



Department
of Energy &
Climate Change

The Justification of Practices Involving Ionising Radiation Regulations 2004

Justification Decision on an application for the use of an ionising source in a gas meter as a new class or type of practice

January 2013

Summary

An application was made under the Justification of Practices Involving Ionising Radiation Regulations 2004 for a Justification Decision on the *use of an ionising source in a gas meter* as a new class or type of practice. This document outlines the relevant regulatory provisions and the process for considering the application. The document then summarises the reasons for the Secretary of State for Energy and Climate Change’s decision, as Justifying Authority, that *using an ionising source in a gas meter* is not justified as a new class or type of practice.

Justification of Practices Involving Ionising Radiation

1. Regulatory Justification is an initial, high-level process confined to the relevant class or type of practice under consideration. Regulatory Justification is based on the internationally accepted principle of radiological protection that no new practice involving exposure to ionising radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. This principle is derived from the recommendations of the International Commission on Radiological Protection (the ICRP)¹ in ICRP Publication 60² and reaffirmed most recently in ICRP Publication 103³.
2. Article 6(1) of European Council Directive 96/29/Euratom of 13 May 1996 (the Basic Safety Standards Directive)⁴ requires Member States to ensure that all new classes or types of practice resulting in exposure to ionising radiation are justified, in advance of being first adopted or first approved, by their economic, social or other benefits in relation to the health detriment they may cause.
3. The requirements of Article 6(1), (2) and in part (5) of the Basic Safety Standards Directive have been implemented in UK law by the Justification of Practices Involving Ionising Radiation Regulations 2004⁵ (the Regulations), which prescribe the process for Justifying a new class or type of practice. This process is referred to as Regulatory Justification. A class or type of practice is “new” if no practice in that class or type was

¹ The ICRP is an independent international body of experts which provides guidance on a range of topics relating to the protection of man from the harmful effects of ionising radiation <http://www.icrp.org/>

² ICRP Publication 60: 1990 Recommendations of the ICRP <http://www.icrp.org/>

³ ICRP Publication 103: 2007 Recommendations of the ICRP <http://www.icrp.org/>

⁴ Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L159, 29.6.1996, p.1) http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9629_en.pdf

⁵ The Justification of Practices Involving Ionising Radiation Regulations 2004, Statutory Instrument 2004 No. 1769 <http://www.opsi.gov.uk/si/si2004/20041769.htm>

carried out in the United Kingdom before 13 May 2000, and the class or type of practice has not previously been found to be Justified by the UK Justifying Authority.

4. This means that before carrying out a practice that is “new” the class or type of practice to which it belongs must go through a Regulatory Justification process. This process will involve an assessment of the economic, social and other benefits associated with the class or type of practice as against its health detriment. If the assessments find that the benefits outweigh the detriments then a Regulatory Justification decision will be made that the class or type of practice is Justified.

The Application

5. In January 2012 Sentec Ltd (the “Applicant”) submitted an application for a Justification Decision in relation to the class or type of practice being: *using an ionising source in a gas meter* as a new class or type of practice under Regulation 9(1) of the Regulations⁶.
6. The Applicant had previously made an application for a Justification Decision of the same practice as an existing class or type of practice under Regulation 12(1). The Secretary of State decided that *using an ionising source in a gas meter* was not an existing class or type of practice under the Regulations⁷.

Process for Considering the Application

7. The Department of Energy and Climate Change (DECC) is the Department responsible for co-ordinating the Regulatory Justification process across Government and is the policy lead for the Regulations. Before the creation of DECC in October 2008, the Department for Environment, Food and Rural Affairs (Defra) had this responsibility and published Guidance⁸ on the application and administration of the Regulations.
8. Under the Regulations, the Justifying Authority in the UK is the responsible Secretary of State and the three Devolved Administrations (the Scottish Government, the Welsh Government and the Northern Ireland Assembly), to the extent that they have competence in respect of the subject matter of a particular Regulatory Justification application. The subject matter of this decision (energy metering) has not been devolved to any of the Devolved Administrations. Therefore, the Secretary of State is the sole Justifying Authority in this case and his decision is UK-wide. The relevant Secretary of State in this area is the Secretary of State for Energy and Climate Change.

⁶ This application is listed on the Justification Register (reference number 17/12) and the documents are available for inspection on request to the Justification Application Centre.

http://www.decc.gov.uk/assets/decc/what%20we%20do/uk%20energy%20supply/energy%20mix/nuclear/radioactivity/1_20100318123942_e_@@_justificationregister.pdf

⁷ Determination on an application for the use of a sealed source to measure gas flow in smart meters as an existing class or type of practice, October 2012: <http://www.decc.gov.uk/assets/decc/11/meeting-energy-demand/nuclear/6656-justification-practices-inv-ionising-2008.pdf>

⁸ The Justification of Practices Involving Ionising Radiation Regulations 2004 (SI 2004 No 1769), Guidance on their application and administration, Version May 2008
<http://www.decc.gov.uk/assets/decc/what%20we%20do/uk%20energy%20supply/energy%20mix/nuclear/radioactivity/justification-guidance.pdf>

9. The Secretary of State has consulted with the Devolved Administrations in making this decision, in accordance with regulation 18(2) of the Regulations and the Concordat on the Implementation of the Justification of Practices Involving Ionising Radiation Regulations 2004 (the Concordat). The Concordat governs the working relations between the Justifying Authorities in a way which respects the devolution settlements.
10. Before making a Regulatory Justification decision the Justifying Authority is also required to consult with statutory consultees: the Health and Safety Executive (HSE), the Food Standards Agency (FSA), the Health Protection Agency (HPA), the Environment Agency (EA), the Scottish Environment Protection Agency (SEPA) and the Department of the Environment for Northern Ireland (the Statutory Consultees).
11. A Justification Liaison Group (JLG) was formed comprising representatives of the Devolved Administrations and the Statutory Consultees⁹. In addition a metering technical expert from the Smart Metering Programme in DECC and an official from the Science and Innovation Directorate of DECC attended.
12. The JLG convened twice during the course of its consideration of the application. The Applicant had attended part of the first meeting to present their application and engage with the JLG on the issues raised.

Content of the Application

13. The Applicant has developed a gas metering technology which uses a sealed radioactive source to ionise the gas and detect the ions downstream by measuring the flow of the ion current. The application contains a summary of the technology describing the assembly of the ionisation chamber which contains a sealed radioactive source. The application shows how the radioactive source would be incorporated into the gas meter. The radionuclide proposed for use in the gas meter is Americium 241 (Am-241), which is incorporated into a thin foil mounted in a metal holder. The application also notes that the source used is the same as the sources found in ionisation smoke detectors.
14. The Applicant sets out a number of anticipated benefits from the use of the technology they have developed:
 - accurate and direct measurement at a wide range of flow rates;
 - inherent resilience, with no moving parts to wear out, reducing servicing requirements;
 - long lifetime of meter ~20 years. With no moving parts to wear and encapsulation protecting the electronics from the corrosive gas atmosphere, the lifetime is expected to be limited by the battery lifetime;
 - few parts therefore low cost, encouraging roll-out by utility companies; and

⁹ The Food Standards Agency (FSA) is a statutory consultee under the Regulations, however, after an initial consultation on the application the FSA indicated that it was not in a position to offer advice in relation to this particular case, given that there were no evident food standards issues involved. The FSA therefore did not form part of the JLG.

- low power requirements.
15. The Applicant has also set out various product design features intended to minimise the potential for exposure of people to the ionising radiation:
- the sealed source is housed in a plastic flow tube which is electromagnetically shielded by a metal coating;
 - the flow tube is placed inside a gas leak-tight sealed metal box containing the gas envelope; and
 - the metal box is inside the outer plastic meter case.
16. The gas consumer or meter engineer would have no access to radioactive sources in the field. The installer or engineer would be shielded from the radioactive source by a metal casing when installing or servicing the meter or replacing its battery. The source would remain shielded by metal casing during normal use and during meter refurbishment.
17. The application was supported by a number of additional documents providing further information about various aspects of the application. These included a radiation risk assessment and a corrosion risk assessment. The Applicant had attended part of the initial JLG meeting to present their application and engage with the JLG on the issues raised.
18. Following this initial meeting of the JLG, the Applicant was invited to provide further information in a number of areas. The Applicant subsequently submitted a technical note addressing a number of the questions raised, an updated radiation risk assessment and an updated corrosion risk assessment. In addition the Applicant provided various scientific research papers and information from gas transporters.

Smart Meters Policy Background

19. It is relevant to note the wider context within which the Applicant has been developing the technology described in the application. The Government's vision is for every home and smaller business in Great Britain to have smart energy meters. The roll-out of smart meters will play an important role in Britain's transition to a low-carbon economy and help meet some of the long-term challenges faced in ensuring an affordable, secure and sustainable energy supply. A major programme, managed by DECC, is underway to design and implement new cross industry arrangements for smart metering, which will lead to the replacement of around 53 million meters, including around 23 million gas meters by the end of 2019. Energy suppliers will be responsible for the procurement and installation of meters in their customers' homes. Whilst some smart meters are being installed now, the mass roll-out is expected to start in late 2014¹⁰.

¹⁰ Details of the programme can be found on the DECC website at http://www.decc.gov.uk/en/content/cms/tackling/smart_meters/smart_meters.aspx

Consideration

20. The principle of justification is that no class or type of practice involving exposures to radiation should be adopted unless it produces sufficient economic, social or other benefit to the exposed individuals or to society in relation to the health detriment it may cause. The Secretary of State has considered the potential health detriments arising from *using an ionising source in a gas meter* in relation to the economic, social or other benefits produced as described below.

Potential Health Detriments

Review of the material provided by the Applicant

21. Information was provided in the application and the supporting material which related to the potential radiation doses from the normal use of the meter as well as those arising from accidents and incidents. The assessments, undertaken by the Health Protection Agency (HPA) for the Applicant related to household occupants and to workers. The information provided in the HPA assessment indicated that estimated radiation doses would be below accepted criteria. In the case of breakdown or degradation of the source the estimated radiation doses are close to accepted criteria.
22. In the proposed new practice the radioactive source will be exposed to the flow of gas as part of its normal mode of operation. The application estimates the operating life of the meter to be about 20 years, noting that the limiting factor is considered to be battery life. Providing the meter remained accurate in metrology terms it could remain in-situ for a period longer than 20 years meaning that the radioactive source could be exposed to gas for more than 20 years.
23. A corrosion risk assessment had been undertaken for the Applicant and was provided with the application. This assessment indicated that the probability of failure, due to corrosion of the materials used in the source following exposure to low concentrations of various compounds present in the gas was low. In addition scientific literature had been provided by the Applicant which provided information about the nature and effect of the interaction of mercury and gold. The Applicant concluded that the likelihood of the source shielding being degraded by exposure to materials in gas was low.

Consideration by DECC of the potential health detriments

24. DECC has consulted with the JLG on the potential health detriments of the proposed new practice and the main areas considered are described below.
25. DECC, in consultation with the JLG, considers a potential for a health detriment to arise from the new practice due to the risk of there being a leak of radioactive material from the sealed source, at any point in the meter's lifecycle including: manufacture, storage, transportation, installation use, servicing and disposal. In many circumstances relevant comparisons can be drawn with existing practices. For instance, as has already been noted, the proposed radioactive source is the same as that used in ionising smoke detectors, and issues surrounding manufacture, storage, transportation and installation would be similar.

26. The JLG identified a potential for health detriments to arise from a leak of radioactive material during the installed lifetime of the meter – that is the period during which it is installed and operating in homes and businesses. The JLG considered two ways such a leak could happen. Firstly through a catastrophic event, for instance an accident physically damaging the radioactive source and leading to an immediate leak. Secondly a gradual leak, for instance due to degradation of the source, resulting in a relatively smaller leak potentially over a long period of time.
27. The JLG noted that the meters and sources were mechanically robust and it considered that threats to the integrity of the source were unlikely to come from physical handling, damage etc. in normal usage. The normal operating environment for this source would involve its exposure to gas flow, and the materials contained within the gas supply, over a long period of time. The JLG considered a key risk arose from the potential for material contained in the gas supply to adversely affect the integrity of the source, leading to an undetected leak of radioactive material over a long period of time. In particular the presence of mercury in the gas supply and the potential for this to react with the material used to contain the source was highlighted by the JLG as a concern.
28. The JLG had considered all the information provided by the Applicant. It had concluded that there was a risk of an undetected leak which could result in radiation exposure over a long period of time. In a worst case scenario exposure could exceed generally accepted levels¹¹ and remain undetected for some time. The JLG had noted that the theoretical evidence provided indicated that this may be a low risk, however on the basis of the evidence provided to date, and in particular the lack of physical tests in the relevant environment, it was not possible to be confident about the degree of risk of leakage.

Economic, Social or other Benefits

Review of material provided by the Applicant

29. The Applicant argued that the use of the radioactive source to measure gas flow would give rise to a number of benefits, including:
- accurate and direct measurement at a wide range of flow rates;
 - inherent resilience, with no moving parts to wear out, reducing servicing requirements;
 - long lifetime of meter ~20 years. With no moving parts to wear and encapsulation protecting the electronics from the corrosive gas atmosphere, the lifetime is expected to be limited by the battery lifetime;
 - few parts therefore low cost, encouraging roll-out by utility companies; and

¹¹ Radioactive sources in/on domestic residential premises are not subject to environmental regulation, but it is generally accepted that a dose constraint of 10 microSievert per year is appropriate for potential doses arising from routine use of consumer goods incorporating a radioactive substance (this is the criteria for exemption from regulatory control specified by EU Council Directive 96/29/EURATOM). The dose limit of 1 milliSievert per year for “other persons” given in the Ionising Radiations Regulations 1999 is the appropriate value to use for doses arising from non-routine accident scenarios.

- low power requirements.
30. In addition the Applicant stated that the new practice would deliver more accurate and direct measurement of gas flow at a wide range of flow rates. This could provide higher resolution information to customers and the potential for more accurate detection of leaks or tampering in comparison to existing meter designs.
31. The Applicant also set out its understanding of the wider benefits of smart metering as being:
- customers have real-time information on tariffs and gas usage;
 - greater visibility of cost causes customers to reduce their consumption;
 - remote credit/ prepayment;
 - tamper and status alerts;
 - safety features: remote disconnection to cut off gas supply in response to alerts; and
 - better information improves ability to predict usage and manage gas resources.
32. The application provided no quantitative assessment of the benefits arising from the proposed new practice. However the Applicant did reference the benefits case set out in the DECC Impact Assessments.

Consideration by DECC of the potential economic, social or other benefits

33. There are various technologies used to measure the flow of gas in a gas meter to measure consumption. Smart meters have additional capabilities linked to the communication of data and remote management of the meter. The communication and remote management capabilities of a smart meter require accurate measurement of gas flow, but the particular technology used to deliver the measurement of gas flow does not in itself deliver the smart meter benefits. It is therefore not appropriate to assign all the quantified benefits of smart meter benefits to the new practice which is a new technology for the measurement of gas flow¹².
34. However it would be relevant to consider the benefits arising from the use of the gas flow measurement technology for which Justification was sought including:
- reduced meter costs – some mechanical or electromechanical measurement devices are relatively complex and difficult to manufacture to the required tolerances – a simpler design may reduce the costs of a meter;

¹² The benefits of smart metering have been quantified for the purposes of the smart meter rollout Impact Assessments: for the domestic sector: <http://www.decc.gov.uk/assets/decc/11/consultation/smart-metering-imp-prog/4906-smart-meter-rollout-domestic-ia-response.pdf> ; For the non-domestic sector: <http://www.decc.gov.uk/assets/decc/11/consultation/smart-metering-imp-prog/4907-smart-meter-rollout-non-domestic-ia-resp.pdf>

- operational efficiencies – the longer a meter can remain in operation the better the return on the initial investment and avoiding the need for site visits to maintain the meter or to replace batteries would reduce meter management costs; and
 - additional safety or monitoring features, which could be incorporated.
35. Assumptions can be made about the potential cost savings and market penetration of a new meter incorporating these features, which indicate a positive benefit. Further substantiation of the claims made in the application would be needed to confirm the likely scale of the savings derived from the new measuring technology.
36. No assessment was made by the Applicant of the wider issue of consumer acceptability of the new technology and it is difficult to make a quantitative assessment in this respect. The Applicant argued that the widespread use of ionising smoke detectors may offer some indication that the use of this type of technology may be acceptable to consumers. However this comparison is not completely analogous in terms of consumer choice or ease of replacement. It is usually energy suppliers who make the decisions regarding the installation of gas meters in their customers' homes and businesses and only qualified persons can undertake the installation.

Decision

37. On the basis of the information available at this time the Secretary of State does not consider that the new practice or activity – *using an ionising source in a gas meter* – is Justified by its economic, social and other benefits in relation to the health detriments it may cause.
38. In reaching his decision, the Secretary of State has had to consider and balance benefits and detriments in areas which are not directly comparable in their substance and effect, and to take into account the evidence available to him at this time.
39. The Secretary of State has taken into account the views of the JLG regarding the evidence related to potential health detriments. He has noted that under normal operating circumstances the expected exposure levels appear to be very low. However he has also noted the JLG's concerns about the evidence provided. In particular whether the evidence sufficiently answers concerns about the long term exposure of the source to gas, where directly applicable testing data was not available.
40. The Secretary of State has noted that there is the potential for the Applicant's gas meter to be installed in a large number of domestic dwellings and other premises. Depending on its success in the marketplace this could mean the installation of a radioactive source in many homes and businesses for a long period of time. The Secretary of State has also noted that further radiological regulatory oversight in the domestic setting would be limited if Justified¹³.

¹³ The principle UK legislation covering occupational and public/ environmental exposures are the Ionising Radiations Regulations 1999 (IRR99) and the Environmental Permitting Regulations (EPR) and Radioactive Substances Act 1993 (RSA93) respectively. The source is unlikely to be subject to IRR99 since these generally relate to workplaces and would be exempt from the EPR/RSA93. Further regulatory interventions within these regimes such as Optimisation and Limitation would not therefore apply.

41. The Secretary of State has noted that, on the basis of the information provided, the new practice could deliver cost savings which would ultimately benefit consumers, although the claims made by the Applicant about the lifetime of the meter and the scale of the cost savings, which would drive these benefits, would require further substantiation to enable robust estimation of the scale of the benefits. He is also mindful that increased competition and innovation in the provision of metering could also bring benefits.
42. The Secretary of State is required to take a high-level view of the potential health detriments in relation to the economic, social or other benefits of the practice or activity. On balance, considering all the evidence available at this time, the Secretary of State considers that the degree of uncertainty over the long term performance of the radioactive source when exposed to gas, means that he cannot be confident that the benefits will outweigh the potential health detriment. He has therefore concluded that, on the basis of the evidence before him, *using an ionising source in a gas meter* is not Justified.

The Scope of the Decision

43. For determinations under Regulation 9, functions performed by Justifying Authorities 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. However, Devolved Administrations must be consulted in advance of any such determination. The Secretary of State has consulted with Devolved Administrations regarding this application and they have indicated their agreement with the conclusions. This Decision has effect in the UK.

Public Availability of the Decision

44. The Secretary of State has informed the Applicant and published this Justification Decision on the DECC website. Notification of this Justification Decision is also made in the London, Edinburgh and Belfast Gazettes as it affects all of the UK.
45. DECC wishes to thank the consultees for their detailed and wide-ranging contributions.

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