fluoroscopy, interventional radiography, computed tomography and in-vivo nuclear medicine</td>
<td>Department of Health</td>
</tr>
<tr>
<td>25. Diagnosis and therapy - veterinary</td>
<td>Use of ionising radiation in radiography, fluoroscopy, computed tomography, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy and brachytherapy</td>
<td>DEFRA</td>
</tr>
<tr>
<td>26. Teaching, including further and higher education and training</td>
<td>Use of radioactive sources, substances and radiation generators</td>
<td>Department for Education</td>
</tr>
<tr>
<td>27. Research and development</td>
<td>Operation of nuclear fission or fusion reactors for R&amp;D purposes</td>
<td>BIS</td>
</tr>
<tr>
<td>28. Ionising radiation metrology</td>
<td>Use of all types of radiation sources to support National Measurement System and use of calibration sources in the testing of equipment</td>
<td>BIS</td>
</tr>
<tr>
<td>29. Transport of radioactive material</td>
<td>Transport of radioactive material by sea in accordance with the IMDG code</td>
<td>Department for Transport</td>
</tr>
<tr>
<td>Transport of radioactive material by air in accordance with the ICAO TI</td>
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<tr>
<td>Transport of radioactive material by road in accordance with ADR</td>
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<tr>
<td>Transport of radioactive material by rail in accordance with RID</td>
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<tr>
<td>Transport of radioactive material in accordance with the IAEA Regulations for safe transport of Radioactive material</td>
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</tr>
</tbody>
</table>

Notes

1. For these existing generic classes or types of practice, the practice includes activities associated with the main purpose of the class or type of practice. This includes, where appropriate, research and development, manufacture, repair, maintenance, supply, assembly, handling, holding, testing (operation and quality assurance), storage, transport (including export and import), decommissioning and waste management, including disposal. However, because transport may be the only element of a class or type of practice which takes place under UK jurisdiction (the remaining elements taking place abroad) it is sometimes necessary to define transport as a class or type of practice in its own right to ensure its due consideration.

2. This list is not necessarily exhaustive and may change as evidence comes to light of a class or type of practice existing prior to 13 May 2000. 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.

3. The Scottish Government, the Welsh Government and the Northern Ireland Executive have responsibilities in so far as existing practices are within devolved competence. Any application received by the Department of the Environment will be passed to whichever Northern Ireland department has lead responsibility for the relevant policy area.