Authorisation for the practice of the use of DXA for the assessment of whole body composition giving rise to a non-medical exposure

GUIDANCE FOR APPLICANTS

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Authorisation for the practice of the use of DXA for the assessment of whole body composition giving rise to a non-medical exposure

Guidance for Applicants

November 2024

ENVIRONMENTAL PROTECTION AGENCY

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Published by Environmental Protection Agency, Ireland

November 2024

Disclaimer

Acknowledgements

The EPA would like to acknowledge the contribution made by the following stakeholders during consultation on the establishment of the requirements outlined in this document:

Faculty of Radiologists Radiation Protection Committee

Health Information and Quality Authority

Institute of Sport

Irish DXA Society

Radiation Protection Advisers

Radiation Protection Officers

Undertakings

ISBN 978-1-80009-226-6

1. CONTENTS

1. Background

Prior to granting authorisation in respect of practices involving non-medical imaging exposure, Regulation 16 (4) (b) of the Radiological Protection Act, 1991 (Ionising Radiation) Regulations 2019 (IRR19) requires the undertaking to submit a detailed plan to the Agency for examination and approval. The plan must demonstrate that it meets the requirements under 16 (4) (a) of IRR19 and include the following at a minimum:

- Evidence that a formal sports training programme approved by a consultant radiologist is in place
- Requirements of S.I. 256 of 2018 are met
- Specific written protocols
- Specific dose constraints in place
- Radiation risk assessment

2. Application

2.1 Sports Training Programme

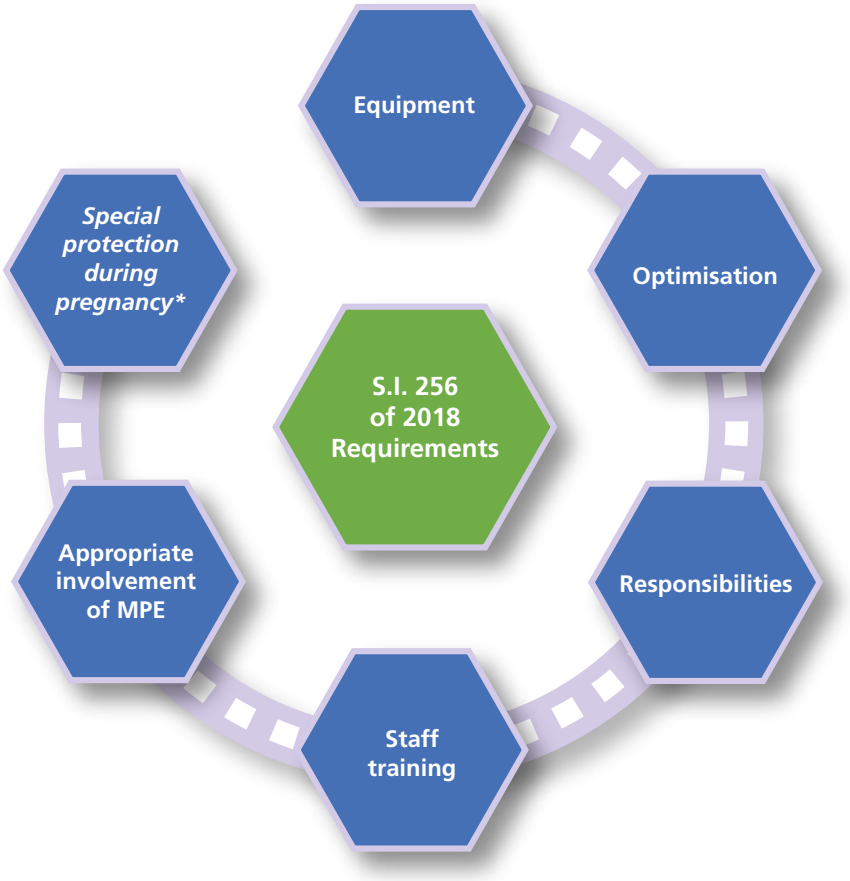
In relation to sporting performance, the use of DXA for body composition assessment is restricted to those athletes participating in a formal sports training programme which has been designed by appropriately trained professionals and been reviewed and approved by a consultant radiologist. It must contain information on:

- Defined objectives of the programme
- Minimum interval between scans
- Maximum number of scans in the full programme
- Restrictions on participants
- Availability and efficacy of alternative non-ionising radiation techniques

The undertaking is required to provide information on the procedure, including an explanation of the risks and benefits, to the participants and to obtain their written consent in advance of any exposures. Approval should be sought from the athlete examined regarding action to be taken should there be any incidental findings unrelated to the scan's purpose.

2.2 Requirements of S.I. 256 of 2018

For practices involving non-medical imaging exposure using medical radiological equipment, Regulation 16 (4) of IRR19 specifies that the relevant requirements for medical exposure set out in S.I. No. 256 of 2018 shall apply. The detailed plan being submitted to the EPA must demonstrate how the undertaking will meet the relevant requirements of S.I. 256 of 2018 which include:



2.2.1 Equipment

Evaluation of imaging and dose performance of DXA scanning equipment following installation must be performed before the equipment may be used. The evaluation should include the suitability of the equipment in terms of the accuracy in assessment of changes in fat/muscle composition and measurements of the entrance surface dose levels for different examinations.

A quality assurance (QA) programme for the equipment shall be developed in consultation with the Radiation Protection Adviser (RPA) and Medical Physics Expert (MPE) and this shall include details of maintenance, calibration, routine quality control (QC) tests and annual QA assessments. The programme shall specify the tests required, their frequency, tolerances, and the persons responsible for carrying out the tests. The QA programme must be fully implemented and records kept.

2.2.2 Optimisation

Exposures resulting from non-medical human imaging must be optimised. The process of optimisation of protection and safety is intended for application to those situations that have been deemed to be justified. Various elements form part of optimisation including but not limited to appropriate selection of equipment; consistent production of adequate information; assessment and evaluation of doses received; QA; and audits. An athlete undergoing the non-medical human imaging procedure is to be afforded at a minimum the same level of protection and safety as if they were a patient undergoing a similar medical imaging procedure.

2.2.3 Responsibilities

Referrals must be on an individual basis, written and via the appropriate referral pathway as defined by Regulation 4 of S.I. 256 of 2018. "Referrer" means a person, being a member of one of the classes of persons referred to in Regulation 4 (1) of S.I. 256 of 2018, who is entitled to refer an individual for medical radiological procedures to a practitioner. There must be a written record of referral with individual exposures justified by a practitioner in advance in accordance with Regulation 5 (6) of S.I. 256 of 2018 and Regulation 5 (9) of IRR19, considering the specific objectives of the procedure and the characteristics of the individual involved.

"Practitioner" has the meaning given to it in Regulation 2 (1) of S.I. 256 of 2018 and means a person, being a member of one of the classes of persons referred to in Regulation 5 of S.I. 256 of 2018, who has clinical responsibility for an individual medical exposure.

The **practical aspects** of the procedure are performed by a person meeting the requirements of Regulation 10 (4) of S.I. 256 of 2018.

Records must be kept by each undertaking detailing the number of athletes undergoing the non-medical imaging procedure each year and the protocols for the procedure being carried out, including:

- Manufacturer, model and software of the DXA system used at baseline and any subsequent follow-up.
- Scan mode utilised (if applicable).
- Detail in full, athlete pre-scan preparation.
- Positioning; use of positioning aids.
- Dose received by individual - exposure data must be recorded to allow assessments to be made of the doses received.

2.2.4 Staff training

Regulation 10 (4) of S.I. 256 of 2018 sets out those who are entitled to conduct practical aspects of medical radiological procedures as specified by the undertaking or practitioner. This shall also apply to non-medical exposures i.e., those performing a DXA scan for assessment of body composition in sports performance. The undertaking is responsible for ensuring that staff operating the DXA scanner are adequately trained in relation to the procedure being performed; evaluation of the clinical image; application of the technique; and use of the imaging protocols provided. Records of staff training must be kept and be readily available if requested.

The standards for education and training should meet those of the professional regulator or in the absence of such, those recommended by the Irish DXA Society. They should, at a minimum, match those required for performing body composition scans using a DXA scanner for medical exposures.

Radiation safety training for staff must meet the requirements outlined in Regulation 22 of S.I. 256 of 2018, as well as those of Regulation 35 of IRR19 which requires that appropriate training, information and instruction be provided to any employees engaged in work with ionising radiation and that this training is repeated at appropriate intervals.

2.2.5 Appropriate involvement of MPE

As per S.I. 256 of 2018 requirements, the undertaking is required to involve an MPE, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure. The level of involvement is commensurate with the radiological risk posed by the practice. MPE advice may be sought on the following aspects:

- An assessment of the benefits and risks of the programme including the objectives of the training programme.
- Optimisation and equipment performance – including QA and QC criteria, dosimetry if applicable, staff training, development and use of new techniques.
- Dose constraints.

Further information on the role of the MPE is available in Part 3 – Regulations 19, 20 and 21 of S.I. 256 of 2018.

*2.2.6 Special protection during pregnancy

Pregnancy is a contraindication to having a DXA scan performed for the assessment of whole body composition.

2.3 Written Protocols

Regulation 16 (4) (a) of IRR19 requires that specific protocols, consistent with the objective of the exposure and required image quality are put in place. The performance and clinical evaluation of scans must be outlined along with sharing of results, in particular incidental findings.

- Consistent preparation and positioning must be maintained with information on fasting state; clothing; time of day; physical activity; and bladder status determined and provided to the athlete in advance.
- Data storage – there must be a secure electronic means of storing signed consent forms and any other associated documentation.
- Incident reporting – procedures to follow in the event of a reasonably foreseeable incident liable to have radiation safety implications as identified in the risk assessment, must be drawn up and disseminated to all relevant staff.

2.4 Dose Constraints

Dose constraints are determined by the undertaking in consultation with an MPE with relevant experience, derived from estimates of dose to individuals undertaking the full programme.

Application of diagnostic reference levels (DRLs) as applied to medical exposures is not possible since the purpose of the exposure is different in non-medical imaging. All individuals who undergo non-medical imaging procedures are considered members of the public and so should be provided protection consistent with that provided for a member of the public, including application of the respective dose limits. It shall be ensured that the sum of doses for the full programme remains within the dose limit for a member of the public.

2.5 Risk Assessment

The risk assessment is fundamental to ensuring that radiation protection in the workplace is optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable. The categorisation of the operator as an exposed worker will be based on the risk assessment and made in consultation with the RPA.

The risk assessment shall also be updated to reflect any increase in workload and considering the occupancy of adjacent rooms – either by staff or members of the public. For those in adjoining rooms the dose will depend on the size of the room where the DXA scanner is located and if the walls are of solid construction or if shielding is adequate – dose estimates should be made at time of installation and commissioning and reviewed in particular if equipment is replaced or there is a change in workload.

The arrangements for occupational radiation protection for those performing non-medical human imaging exposures must be at least the same as for those performing medical exposures using the same equipment.

3. Authorisation

All undertakings conducting a radiological practice must fully comply with the relevant provisions of IRR19 and any conditions attached to an authorisation and are subject to compliance assessment including inspection by the EPA. The undertaking must consult with an approved RPA at the outset that will advise on all aspects of radiation protection.

Note: **The practice of the use of dual energy x-ray absorptiometry (DXA) for the assessment of whole body composition in sports performance giving rise to a non-medical exposure is not currently available to select on EDEN.**

3.1 Detailed Plan

Before granting authorisation for the practice of *the use of DXA for the assessment of whole body composition in sports performance giving rise to a non-medical exposure*, the EPA requires the undertaking to submit as part of their application a detailed plan by email to *ORPedensupport@epa.ie* demonstrating that it meets the requirements as outlined in section 2 of this guidance.

3.2 Applicant Checklist

✔	
	Evidence that a formal sports training programme approved by a consultant radiologist is in place
	Evidence that the requirements of S.I. 256 of 2018 are met
	Specific written protocols in place
	Specific dose constraints in place
	Radiation risk assessment in consultation with RPA

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Printed on environmentally friendly paper stock