### **Developers** guidance

# Complying with Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)

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#### This is required guidance

It is legally required and it is an essential activity.

#### This Guide covers:

• England

#### From:

• Care Quality Commission (CQC)



The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) provide a framework for the safe use of ionising radiation in medical and non-medical imaging, including use of medical devices. Only appropriately qualified and trained human operators can be responsible for the clinical evaluation of any ionising radiation exposure. Legally, AI and data-driven technologies cannot replace human decision making and should only support it.

## **Ionising radiation and medical devices**

The Care Quality Commission (CQC) enforces the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R).

These regulations aim to make sure that medical ionising radiation is used safely to protect patients from the risk of harm.

IR(ME)R sets out the responsibilities of duty holders for radiation protection and the basic safety standards that they must meet. Duty holders include the:

- employer
- referrer
- practitioner, and
- operator

You can find these regulations in the:

- Ionising Radiation (Medical Exposure) Regulations 2017
- Ionising Radiation (Medical Exposure (Amendment) Regulations 2018