



Department for
Energy Security
& Net Zero

The Justification of Practices Involving Ionising Radiation Regulations 2004

Guidance on their application and
administration

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Foreword

1. The [Justification of Practices Involving Ionising Radiation Regulations 2004](#) came into force in August 2004. The Regulations have been amended by the Justification of Practices Involving Ionising Radiation (Amendment) Regulations 2018, which come into force in April 2018. References in this guidance to the “Regulations” are to the 2004 Regulations as amended by the 2018 Regulations.
2. The Regulations 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.
3. “Justified” means that the individual or societal benefit resulting from a class or type of practice outweighs the health detriment that it may cause. In addition, existing classes or types of practice may be reviewed as to their justification whenever new and important evidence about their efficacy or consequences is acquired.
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 \(IRR17\)](#) (in Great Britain), Schedule 23 of the [Environmental Permitting \(England and Wales\) Regulations 2016](#) (EPR16) (in England and Wales), [Ionising Radiation \(Medical Exposure\) Regulations 2017](#) (in Great Britain) and the [Radioactive Substances Act 1993 \(RSA93\)](#) (in Scotland and Northern Ireland). If you require further advice on these you should contact:
 - IRR17: Health and Safety Executive
 - EPR16: Environment Agency and Natural Resources Wales
 - IR(ME)R17: Health and Safety Executive
 - RSA93: Scottish Environment Protection Agency and Department of Environment (Northern Ireland)
5. The 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 Register](#). A list of classes or types of practice in existence prior to 6 February 2018 can be found at Annex 2 of this guidance.
6. The Regulations also prohibit the deliberate addition of radioactive substances to certain goods, the “activation” of materials in certain products and the import and export of certain goods.
7. The Regulations also include specific requirements that apply to practices involving the deliberate exposure of humans to ionising radiation for non-medical imaging purposes using non-medical equipment.

8. This guidance is issued by the Department for Energy Security & Net Zero (DESNZ) in conjunction with the devolved administrations and is applicable from 18 April 2018 when the amendments come into force. Any enquiries about the guidance or the Regulations themselves should be addressed to the Justification Application Centre:
justifications@beis.gov.uk

What is Justification?

9. Justification is a process 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.
10. The process of justification requires that before a practice is introduced, it should be shown to give an overall benefit. It is also implicit 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.
11. 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.
12. 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 issues that are relevant to the practice (for example, 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.
13. 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 conducted. There are other regulatory provisions that need to be met (i.e. IRR17, EPR16, RSA93 and IR(ME)R17) and these control the manner in which a practice is conducted in order to ensure compliance with the ICRP principles of optimisation and dose limitation (see Annex 1).

Why do we need the Regulations?

14. The Regulations implement the UK's International Obligations on basic safety standards for protection against dangers arising from exposure to ionising radiation.

What are the main provisions of the Regulations?

15. 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;
- practices involving the activation of materials used in toys or personal ornaments which results in a potentially harmful increase in activity are prohibited,
- any person intending to manufacture or import a consumer product for which the intended use is likely to belong to a new class or type of practice must, prior to commencing manufacture or import, make an application to the Justifying Authority for a justification decision (see paragraphs 38-42 for a definition of the Justifying Authority).
- practices involving the deliberate exposure of humans to ionising radiation for non-medical imaging purposes are given special attention, covered in paragraphs 85-97 of this guidance.
- 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;
- 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: justifications@beis.gov.uk) has been established; and
- a [register containing details of applications and decisions](#) is maintained on the GOV.UK website.

What constitutes a practice?

16. A “practice” is “a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation”. It applies to the following activities:
- 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;

- human activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:
 - the operation of aircraft and spacecraft, in relation to the exposure of crews;
 - the processing of materials with naturally-occurring radionuclides; and
 - any other practice specified by the Member State.
17. 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.
18. 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.
19. 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.
20. 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 IRR17, the EPR16 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 option, that the best practicable means are employed in its implementation and that all radiation exposures will be as low as reasonably practicable.
21. 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, where there are cases when only the transport of radioactive material occurs within the UK (and no other part of the practice occurs in the UK) it will therefore be considered a practice in its own right.
22. 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 Regulations.
23. 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 2017](#) require justification of each individual exposure, whether or not it falls within an existing or 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?

24. The REgulations refer 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. The Regulations do not differentiate between classes of practice and types of practice; they may be widely or narrowly defined in particular cases.
25. Under regulation 4(2), “justified” in relation to a new 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. Health detriment is the reduction in length and quality of life occurring in a population following exposure, including those arising from tissue reactions, 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).
26. 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.

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.

What is a new class or type of practice?

27. A new class or type of practice is one of a type or class that was not undertaken within the United Kingdom before 6 February 2018.
28. A class or type of practice is also new if it was carried out in the United Kingdom before 6 February 2018, but was in breach of a requirement not to carry out a practice of that class or type until that class or type has been found to be justified.
29. No one may carry out 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?

30. 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 6 February 2018. A list of these practices can be found at Annex 2.
31. For the purpose of the 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?

32. 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.
33. 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 40).

34. 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 [concordat 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 UK Government departments.
35. Annex 2, which lists existing practices, also shows which UK Government 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 on the consideration of applications (see below).
36. The Justifying Authority must not exercise functions under the Regulations in relation to a practice unless they are functionally separate from all other persons concerned with the promotion or utilisation of that particular practice. Where, for example, a Secretary of State is concerned – or is functionally linked with someone else concerned – with the promotion or utilisation of a practice, the effect of this restriction is that another Secretary of State, who is not concerned in this way, would need to exercise the relevant functions as the Justifying Authority.

What types of application may be made?

37. There are three types of application that may be made by any person to the Justifying Authority in relation to any class or type of practice. 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); and
 - 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).
38. There are also specific applications that may be made in relation to practices involving non-medical imaging exposure that do not use medical radiological equipment. These are discussed at paragraphs 85-97 of this guidance.
39. 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.
40. 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;
 - 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; and
 - an indication of the expected extent of the practice.
41. No comparison needs to be made with alternative practices delivering the same or similar benefits.
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.
43. Under regulation 10, any person may apply to a Justifying Authority for a review of the justification of an existing class or type of practice whenever new and important evidence about its efficacy or potential consequences is acquired. They may also apply whenever new or important evidence about the efficacy or potential consequences of other techniques or technologies that has the same objective is acquired. A Justifying Authority may also 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 6 February 2018 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.

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.
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 are 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 will involve an examination (possibly detailed) of the benefits and detriments of the practice and a comparison with those of existing classes or types.

Where should an application be sent?

46. Applications should be sent to the Justification Application Centre:
justifications@beis.gov.uk.
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 Justification Liaison Group (JLG) for processing.

When should an application be made?

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

How will the decision be made?

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.
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; and
 - Consider evidence on the efficacy and consequences and whether this is new and important.
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.
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.
53. For matters that are reserved to the UK Government, the Government will consult and take into account the views of the devolved administrations before reaching a decision.
54. Any decision document accompanying a decision or determination will set out the considerations and the rationale for the decision¹.
55. It should be noted that justification decisions have to be made by individual countries and cannot apply to other countries other than the one the decision as made in. The UK cannot rely on a decision made in another country to determine or decide the justification of a class or type of practice, though such decisions may be relevant in a specific case and may be taken into account.

¹ For an example of a decision document see the ABWR document at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384112/abwr_justification_decision_document.pdf

Who will the Justifying Authority seek information from?

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.
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.
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;
 - UK Health Security Agency;
 - Environment Agency;
 - Scottish Environment Protection Agency;
 - Natural Resources Wales; and
 - Department of Environment Northern Ireland
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.
60. Where the Justifying Authority considers that any application is of sufficient importance and wide public interest, it 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?

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.
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); or
 - introduces or changes the conditions attached to be justification of a class or type of practice under regulation 11
- will be made in the form of secondary legislation through one or more SIs. The legislation will specify any conditions that the Justifying Authority considers appropriate. These conditions are important because they may set the boundaries of the class or type of practice covered by the decision.
63. For matters that are entirely reserved to the UK government, a single SI will be laid before the UK Parliament. For devolved matters, separate SIs would be laid before the UK Parliament, the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly, as appropriate.
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.
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?

66. No fees are currently payable in respect of an application or copies of the register.

How long will the application take to process?

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?

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

How are the Regulations enforced?

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;
 - any personal ornament, toy or cosmetic to which any radioactive substance has been added in production has been imported or exported;

- a practice takes place involving the activation of materials used in toys or personal ornaments where the activation results in an increase in activity that could be considered detrimental to human health, or such products or materials are imported or exported; or
 - there is a breach of one of the specific requirements that apply to practices involving non-medical imaging exposure not using medical radiological equipment (see paragraphs 85-97 below).
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.
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 at least 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.
73. In order to issue a contravention notice, the Justifying Authority must be able to reach a view that a “relevant breach” has occurred. The information that enables the Justifying Authority to reach such a view may arise from the inspection programme or from specific investigations undertaken once the possibility of a relevant breach has come to light. Where the circumstances that constitute a potential relevant breach are also subject to a separate complaints procedure, information collected as part of that complaints procedure may also (where available to the Justifying Authority) help the Justifying Authority to reach a view on whether a relevant breach has occurred.

What offences do the Regulations create?

74. It is an offence for a person to:
- fail to comply, without reasonable excuse, 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?

75. 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?

76. The enforcement powers exercisable under the regulations are broadly those of section 108 of the [Environment Act 1995](#). 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.
77. The Justifying Authority may also delegate the inspection functions under regulation 23A. The inspections programme is established to monitor whether a person has committed a relevant breach or has failed to comply with any of the requirements in an approval of a practice that involves non-medical imaging exposure.

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

78. It must be emphasised that the generic justification decisions made under the Regulations are only the first stage of the regulatory process. Further 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 \(EIA\)](#) and [Strategic Environment Assessments \(SEA\)](#) 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.

Practices involving non-medical imaging exposures (NMIE)

79. Part 7A of the Regulations contains provisions that apply specifically to practices involving non-medical imaging exposure (NMIE) that do not use medical radiological equipment. These are referred to as “imaging practices” in Part 7A.

80. Such imaging practices are expected to be carried out mainly in prisons and at ports. This guidance is intended to provide a general introduction to the specific provisions relating to imaging practices in the Regulations.

Identification of imaging practices

81. Regulation 21B contains a requirement to take steps to ensure the identification of imaging practices.

Determinations for NMIE practices

82. Regulation 21C sets out a specific determinations procedure for imaging practices that is carried out by the Justifying Authority. The purpose of the procedure is to ensure that new particular applications of classes and types of imaging practice – referred to in the regulation 21C as “particular imaging practices” – are subject to a determination before they are carried out for the first time. The Justifying Authority will determine whether the new particular imaging practice belongs to an existing class or type of practice, i.e. whether the particular imaging practice has similar characteristics to, and displays the same (positive) balance of benefits and detriments, as the relevant existing class or type of practice.
83. The application procedure for someone seeking a determination in respect of a particular imaging practice is the same as for determinations in respect of other classes and types of practice.

Individual justification or regular reviews of exposures

84. Under regulation 21D, a person carrying out a practice involving NMIE should either:
- a. ensure that each individual exposure is justified (i.e. that its individual or societal benefits outweigh the health detriment that it may cause); or
 - b. carry out regular reviews of the implementation of the practice and provide reports summarising the results of those reviews to the Justifying Authority.
85. The regularity of the reviews to be undertaken will depend on the specific circumstances of the practice, Relevant factors may include the number of scans taking place in an establishment and the frequency with which any given individuals are scanned (e.g. whether there is repeated scanning of the same individual).

Requirements for imaging practices

86. Regulation 21E contains provisions on “approvals” and the requirements for practices that are contained in them. As part of an approval for an imaging practice, the Justifying Authority will set out the requirements, including criteria for implementation that must be complied with when the imaging practice is being carried out.
87. The application for an approval would not need to be detailed, but the following information is likely to be required as a minimum:
 88. a statement of the identity of the person proposing to carry out the imaging practice; and
 89. a description of the imaging practice they propose to carry out and the situation(s) it will be carried out in.
90. If the Justifying Authority grants an approval, that approval will contain requirements for the carrying out of the practice to which it relates. Requirements for the practice are relevant to the particular use of an imaging practice: it is expected that they will set out – at a high level – key requirements necessary to ensure the safe operation of the equipment in its particular context.
91. The Justifying Authority may, following a notice procedure, withdraw an approval from a person if the Justifying Authority is of the view that the person has breached the requirements for the practice and has failed to take steps prescribed to that person by the Justifying Authority to remedy that breach.

Information and consent requirements

92. Under regulation 21G, all persons who may be subject to an exposure as part of an imaging practice must be provided with appropriate and relevant guidance to ensure they are aware of the purpose of the scan and associated health and safety implications.
93. Regulation 21G also contains a requirement for obtaining prior consent from the person who is to be subjected to the exposure. The consent requirement imposed by regulation 21G does not apply to law enforcement authorities, including prisons. Further details are included in regulation 21G of the Regulations.

Prohibition of radioactive substances in personal ornaments, toys and cosmetics

94. The prohibition relating to personal ornaments and their import and export is addressed in Regulation 20. It is intended that the Regulations apply to articles to be worn on the person where the radioactivity has no function other than decoration.
95. 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.
96. The prohibition relating to the import or export of cosmetics is also 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.
97. The prohibitions in regulation 20 also extend to:
98. practices involving the activation of materials used in toys or personal ornaments where that activation results in an increase in activity that could be considered detrimental to human health;
99. the import or export of toys or personal ornaments in which materials have been activated; and
100. the import or export of materials that have been activated for use in toys or personal ornaments.
101. "Activation" is "a process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained".

Practices involving consumer products

102. Under regulation 20A, any person intending to manufacture or import a consumer product for which the intended use is likely to belong to a new class or type of practice

must make an application to the Justifying Authority for a justification decision before commencing manufacture or import. The application must provide the information listed in paragraph 1 of Schedule A1 of the Regulations.

103. Once sufficient information has been provided, the Justifying Authority will make a justification decision in respect of the relevant new class or type of practice. In doing so, the Justifying Authority will take into account the information provided to it (listed in paragraph 1 of Schedule A1 of the Regulations) and will also assess the factors listed in paragraph 2 of Schedule A1.
104. In addition, regulation 20A prohibits the selling or making available to the public of consumer products where their intended use would be an unjustified practice or would not meet the criteria described in one or more of the categories listed in paragraph 1 of Schedule 1 of IRR17.
105. Under regulation 20B, any class or type of practice that involves the activation of material in consumer products where that activation results in an increase in activity that could be considered detrimental to human health is treated as “new” for the purposes of the Regulations unless a positive justification decision has been made in respect of it. As a result, an existing class or type of practice of this kind that was previously carried out in the UK before the introduction of the justification regime cannot now be carried out unless and until there is a justification decision that that class or type of practice is justified.

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 bio-kinetic 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 types of practice existing prior to 6 February 2018

Please note that this list is not exhaustive and may be updated as evidence comes to light of a class or type of practice existing prior to 6 February 2018.

Area	Classes or type of practice	Lead Department
1. Enrichment of uranium	Use of the centrifuge process	DESNZ
2. Production of nuclear fuel	Manufacture of uranium metal and oxide fuel for power reactors	DESNZ
	Manufacture of mixed oxide fuel for power reactors	
	Manufacture of uranium fuel for research for materials testing reactors	
	Manufacture of experimental nuclear fuel	
3. Generation of electricity by nuclear reactors	Operation of Magnox power stations	DESNZ
	Operation of advanced gas-cooled power stations	
	Operation of pressurised and boiling water power stations	
4. Recovery of usable products from spent nuclear fuel	Reprocessing of uranium metal from power reactors	DESNZ
	Reprocessing of uranium oxide fuel from power reactors	
	Reprocessing of fuel from research/materials testing/prototype reactors	
5. Production of radioisotopes	Manufacture of radioisotopes using nuclear reactors and accelerators	DESNZ
6. Production of radioactive products	Manufacture of radioactive sources, substances and radiopharmaceuticals	DESNZ
7. Non-destructive testing	Use of radioactive sources, substances and radiation generators for radiography	DESNZ

8. Radiation processing of food	Use of gamma or electron beam radiation sources to reduce bacterial levels, sterilise, disinfect or modify materials	Food Standards Agency
9. Radiation processing of products	Use of gamma, x-ray or electron beam radiation sources to reduce bacterial levels, sterilise, disinfect or modify materials	DESNZ
10. Substance measurement and process control	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	DESNZ
	Use of neutron sources for moisture gauging	
11. Detection and analysis	Use of sealed sources and x-ray generators for analysis	DESNZ
	Use of beta sources for gas chromatography detectors	
	Use of radioactive sources for leak detection, chemical and explosives detection	
	Use of neutron sources for activation analysis	
12. Elimination of static electricity	Use of radioactive sources to eliminate static electricity	DESNZ
13. Illumination	Use and repair of gaseous tritium light sources for illumination, in safety signs and equipment, sighting and location markers, watches and instruments.	DESNZ
14. Electronic apparatus	Use of electronic apparatus containing radioactive substances, e.g. tritium in spark gap devices	DESNZ
15. Safety devices	Use of ionising radiation in smoke and fire detectors and other safety instruments	DESNZ
16. Security screening	Use of x-rays, gamma rays or neutron apparatus to examine packages, baggage, containers or vehicles	Home Office
	Use of x-rays to radiograph suspected smugglers	
	Use of x-rays or gamma rays to detect people seeking illegal entry to the UK in vehicles or freight	
	Use of back-scatter imaging for the detection of concealed items on the person	

	Use of x-rays, gamma rays or neutron sources to detect concealed items in buildings	
17. Equipment producing ionising radiation incidentally	Use of electron beam welders, electron microscopes, radar, thermionic valves, cathode ray tubes, ion implantation machines and high voltage switchgear	DESNZ
18. Radioactive tracers	Use of radioactive tracers in industrial process controls	DESNZ
	Use of radioactive tracers for medical or biological techniques	DHSC
	Use of radioactive tracers for environmental tests	Defra
19. Diagnosis – medical	Use of ionising radiation in radiography, fluoroscopy, computed tomography, in-vivo nuclear and in-vitro nuclear medicine	DHSC
20. Treatment – medical	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	DHSC
21. Occupational health screening	Use of ionising radiation in radiography and in- vitro nuclear medicine	DHSC
22. Health screening	Use of ionising radiation in radiography and in- vitro nuclear medicine	DHSC
23. Medical and biomedical research	Use of ionising radiation in radiography, fluoroscopy, interventional radiography, computed tomography, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy, brachytherapy and neutron analysis	DHSC
24.. Examinations performed for insurance or legal purposes without a medical indication	Use of ionising radiation in radiography, fluoroscopy, interventional radiography, computed tomography and in-vivo nuclear medicine	DHSC
25. Diagnosis and therapy – veterinary	Use of ionising radiation in radiography, fluoroscopy, computed tomography, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy and brachytherapy	Defra

26. Teaching, including further and higher education and training	Use of radioactive sources, substances and radiation generators	Department for Education
27. Research and development	Operation of nuclear fission or fusion reactors for R&D purposes	DESNZ
28. Ionising radiation metrology	Use of all types of radiation sources to support National Measurement System and use of calibration sources in the testing of equipment	DESNZ
29. Transport of radioactive material	Transport of radioactive material by sea in accordance with the IMDG code	Department for Transport
	Transport of radioactive material by road in accordance with ADR	
	Transport of radioactive material by rail in accordance with RID	
	Transport of radioactive material in accordance with the IAEA Regulations for safe transport of Radioactive material	
30. Use of uranium and thorium (other than for its fertile, fissile or radioactive properties)	Use of uranium and thorium compounds as Laboratory reagents	DESNZ
	Use of depleted uranium in counterweights	
	Thorium alloy manufacture, for example for aircraft parts and the use of thoriated products, such as special types of welding electrodes	
	Other uses of uranium and thorium other than for their fertile, fissile or radioactive properties	
31. Activities that may result in the occurrence of Naturally Occurring Radioactive Material (NORM)	The extraction and production of rare earth elements and rare earth element alloys	DESNZ
	The mining and processing of ores other than uranium ore	
	The production of oil and gas	

	The removal and management of radioactive scales and precipitates from equipment associated with industrial activities	
	The manufacture of titanium dioxide pigments	
	The extraction and refining of zircon and manufacture of zirconium compounds	
	The production of tin, copper, aluminium, zinc, lead and iron and steel	
	Any activity related to coal mine de-watering plants	
	China clay extraction	
	Geothermal energy production	
	Water treatment associated with provision of drinking water	Defra

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 6 February 2018. 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.

This publication is available from: www.gov.uk/government/publications/the-justification-of-practices-involving-ionising-radiation-regulations-2004-guidance-on-their-application-and-administration

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