STATUTORY RULES OF NORTHERN IRELAND

2018 No. 17

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

Justification of individual exposures

11.—(1) A person must not carry out an exposure unless—

(a) in the case of the administration of radioactive substances, the practitioner and employer are licensed to undertake the intended exposure;

(b) it has been justified by the practitioner as showing a sufficient net benefit giving appropriate weight to the matters set out in paragraph (2);

(c) it has been authorised by the practitioner or, where paragraph (5) applies, the operator;

(d) in the case of an exposure taking place in the course of a research programme under regulation 3(c), that programme has been approved by an ethics committee and in the case of the administration of radioactive substances, approved by an expert committee who can advise on the administration of radioactive substances to humans;

(e) in the case of an exposure falling within regulation 3(f) (non-medical imaging), it complies with the employer's procedures for such exposures; and

(f) in the case of an individual of childbearing potential, the person has enquired whether that individual is pregnant or breastfeeding, if relevant.

(2) The matters referred to in paragraph (1)(b) are—

(a) the specific objectives of the exposure and the characteristics of the individual involved;

(b) the total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure;

(c) the individual detriment that the exposure may cause; and

(d) the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

(3) In considering the weight to be given to the matters referred to in paragraph (2), the practitioner justifying an exposure in accordance with paragraph (1)(b) must have regard, in particular to—

(a) recommendations from appropriate medical scientific societies or relevant bodies where a procedure is to be performed as part of any health screening programme;

(b) whether in circumstances where there is to be an exposure to a carer or comforter such an exposure would show a sufficient net benefit taking into account—

(i) the likely direct health benefits to a patient;

(ii) the possible benefits to the carer or comforter; and

(iii) the detriment that the exposure might cause;

(c) in the case of asymptomatic individuals on whom any medical radiological procedure—

(i) is to be performed for the early detection of disease;

(ii) is to be performed as part of a health screening programme;

(iii) requires specific documented justification for that individual by the practitioner, in consultation with the referrer,

any guidelines issued by appropriate medical scientific societies, relevant bodies or published by the Department;

(d) the urgency of the exposure, where appropriate, in cases involving—

(i) an individual where pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the person concerned and any unborn child; and

(ii) an individual who is breastfeeding and who undergoes an exposure involving the administration of radioactive substances, taking into account the exposure of both the individual and the child.

(4) In deciding whether to justify an exposure under paragraph (1)(b) the practitioner must take account of any data supplied by the referrer pursuant to regulation 10(5) and must consider such data in order to avoid unnecessary exposure.

(5) Where it is not practicable for the practitioner to authorise an exposure as required by paragraph (1)(c), the operator must do so in accordance with guidelines issued by the practitioner.

(6) In this regulation—

"ethics committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(**1**);

(b) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Department;

"individual detriment" means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and in the latter case, implies a probability rather than a certainty of appearance.

(**1**) S.I. 2004/1031