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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations implement Article 6(1), 6(2) and in part Article 6(5) of Council Directive 96/29/Euratom (OJNo. L159, 29.6.96, p.1) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (“the Directive”). They extend to the whole of the United Kingdom.

The Regulations introduce the international radiological protection principle of generic “justification” of classes of practices involving exposure to ionising radiation, that is weighing the health detriments of such practices against economic, social or other benefits, to implement Article 6(1) and 6(2) of the Directive, which in turn gives effect to Recommendation No. 60 of the International Commission on Radiological Protection<sup>(1)</sup>. They also prohibit the addition of radioactive materials to certain goods, and the import or export of certain goods (see part 6 below) and preserve a saving in respect of individually justified medical exposure where the practice is not generally justified (see part 7 below).

The Regulations are in 8 parts.

*Part 1 (Interpretation and General—regulations 1-3)* limits the application of these Regulations to practices which are within the scope of the Directive (regulation 2) and provides that words have the same meaning in the Regulations as in the Directive (regulation 3).

*Part 2 (General Principles—regulations 4-8)* prohibits practices unless they have been justified, or they were ‘existing practices’ carried out before 13 May 2000- the date the Directive came into force (regulation 4). Regulation 5 prohibits the carrying out of any practice after the class or type has been found not to be justified, and any time allowed for ceasing the practice has expired.

Regulation 6 defines the relevant Justifying Authority, which takes justification decisions and performs most functions under the Regulations (a few functions are performed by the Secretary of State.) The Justifying Authority is the Scottish Ministers, National Assembly for Wales or a Northern Ireland Department, to the extent that devolution allows, and the Secretary of State in respect of England and for matters that are not devolved.

Regulation 7 makes transitional provision for practices started before the Regulations came into force but after 13 May 2000. Regulation 8 validates certain justification decisions made before the Regulations came into force.

*Part 3 (Applications and Determinations—regulations 9-12)* sets out the conditions under which applications may be made for justification decisions and under which justification decisions may or must be made. Regulation 11 permits conditions to be attached to justification decisions, and provides that the Justifying Authority may require operators or other persons to take appropriate steps consequential upon a justification decision. Regulation 12 provides for the Secretary of State to decide whether a practice is new or existing.

*Part 4 (Procedures—regulations 13-15)* provides a mechanism for any application to be determined by the appropriate Justifying Authority (regulation 13) regardless of where it is made. Regulation 14 specifies that a justification decision affecting a class or type of practice must be made in the form of regulations, such as regulations made under section 2(2) of the European Communities Act 1972 (the power to make such regulations is not conferred by these Regulations). Regulation 14

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(1) Copies can be obtained from Elsevier Science, <http://www.elsevierhealth.com/journals/icrp>.

*Status: This is the original version (as it was originally made).*

contains further provisions for notice, advertisement and use of information technology. Regulation 15 requires the decision maker to tell an applicant how long it will take to make a decision.

*Part 5 (Information, Consultation and Publicity—regulations 16-19)* deals with acquisition and publication of information by the Justifying Authority. Regulation 16 enables the Justifying Authority to require information from persons on whom a notice is served. Regulation 17 gives a power to hold inquiries or hearings, and to summon witnesses and award costs. Regulation 18 provides for consultation and specifies statutory consultees. Regulation 19 requires the Secretary of State to keep a register of applications, decisions and other appropriate information.

*Part 6 (Personal Ornaments, Toys and Cosmetics – regulation 20)* completes the implementation of Article 6(5) of the Directive, by prohibiting the addition of radioactive substances to personal ornaments or toys, and forbidding the import of personal ornaments, toys or cosmetics to which radioactive substances have been added. The addition of radioactive substances to cosmetics is already prohibited by Schedule 3, Part 1 of the Cosmetic Products (Safety) Regulations 2003 (SI 2003/835). The Food Safety Act 1990 (c. 16) (sections 7 and 18(1)(c)) makes similar provision in relation to foodstuffs. The Toys (Safety) Regulations 1995 are the subject of a consequential amendment, replacing a reference to the repealed Council Directive 80/836/Euratom (which permitted radioactive substances to be used in toys, and the importation of such toys, provided there was prior authorisation) with the Directive's total prohibition on the addition of radioactive substances in the production of toys, and on their import or export.

*Part 7 (Justification of classes or types of practice involving a medical exposure – regulation 21)* preserves the saving, in Article 3 of Council Directive 97/43/Euratom and regulation 6 of the Ionising Radiation (Medical Exposure) Regulations 2000 (S.I.2000/1059), which permits exposure of individuals to radiation where it is medically justified for that individual even where the practice is not justified in general.

*Part 8 (Enforcement and Offences – regulations 22-27)* makes provision for contravention notices to be served in the event of matters constituting a relevant breach of the Regulations (regulation 22) and for enforcement powers and offences. The enforcement powers (regulation 23 and Schedule 1), being those in the Environment Act 1995 with consequential changes, include powers of entry, seizure, examination, sampling, questioning and, where necessary, use of reasonable force, the issue of warrants, and a duty to compensate. Regulation 24 creates offences of breach of a contravention notice, provision of false information and obstructing enforcement. Regulation 25 and Schedules 2-4 provide for corporate offences in different countries of the United Kingdom. Regulation 26, which does not apply in Scotland, restricts prosecutions other than by or with the consent of the Justifying Authority. Regulation 27 permits delegation of enforcement powers and associated investigatory powers.

A full Regulatory Impact Assessment of the effect that this instrument will have on the costs of business, and a transposition note, have been prepared and are available from Mr Chris Wilson, Department for Environment, Food and Rural Affairs, Zone 4/E5, Ashdown House, 123 Victoria Street, London SW1E 6DE.