Title: The Justification of Practices Involving Ionising Radiation Regulations 2004	Post Implementation Review
PIR No: DESNZ007(PIR)-23-ND	**Date: 17/04/2023**
Original IA/RPC No: N/A	**Type of regulation: Domestic**
Lead department or agency:	**Type of review: Statutory**
Department for Energy Security and Net Zero	**Date measure came into force:**
Other departments or agencies: N/A	**02/08/2004**
	Recommendation: Keep
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1. What were the policy objectives of the measure?

Justification is one of the key principles of radiological protection established by the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) on which the radiological framework of the UK is based. Industries using radiation range from nuclear power plants to hospitals, universities, and research laboratories.

The regulations set out requirements designed for the protection of workers and the public against the dangers of ionising radiation without unduly limiting the beneficial uses of the practices giving rise to radiation exposure. All new classes or types of practice resulting in exposure to ionising radiation need to be justified before they are first used. The justification decision takes account of the economic, social, and other benefits in relation to the potential health detriment that the new class or type of practice might cause. There is provision for the review of existing practices whenever new and important evidence about the efficacy or consequences of that practice is acquired.

2. What evidence has informed the PIR?

Input on this PIR was sought from a wide range of industry stakeholders, radioactive substances policy leads in other relevant government departments, the environmental regulators and the devolved administrations.

Evidence was provided by the Environment Agency, the Scottish Environment Protection Agency, Natural Resource Wales, the Office for Nuclear Regulation, the Health and Safety Executive and UK Health Security Agency. These agencies are statutory consultees for the Justification of Practices Regulations and use their technical expertise to weigh up the benefits and detriments of applications to use ionising radiation.

Views were also provided by industry stakeholders or other government departments who have either previously submitted justification applications or are in the process of doing so. The evidence was collated via a combination of written responses as well as meetings with interested parties.

3. To what extent have the policy objectives been achieved?

The regulations have been successful in justifying practices in order to produce sufficient benefit to the exposed individuals or society to offset the radiation detriment that they may cause. The generic justification introduced by the regulations, which replaced the previous individual site-by-site justification under the Radioactive Substances Act 1993, is less onerous for industry. Feedback from stakeholders is that the transparent system for all justification decisions (published, as appropriate, on a publicly available register) remains appropriate. However, responses indicate that further clarification of the administrative process in the accompanying guidance would be useful.

Sign-off for de minimis assessment: Minister

I have read the de minimis assessment and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Andrew Bowie Date: ***17/04/2023***

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions?

Overall, it was assumed that a formal system in which justification is applied generically, rather than at a site-by-site level, would be less burdensome. The establishment of a transparent system for all justification decisions, and the capability to review justification decisions whenever new and important evidence is acquired, would provide stakeholders with certainty and confidence when developing their justification applications.

5. Were there any unintended consequences?

Some respondents advised that it would be helpful for their organisations to be approached in a centralised way for all justification decisions rather than to different named individuals for the various topic areas. This would allow the most appropriate individual to input to the justification decision, for example, where a practice may have implications in both the medical and occupational sectors.

6. Has the evidence identified any opportunities for reducing the burden on business?

Respondents agreed that the generic justification introduced by the regulations are less onerous than the previous individual site-by-site justification and adequately incorporate the relevant basic safety standards to protect human health, workers and the environment. The guidance lists existing practices, shows which UK Government departments are responsible for justification decisions in different subject areas, and invites public participation, further increasing certainty and confidence. There is provision in the regulations for the review of existing practices, whenever there is new and important evidence about the efficacy or consequences of the practice. Some respondents suggested that it would be beneficial to have further clarification in the guidance of the review process to ensure such evidence is not missed.

Some respondents felt that the level at which some classes and types of practices are being justified is still too specific and that justification decisions could be made at an even more generic level. There was also a call for more consistency in the definitions of some classes or types of practices in the administrative guidance as it was felt that there was a range of specificity. It was also felt that input from the devolved administrations on justification applications could sometimes be sought earlier in the process.

We intend to explore how the administrative guidance could be clarified and will work with stakeholders to address the points that have been made.

7. How does the UK approach compare with the implementation of similar measures internationally, including how EU member states implemented EU requirements that are comparable or now form part of retained EU law, or how other countries have implemented international agreements? (Maximum 5 lines)

The UK's implementation of justification is broadly in line with how it is implemented in other countries and how the 2013 Directive is implemented in EU Member States. Although there are slight procedural differences between some countries approaches, overall, implementation is consistent with the requirements of the IAEA and ICRP.

Annex A

The Justification of Practices Involving Ionising Radiation Regulations 2004

Background

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 and the Justification Decision Power (Amendment)(EU Exit) Regulations 2019.

2. The Regulations provide a framework in which justification decisions are made. Justification is a process which requires, before any new class or type of practice involving ionising radiation can be introduced in the UK, an assessment 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).

3. Justification is relevant when a new practice is being introduced or an existing practice is being reviewed in the light of new information about its efficacy or consequences. 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.

4. 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.

5. 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 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.

What are the main provisions of the Regulations?

7 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;

- practices involving the deliberate exposure of humans to ionising radiation for non-medical imaging purposes are given special attention;
- 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 Centre, has been established; and
- a register containing details of applications and decisions is maintained on the GOV.UK website.

Annex B

Methodology

Stakeholders were asked how the regulations were working and whether the policy objectives and the original assumptions were still relevant. They were invited to identify opportunities to reduce the burden on businesses and were also asked whether they had identified any unintended consequences of the regulations.

Stakeholder engagement was through correspondence as well as face-to-face meetings. A "light-touch" review was considered proportionate as the net costs and benefits fall below the de minimis threshold (+/- £5m). Views were received from the environmental regulators in the UK as well as from private and public stakeholders and relevant trade associations. Stakeholders who have previously submitted applications, have live applications or expect to submit applications were also consulted.

Summary of stakeholder responses

Stakeholders felt that the regulations remain relevant, and that the generic justification it introduced is less onerous than the site-by-site justification under the previous regime. They considered the UK approach to justification remains consistent with the requirements of the International Atomic Energy Agency (IAEA) and the International Commission for Radiological Protection (ICRP and that justification continues to be one of the key principles of radiation protection for these international organisations.

Some stakeholders felt that, in some instances, the level at which some classes or types of practice is being justified is still too narrow and that justification decisions could be made by the Justifying Authority to cover a broader range of classes or types of practices. It was also suggested that for some practices there is some inconsistency in some of the definitions in the administrative guidance. The enforcement mechanisms available in the regulations could be more effectively used to deal with identified instances of non-compliance.

Response

The regulations already provide the Secretary of State, as the Justifying Authority, with a broad discretion to decide what should constitute a class or type of practice. The class or type of practice needs to be justified by weighing up its economic, social or other benefits against the health detriment it may cause. The technical evidence provided by applicants should be sufficient to enable the Justifying Authority to be able to compare the relevant benefits and detriments of all the practices that are proposed to be included in a class or type of practice. Where a proposed class or type of practice would include a broader range of practices, expert evidence should demonstrate the extent to which all the practices proposed to be included are similar and also the extent to which they are different. The evidence should also show that the ways in which the practices are different are not so significant as to put any of them into a different class or type of practice. The Justifying Authority will consider such evidence when making a decision on what should be included in a class or type of practice.

This formal PIR allows us to look at appropriate steps to reduce burdens in line with the commitment we made in the British Energy Security Strategy to work with regulators to understand the potential for any streamlining or removal of duplication from the consenting and licensing of new nuclear power stations, without impacting the robust safety, security and environmental protections. We intend to work with stakeholders to clarify the guidance to ensure applicants can submit more robust applications backed up by expert technical evidence. This work will also look at ensuring consistent definition of the practices listed in the guidance as well as a clarification on how the enforcement mechanisms should be used.