Diagnostic and screening procedures

Description
This regulated activity includes a wide range of procedures related to diagnostics, screening and physiological measurement.

All diagnostic procedures involving the use of any form of radiation (including x-ray), ultrasound or magnetic resonance imaging to examine the body are included. This will include all main forms of diagnostic radiology, radiography and sonography (including antenatal ultrasound scans), but it will not include use of the same technology for therapeutic purposes such as radiotherapy or some forms of interventional radiology (those will require registration for the activity of ‘treatment of disease, disorder or injury’). The activity also includes the analysis and reporting of the examinations that are carried out.

If the provider using the x-ray, ultrasound or magnetic resonance imaging is the same provider who is carrying out the analysis and reporting, then this may be included within a single registration; if a remote contractor is used for diagnostic analysis, the analysis and reporting will require registration in its own right.

Where diagnostic images are reported remotely by a subcontracted provider who is outside England, the subcontractor will not be registerable as they fall outside of CQC’s remit. However, we will hold to account the registered provider who made the contract with the subcontractor for the way the service is delivered and to make sure that there are appropriate arrangements for the service to be delivered, including arrangements for quality assurance.

The activity includes many, if not all, forms of endoscopy because it captures procedures if they involve the use of:

- Instruments or equipment, which are inserted into the body to:
  - view inside of the body, or
  - gather physiological data.

The activity includes instances of taking a sample or biopsy because it captures procedures if they involve removal of tissue, cells or fluids from the body, for the purpose of diagnosing disease, disorder or injury or monitoring its cause or extent. Therefore, anyone who ‘removes’ tissue, cells or fluids from the body for diagnostic reasons must register.

The activity also includes anyone who uses equipment to examine tissue, cells or fluids from the body to obtain information on the cause and extent of a disease, disorder or injury. If the provider removing the sample is the same provider who is carrying out the examination then this may be included within a single registration; if a remote contractor is used for diagnostic analysis, such as a laboratory company, the analysis will also require registration in its own right.

There are a number of exclusions that apply to this activity, which are set out further on in this section.
This regulated activity also includes physiological measurement; that is the use of equipment to measure or monitor physiological data in relation to the following systems:

- audio-vestibular
- vision
- neurological
- cardiovascular
- respiratory
- gastro-intestinal system, or
- urinary system

for the purposes of obtaining information on the causes and extent of a disease, disorder or injury, or the response to a therapeutic intervention, where such information is needed for the purposes of the planning and delivery of care or treatment.

Physiological measurement diagnostic services provide a wide range of specialist investigations and procedures that are often an essential part of care and treatment for patients. Physiological measurement includes not only assessment of the function of major organ systems, but also measurement and tests that are part of normal clinical care when carrying out other regulated activities that a provider will already be registered for under the Health and Social Care Act 2008 (HSCA).

**Exclusions**

The following physiological tests are **not** included within the definition of physiological measurement and so will not lead to registration for this regulated activity:

- 12 lead electrocardiograph recording (ECG)
- Pulse oximetry when used for ‘spot’ recording
- Peak expiratory flow measured by a peak flow meter
- Screening or non-diagnostic spirometry
- Non-ambulatory blood pressure recording
- Use of an auroscope
- Carrying out a hearing needs assessment or supply and fitting of a hearing aid carried out by a hearing aid dispenser or a person acting under the direction or supervision of a hearing aid dispenser, where:
  a) The person is aged 19 or over, or
  b) The person is under 19 and the procedure is carried out in, or arranged by, a school or 16-19 Academy.

The following procedures are also excluded from this activity:

- Procedures carried out for research, or analysing and reporting such procedures. However, this exemption only applies where those research procedures do not form part of a person’s care or treatment. As an example, a university that has an imaging department would only be required to register with us if they carry out a radiological
examination as part of the care of a patient. This is because such procedures would be part of a person’s treatment pathway. They would not be required to register with us if they restricted their examinations to research exposures on subjects or for teaching purposes using ‘phantoms’.

- The national cancer screening programmes are excluded. However, other national screening programmes are not excluded and must register if they are providing any aspect of the regulated activity.

- The taking of x-rays by registered chiropractors or the use of ultrasound by registered physiotherapists.

- Fitness screening procedures in a gymnasium, related to the use of fitness equipment or fitness activities, (treadmill tests for clinical purposes, however, are not exempt).

- Blood tests carried out by means of a pin prick test, or removing blood from a vein where the sample is not sent to a laboratory for analysis.

- Taking urine samples where the sample is not sent to a laboratory to be analysed.

- The sending of samples of body fluids to a place to be analysed, where the samples are not collected or taken by the provider. For example, when a person produces a urine sample and the provider sends it away to be tested.

- Procedures carried out by a person in connection with any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority.

- The taking or analysing of samples of tissue, cells or fluids in order to determine the existence of a genetically inherited disease or disorder, or to determine the influence of an individual’s genetic variation on a drug response. However, such tests are not exempt if carried out as part of:
  a.) the planning or delivery of the individual’s treatment or care, or
  b.) a national screening programme other than a national cancer screening programme.

A provider may be registered for this regulated activity in addition to any number of other activities. This activity is not restricted to services provided by health care professionals.

There are certain low risk procedures that we will consider as part of a provider’s overall registration with us; in other words providers registered with us will not have to register for this activity solely because they carry out the following procedures:

- Taking blood or urine samples.
- The analysis of urine or stools by means of a dip stick or other reagent.
- The taking of a swab from any external part of the body or from the mouth, ear, nose or throat.
- Removing skin scrapings.
Decision tree for 'diagnostic and screening procedures'

Does the service involve technology listed above, to monitor or measure inside the body?  

Does the service involve removal of bodily cells, fluid or tissue to discover cause, presence or extent of disease, disorder or injury?  

Does the service involve the use of equipment to examine bodily cells, fluid or tissue to obtain information on the cause and extent of disease, disorder or injury?  

Does the service involve use of equipment for physiological measurement as described above to help plan or deliver care?  

Yes to any  

No to all  

The following physiological tests are not included:  
- Use of an arthroscope  
- 12 lead electrocardiograph recording  
- Pulse oximetry when used for spot recording  
- Screening or non-diagnostic spirometry  
- Non-ambulatory blood pressure recording  
- Carrying out hearing aid assessments where the person is over 19 years of age or arranged by a school or academy  

Out of scope  

Is the following exempt:  
- National cancer screening programmes  
- Life-saving blood tests not needing to be sent for analysis  
- Taking urine samples not needing to be sent for analysis  
- Sending samples for analysis where the samples are not taken or analysed by the provider  
- Fitness testing in a gym for fitness purposes  
- X-ray by chiropractors  
- Diagnostic ultrasound by physiotherapists  
- Procedures carried out for research (where the research does not form part of a person’s care or treatment)  
- Procedures licensed by HEFA  
- Taking or analysing samples for genetic testing  

In scope  

Is the service solely:  
- Taking blood or urine samples  
- Analysis or urine or stools by means of a dipstick or other reagent  
- Taking a swab from an external part of the body or ear, nose or mouth  
- Removing skin scrapings  

Yes  

No  

In scope

Scope of registration: August 2013