# Decision on whether accreditation is in the public interest

Register of Clinical Technologists (RCT)

August 2024



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### The Accreditation process.

#### How we assess organisations against Standard One ('public interest test')

The Professional Standards Authority accredits registers of people working in health and social care occupations not regulated by law. To be accredited, organisations holding such registers must prove they meet our Standards for Accredited Registers (the Standards). Once accredited, we check that Registers continue to meet our Standards.

There are nine Standards. Registers must meet Standard One before we can assess against how the register meets the remaining Standards. Standard One checks eligibility under our legislation, and if accreditation is in the public interest.

Organisations may apply for a preliminary assessment against Standard One before submitting a full application.

Following its introduction in July 2021, we have been assessing currently Accredited Registers against Standard One. Some of these decisions are made by the Accreditation Team, but if the decision is more complex it is made by an Accreditation Panel. These decisions are published. The evidence considered by the Accreditation Panel includes the organisation's application, a desk-based review of relevant sources of evidence about the benefits and risks of the role(s) registered, and responses received through our 'Share your experience' public consultation.

If the Panel decides that the activities of registrants fall within the definition of healthcare, and that overall, the benefits of the services of practitioners outweigh the risks then it will determine that Standard One is met. The Accreditation Panel can also issue Conditions if it does not think Standard One is fully met, and/or Recommendations aimed at promoting good practice.

More about how we assess against Standard One can be found in our Supplementary Guidance for Standard One<sup>2</sup>.

## About the Register of Clinical Technologists (RCT)

Name of	Register of Clinical Technologists (RCT)
Organisation	
Website	www.therct.org.uk
Website	www.triorot.org.uk

<sup>&</sup>lt;sup>1</sup> Standards for Accredited Registers (professionalstandards.org.uk)

<sup>&</sup>lt;sup>2</sup> Accredited Registers supplementary guidance standard one (professionalstandards.org.uk)

Type of Organisation	Private company (registration 3080332)
Role(s) covered	Clinical Technologists working in nuclear medicine, radiotherapy physics, radiation physics, medical engineering, radiation engineering, rehabilitation engineering, renal technology, and sonography.
Number of registrants	2420 on 1 January 2024.
Overview of Governance	The RCT is administered by the RCT Management Board. This includes:  • the registrar  • two named representatives of each professional organisation participating in the management of the RCT: the Association of Renal Technologists (ART), the Institute of Healthcare Engineering and Estate Management (IHEEM) and the Institute of Physics and Engineering in Medicine (IPEM)  • two representatives elected from the RCT registrant body.  • two lay members  The RCT Management Board is responsible for all aspects of the management of the register including overseeing the registration process. It is also responsible for reviewing and updating the criteria for membership of the RCT as well as all processes and documentation used. It is supported by an administrative team from the IPEM office.  Complaints are considered by the Professional Conduct Committee (PCC) which includes lay involvement.
Overview of the aims of the register	The purpose of the RCT is to protect the public. As clinical technologists make decisions every day that can affect patients' health, safety, and welfare it is recognised that the public will want to be assured that these individuals have been fully trained and assessed and that they regularly update their skills. The RCT sets the standard for clinical technologist training and conduct and ensures high standards of practice are maintained amongst its registrants.

#### **Inherent risks of practice**

This section uses the criteria developed as part of the Authority's Right Touch Assurance tool<sup>3</sup> to give an overview of the work of clinical technologists.

Risk criteria	Clinical Technologists
Scale of risk	
associated with	a. The practice of Clinical Technologists is divided into Clinical Physics,
Clinical Technologists	Clinical Engineering and Sonography. They work in the following
a What do Clinical	disciplines:
a. What do Clinical Technologists do?	·
reciniologists do?	<ul> <li>Clinical Physics Technologists:</li> </ul>
b. How many	Nuclear medicine
Clinical	Radiotherapy physics
Technologists. are	<ul> <li>Radiation physics</li> </ul>
there?	Danie Danista martini
	Olivinal Francisco dia Tanka da siste
c. Where do	
Clinical	Medical engineering
Technologists	<ul> <li>Radiation engineering</li> </ul>
work?	<ul> <li>Rehabilitation engineering</li> </ul>
d. Size of	<ul> <li>Renal technology</li> </ul>
actual/potential	Sonography
service user group	b. 2420 registrants on 1 January 2024. The number of people practising
	in these roles but not registered with the RCT is unknown. It is
	estimated there are approximately 3000 sonographers practising in the
	UK although these are not regulated as a distinct group, with the
	majority also being registered with a statutory regulator, generally as a
	radiographer, nurse, or midwife (PSA, 2019) <sup>4</sup> .
	c. The RCT's Scope of practice states that 'Clinical Technologists work
	in NHS hospitals, private health care, academic institutions, and the
	medical device industry The RCT operates in England and Wales.
	d. Not all roles have direct contact with service users. However, the
	potential service user group is wide ranging due to the nature of the
	services offered and employment within the NHS.
	The state of the s
Means of assurance	Registrants can be Healthcare Scientists specialising in the practical
	application of physics, engineering, and technology to clinical practice.
	Registrants can also be Sonographers who are health care
	professionals specialising in ultrasound imaging and interventional
	procedures using ultrasound guidance'5
	procedures using uniasound guidance

The means of assurance will depend on the practice setting. Those working within the NHS will be subject to criminal records and other pre-employment checks.

## 3. About the sector in which Clinical Technologists operate

Clinical technologists are healthcare scientists working in a range of clinical and healthcare locations including NHS hospitals, private health care, academic institutions, and the medical device industry. Clinical Technologists are trained to perform complex procedures on patients, look after specialist medical devices and prepare treatments such as radioactive injections. The practice of clinical technology is divided into medical physics and clinical engineering.

#### 4. Risk perception

- Need for public confidence in Clinical Technologists?
- Need for assurance for employers or other stakeholders?

Clinical Technologists are engaged in the practical application of physics, engineering, and technology to clinical practice. These applications relate directly to the diagnosis, treatment, and prevention of disease, as well as to maintaining and improving the quality of patients' lives. Consequently, it is important for the public and employers to have confidence in their work.

In 2019, the PSA published a report evaluating the inherent risks of sonography, *Right-touch assurance for sonographers based on risk of harm arising from practice<sup>5</sup>.* We had been commissioned by Health Education England (HEE) to assess the risk of harm arising from the practice of sonographers, using our right-touch assurance model<sup>6</sup> to analyse evidence and provide advice to HEE on the options for regulatory assurance when considering future development of the role. The report found that there was not a clear case for immediate regulation of sonographers, and that risks could be managed more effectively by strengthening clinical governance and encouraging unregistered sonographers to join an Accredited Register. It also found that statutory regulation may need to be considered in the future if the route to entry to the profession and to other key risk areas changed.

## 3. Share your experience.

As part of our assessments, we seek feedback from service users, the public, professional and representative organisations, employers, and others on their experience of a Register.

We received one response to our invitation to share experience on the RCT application for assessment against Standard One. This included evidence about the risks of sonography, which has been considered within this report. This includes the

pregnancy loss review report<sup>3</sup>, which highlighted the lack of professional regulation for sonographers as a risk. Although this is not directly within the RCT's remit, protection of the title "sonographer" could help to mitigate this risk. The significance of individuals possessing ultrasound education, training, or competence as a sonographer as a result of HCPC registration as a radiographer was brought out by the response. Increasing the number of sonographers recruited internationally to assist in staffing their Community Diagnostic Centres (CDCs) was another emphasis. This can result in an inflow of applications through the RCT equivalency route, necessitating timely action.

#### 4 Outcome

The Accreditation Panel met on 7 June 2024 to consider the RCT's application for an assessment against Standard One ('public interest test'). Overall, the Accreditation Panel determined Standard One was met.

We also identified some recommendations for the RCT:

- **Recommendation One:** Occupational risks should be incorporated in the risk matrix with mitigations on minimising occupational risks.
- Recommendation Two: The risk matrix should be updated to identify potential
  risks and how specific risks associated with obstetric sonography are being
  mitigated.

This section of the report summarises the key considerations in reaching this conclusion for each part of Standard One.

#### Standard 1: Eligibility and 'public interest test'

This section of the report summarises the key considerations in reaching this conclusion for each part of Standard One.

#### Summary

The Panel found Standard one was met at its meeting on 7 June 2024. As noted above, we also considered that the risks associated with the role of sonography appear sufficiently high, and potential impacts on patients sufficiently great, to

<sup>&</sup>lt;sup>3</sup> <u>CP 805 – The Independent Pregnancy Loss Review – Care and support when baby loss occurs before</u> 24 weeks gestation – July 2023 (publishing.service.gov.uk)

recommend that the UK Government should consider whether accredited voluntary registration is likely to be adequate.

#### The Accreditation Panel's findings

#### Standard 1a: Eligibility under our legislation

The Authority's powers of accreditation are set out in Section 25E of the National Health Service Reform and Health Care Professions Act 2002<sup>4</sup>. Standard 1a considers whether a Register is eligible for accreditation, based on whether the role(s) it registers can be considered to provide health and care services and are not required by law to be registered with a statutory body to practise in the UK.

RCT outlined that 'Clinical Technologists are Healthcare Scientists specialising in the practical application of physics, engineering, and technology to clinical practice.' The practice of Clinical Technologists is divided into Clinical Physics, Clinical Engineering and Sonography. Many sonographers will already have registration with the HCPC if they are practising in a statutory role, such as radiography, but that to work as a sonographer, registration is not required by law.

The Accreditation Panel found that the role of Clinical Technologist falls within the scope of the Accredited Registers programme and concluded that Standard 1a was met.

#### Standard 1b: Public interest considerations

Under Standard 1b, we consider whether it is likely to be in the best interests of patients, service users and the public to accredit a register, with consideration of the types of activities practised by its registrants. This involves consideration of the overall balance of the benefits and risks of the activities.

Factors considered by the Accreditation Panel are discussed below.

i. Evidence that the activities carried out by registrants are likely to be beneficial.

#### Clinical technologists employed by NHS.

Clinical Technologists mostly work in the NHS and are a recognised and needed part of the workforce<sup>5</sup>. A few posts (often for qualified and registered clinical technologists) are also periodically advertised outside of the NHS in private businesses. These companies are often ones that produce medical equipment or offer private treatment.

<sup>&</sup>lt;sup>4</sup> Roles that are required to be enrolled with a statutory register to practise in the UK are set out in Section 25E (2) of the National Health Service Reform and Health Care Professions Act 2002, available at: <a href="National Health Service Reform and Health Care Professions Act 2002">National Health Service Reform and Health Care Professions Act 2002</a> (legislation.gov.uk)

<sup>&</sup>lt;sup>5</sup> https://www.stepintothenhs.nhs.uk/careers/clinical-technologist

Before looking at the individual benefits of each role registered by the RCT, it is also important to consider the broad benefits that people may get from clinical technologists in general.

Clinical technologists (CTs) work independently, or as part of multidisciplinary teams, providing specialist physics services and technical knowledge enabling patient care. Clinical technologists ensure that the technology and equipment used to diagnose and treat patients in hospitals and other medical settings is safe, accurate, well-maintained, and monitored to a high standard. According to scope of practice, 'Clinical Technologists work as "Operator" under the requirements of the IR(ME)R regulations'<sup>6</sup>.

This research paper<sup>7</sup> described the support provided by CTs for medical equipment (monitors, ventilators, and infusion devices) that is essential in providing care for critically sick patients and how maintaining this equipment is a crucial component of what they perform. They operate medical equipment, perform quality control procedures, and review and interpret quality control results.

Medical device risk management - Medical Engineering Technologists

Medical device risk management is about ensuring that medical equipment is functioning correctly and is safe to use. All medical equipment needs to be checked to ensure it is working correctly and safe for patients. As a clinical scientist in medical device risk management, it would be the medical engineering technologist's role to do this. They work with general and specialised medical equipment used in wards, critical care areas, hospital laboratories, outpatient departments and community care. They perform planned preventative maintenance, fault finding and repair, calibration, and safety testing procedures on a wide range of medical devices.<sup>8</sup>

#### **Nuclear Medicine Technologists**

Nuclear Medicine Clinical Technologists specifically work in radio pharmacy, Imaging/Therapy procedures, non-imaging procedures and radiation protection. As per the British Nuclear Medicine Society report, 'Nuclear Medicine Technologists can assist in performing complex procedures on patients, operate and manage specialist medical devices and prepare treatments such as radioactive injections. Their work is critical for patient safety and welfare<sup>9</sup>.

Radiotherapy: For treatment of Cancer

Clinical technologists are responsible for maintaining, monitoring, and sometimes operating the equipment and instruments used to treat radiotherapy patients. Patients often undergo radiotherapy every day for several weeks, so it is vital to ensure that the treatment is delivered safely and accurately. Radiotherapy teams are also responsible

<sup>&</sup>lt;sup>6</sup> RCT-Scopes-of-Practice-Mar-2022-v12.pdf (therct.org.uk)

<sup>&</sup>lt;sup>7</sup> The importance of Clinical Technology and vital medical equipment « Quercus Foundation

<sup>8</sup> RCT-Scopes-of-Practice-Mar-2022-v12.pdf (therct.org.uk)

<sup>&</sup>lt;sup>9</sup> What does a Nuclear Medicine Technologist do? - British Nuclear Medicine Society (bnms.org.uk)

for ensuring that equipment used in radiotherapy is calibrated precisely and used safely, during a course of treatment<sup>10</sup>.

Radiation Engineering Clinical Technologists work within radiotherapy and radiology providing specialist engineering services and in multi-disciplinary teams optimising and advancing radiation technology. Radiation Physics Technologists participate in audit facilities using all forms of ionising and non-ionising radiation, for compliance with legislation. They measure shielding and protection in new and existing radiation facilities.

Rehabilitation Engineering Clinical Technologist - Supporting disability.

This role supports in meeting the needs of individuals with disabilities and long-term conditions<sup>11</sup>. They develop cost effective assistive devices where commercial options are not able to meet needs by people with disabilities and contributes to patient assessments for assistive devices recommending solutions to meet individual client needs.

Renal Engineering Clinical Technologists - Supporting Haemodialysis

Renal Technologists specifically install and work on specialised medical equipment used in wards, critical care areas, the community and other haemodialysis units located at other hospitals. They measure and quality control the specialist water used for Haemodialysis<sup>12</sup> and ensure Renal Replacement equipment is enabled, safe and available for use. They work in multi-disciplinary teams optimising and advancing Renal technology in patient care.'

The Association of Renal Technologists is also responsible for the administration of the RCT. They promote the field of work shared by technicians, technologists, engineers, scientists, and other members of the multi-professional team working within the sphere of Renal Technology<sup>13</sup>.

Bone Densitometry Technologists - Diagnosing osteoporosis.

Bone Densitometry Technologists use a special type of x-ray equipment to measure bone mineral density at a specific anatomical site (usually the wrist, heel, spine, or hip) or to calculate total body bone mineral content. Results can be used by physicians to estimate the amount of bone loss due to osteoporosis<sup>14</sup>. A bone density scan results can help predict risk of a fracture so can start taking steps to prevent one<sup>15</sup>

<sup>&</sup>lt;sup>10</sup>. Radiotherapy Physics — Physical Sciences - Healthcare science specialties explained -Healthcare Science (hee.nhs.uk)

<sup>&</sup>lt;sup>11</sup> Rehabilitation Engineering (nih.gov)

<sup>12</sup> RCT-Scopes-of-Practice-Mar-2022-v12.pdf (therct.org.uk)

<sup>&</sup>lt;sup>13</sup> About Us - Association of Renal Technologists.

<sup>&</sup>lt;sup>14</sup> Bone Densitometry for Technologists | SpringerLink

<sup>&</sup>lt;sup>15</sup> Why you need a bone density scan - Harvard Health

They work as and be entitled in employers' procedures under IR(ME)R to function as "Operator" under the requirements of the IR(ME)R regulations<sup>16</sup>.

#### Sonography

#### Visual images of anatomical structures

One of the most frequently utilised imaging techniques in medicine today is ultrasound (US). When compared to other imaging modalities like magnetic resonance and computed tomography, it is portable and radiation-risk free. Additionally, US pictures offer a "cross-sectional" perspective of anatomical structures since they are tomographic. Since the images can be captured in "real time," they can be used as immediate visual guidance for a variety of interventional procedures, such as those for regional anaesthesia and pain management. A sonogram is a rapid and painless process that obtains a live image<sup>17</sup>. Ultrasound scanning gives a clear picture of soft tissues that do not show up well on x-ray images<sup>18</sup>.

#### Diagnosing certain medical conditions

Sonography is useful for evaluating the size, shape, and density of tissues to help diagnose certain medical conditions. Abdominal ultrasound is often used to diagnose gallbladder disease or gallstones, kidney stones or kidney disease, liver disease, appendicitis, ovarian cysts, ectopic pregnancy, uterine growths or fibroids and other conditions'<sup>19.</sup>

#### For Expectant Mothers<sup>20</sup>

'A sonogram is most used to monitor the development of the uterus and foetus during pregnancy. Ultrasound is the most widely used medical imaging method for viewing the foetus during pregnancy'<sup>21</sup>.

Obstetric ultrasound employs sound waves to create images of the mother's uterus and ovaries as well as the baby (embryo or foetus) within a pregnant woman. The most recognised peer-reviewed journal on imaging in the field of obstetrics and gynaecology, Ultrasound in Obstetrics and Gynaecology (UOG),<sup>22</sup> has published many relevant articles and studies.

<sup>&</sup>lt;sup>16</sup> RCT-Scopes-of-Practice-Mar-2022-v12.pdf (therct.org.uk)

<sup>&</sup>lt;sup>17</sup> ResearchGate

<sup>&</sup>lt;sup>18</sup> Obstetric Ultrasound (radiologyinfo.org)

<sup>&</sup>lt;sup>19</sup> Sonography: How a Sonogram Test Works and What It Shows (verywellhealth.com)

<sup>&</sup>lt;sup>20</sup> Ultrasound in Pregnancy | ACOG

<sup>&</sup>lt;sup>21</sup> Ultrasound Imaging | FDA

<sup>&</sup>lt;sup>22</sup> Journal (isuog.org)

Diagnosis of early pregnancy failure and ectopic pregnancy

Research shows that ectopic pregnancy and early pregnancy failure are frequent clinical diagnoses for which ultrasonography can be helpful. Ultrasound has a major role in the diagnosis and management of the patient with a suspected ectopic pregnancy<sup>23</sup>.

The Accreditation Panel agreed that there is strong evidence for the benefits of the activities undertaken by Clinical technologists.

ii. Evidence that any harms or risks likely to arise from the activities are justifiable and appropriately mitigated by the register's requirements for registration.

The Accreditation Panel considered the risks associated with the practice of Clinical Technologists. These have been identified from our desk-based research, and those identified by the RCT in its risk matrix. We found that the RCT's risk matrix appeared to capture the key risks associated with the roles.

The RCT identifies risks in relation to specific roles which includes risk from usage of medical equipment, renal technology, nuclear medicine and many more. The most significant risks are listed below.

Risks arising from lack of technical competence.

Risks associated with a lack of professional competence have been identified by the RCT. Among these is the risk of registrants who are unable to recognise underlying problems and who fail to direct service users to the right kind of certified expert. Another risk they have found is the inappropriate expansion of technologists' roles, which occurs when they take on new responsibilities beyond their areas of expertise because of staff shortages or workplace constraints. In addition, professional judgement where CTs are often consulted by clinical staff to assist in the selection and advise on the correct prescription of medical devices. Poor advice can lead to incorrect applications of technologies that could harm patients. Clinical technologists "make decisions that affect patients' health, safety, and welfare on a daily basis," according to RCT. The information we looked at seems to indicate that CTs have high degree of autonomy.

Risk from home visits and independent practice.

It was stated in the risk matrix that "It is vitally important that CTs' knowledge, skills, and professional competence be maintained to the required standards to keep the public safe," as they frequently work alone in hospital settings or in patients' homes without direct supervision. Because some registrants may work in direct contact with

<sup>&</sup>lt;sup>23</sup> <u>Ultrasound criteria for diagnosis of early pregnancy failure and ectopic pregnancy - PubMed (nih.gov).</u> <u>Ultrasound in pregnancy - PubMed (nih.gov)</u>

patients, conducting one-on-one consultations, and become aware of an individual being mistreated by others we were concerned about CTs working in patients' homes. Renal and rehab engineers would be the primary practice areas that would operate in a patient's home, according to RCT, a few medical engineers may be attending in patients' homes. If done at home, there would be no risk of radiation exposure, which would make it distinct from doing it in a hospital. RCT registration and continued registration rely upon meeting requirements for competence, training, and qualification. Additionally, they need to pursue Continuing Professional Development (CPD) to keep up their competency. This is covered in the RCT Code of Conduct as well.

#### Risks from Radiation

RCT in this field has identified numerous radiation risks (summarised below), which are mitigated. through guidance incorporated in clinical technologist courses and CPD.

- Inaccurate evaluation of safe working conditions, staff and the public could lead to the breach of IRR17 guidelines on radiation exposure and exceeding of dose limits.
- Inaccurate evaluation or interpretation of ionising equipment results during commissioning and routine assessments may result in high radiation exposures to staff members and patients, with differing outcomes.
- Improper waste labelling and disposal could expose patients, employees, and the public to radiation. Radiation engineers work closely with patients to diagnose and treat them; errors could endanger patients or personnel, and
- Using a linear accelerator to make routine outputs; there is a chance to obtain false in-tolerance readings.

#### Occupational Risks

There are occupational risks associated with clinical technologists' role. We noted that occupational risks are significant, particularly those related to radiation and nuclear medicine<sup>24</sup>. Any radiation exposure poses a potential risk to both patients and healthcare workers alike. Therefore, the Accreditation Panel recommended:

#### **Recommendation One:**

 Occupational risks should be incorporated in the risk matrix with mitigations on minimising occupational risks.

<sup>&</sup>lt;sup>24</sup> Review of Common Occupational Hazards and Safety Concerns for Nuclear Medicine Technologists | Journal of Nuclear Medicine Technology (snmjournals.org).

#### Risk associated with Sonography

The RCT has identified several risks associated with sonographers' lack of competency. These risks include misdiagnosis, equipment misuse, failing to maintain current skills or standards, and patient injury from inadequate governance procedures. The specific education and training route and clinical governance guidelines are key mitigations by RCT.

Sonography may pose risks to patients, such as cross-infection from poor hygiene procedures and physical effects of ultrasound scanning. In addition to education and training, employer infection control policies and procedures as well as adhering to guidelines for the sanitization and cleaning of ultrasound equipment are examples of mitigations by RCT.

We noted that there is a considerable risk associated with sonographers administering medications (often microbubble contrast agents or joint steroid injections). The worst-case scenario was described as anaphylactic shock that results in the patient's death. Minor side effects and pathology resulting from improperly administered steroids are among the others. RCT informed us that the mitigation is that only sonographers who are statutorily registered can use <a href="Patient group directions">Patient group directions</a> for the administration of drugs and medicines, and pursue independent or supplemental prescriber training. Sonographers who are not statutorily registered can use Patient specific directions but must ensure their competence<sup>25</sup>.

Obstetric ultrasound carries several concerns, such as the potential for misdiagnosis during pregnancy, the use of doptones, and inadequate information sharing with expectant parents. It was mentioned that only qualified healthcare professionals should use doptones when necessary for patient care. If these devices are used by unskilled individuals, the foetus may be exposed to extended and harmful energy levels or may get information that the user interprets erroneously<sup>26</sup>.

The independent pregnancy loss review report<sup>27</sup> mentioned that while the UK is one of a few countries where sonographers routinely deliver information about unexpected findings, there is no recognised or standardised pre-qualification training for sonographers and ultrasound practitioners in communication.'

We issued two Conditions to the RCT at its last accreditation renewal aimed at ensuring sonography benefits and limitations are available for the members of the public.

<sup>&</sup>lt;sup>25</sup> Sonography and the regulation of workforce | NHS Employers

<sup>&</sup>lt;sup>26</sup> Ultrasound Imaging | FDA

<sup>&</sup>lt;sup>27</sup> <u>CP 805 – The Independent Pregnancy Loss Review – Care and support when baby loss occurs before 24 weeks gestation – July 2023 (publishing.service.gov.uk)</u>

- The RCT should develop a proactive approach to working with employers, service users and other stakeholders. This should include sharing information about risks arising from the practices of clinical technologists and sonographers, and concerns about registrants, with the systems regulators and employers.
- The RCT should review the content of its website to make sure that key information is up to date and accurate. Information about sonography should be integrated into the main webpages. This should include clearer information for the public about sonography, to support informed choice. Information about the benefits, and limitations of the roles registered should be included.

According to the <u>Right touch assurance for sonographers</u> (RTA) report, significant risk is associated with transvaginal approach during obstetric ultrasound because these inspections are intimate, there is a chance of sexual assault or a violation of sexual boundaries. Therefore, the Accreditation Panel recommended that:

#### **Recommendation Two:**

• The risk matrix should be updated to identify potential risks and how specific risks associated with obstetric sonography are being mitigated.

The RTA (2019) mentioned that at the time there was not a clear case for statutory regulation. It noted that most sonographers are already regulated in other professional roles. It stated that the risk of unregistered sonographers could be further mitigated by encouraging more people to register with the Public Voluntary Register of Sonographers (PVRS).

On February 28th, 2021, the PVRS has transferred to the RCT. When the PVRS transferred to the RCT, 280 sonographers were registered. This number has increased to 380 registrants as on January 2023<sup>28</sup>. There were around 3,000 ultrasound practitioners working in the UK as of 2019. The report on sonographer regulation by The Society of Radiographers in March 2024 that was submitted as part of the SYE said that 'Other sonographers have undertaken 'direct entry courses' in the UK after completing a relevant degree (postgraduate ultrasound course) or straight from college (undergraduate ultrasound course). The number of these 'direct entry' courses is increasing and will need to grow further to respond to the urgent requirement to grow the ultrasound workforce as quickly as is possible. As the sonographer shortages worsen the need to educate more qualified, competent staff becomes more acute'.

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<sup>&</sup>lt;sup>28</sup> SoR Report

#### Risks that are beyond the RCT's control

The RTA report stated that 'statutory regulation would need to be considered in future, if the changes to routes entry to the profession and to the practice of sonography identified in the report materialise. This includes any significant increase in the number entering the role through the under-graduate route and increased vulnerability and complexity of patients undergoing ultrasound procedures. An Independent Review<sup>29</sup> by the by the Secretary of State for Health and Social Care highlights concerns about the lack of regulation for sonographers and the increasing use of private sonography clinics. It stated that people seeking reassurance or souvenir scans from private clinics should be able to trust that their sonographers are qualified and regulated. According to <a href="MHS Employers">MHS Employers</a>, developments in direct entry postgraduate and undergraduate ultrasound education have enabled non-healthcare professionals to enter the sonographer workforce. Many sonographers working in the UK are educated and trained overseas. Employers must make their own assessment of competency.

This suggests that the risks presented by sonography from unregistered practitioners may have increased since 2019. However, more data and evidence would be needed to determine this.

The Accreditation Panel found that overall, it is in the public interest to accredit the RCT. Doing so would help strengthen public protection for a role that undertakes high risk interventions.

According to the SoR study<sup>30</sup>, "since sonographers are required to conduct, analyse, interpret, and write reports on the ultrasound examinations they perform and on which clinical decisions are made, failure to meet RCT or statutory regulatory requirements for entry onto a register can put patients at significant risk." We have applied our methodology for assessing the inherent risk of roles in detail, *Right Touch Assurance (RTA)* (2019), to the role of sonographers. However, as stated above, the risks may have changed since we undertook this assessment.

Some sonographers are currently required to register with the HCPC as part of their primary profession as radiographers. The Accreditation Panel noted that the

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<sup>&</sup>lt;sup>29</sup> <u>CP 805 – The Independent Pregnancy Loss Review – Care and support when baby loss occurs</u> before 24 weeks gestation – July 2023 (publishing.service.gov.uk)

<sup>&</sup>lt;sup>30</sup>professionalstandards.sharepoint.com/sites/fs02/Documents/Forms/AllItems.aspx?id=%2Fsites%2F fs02%2FDocuments%2F1%29 Assessments%2FRCT%2FRCT

SYE%2F2024%2F2024%2E03%2E23 Sonographer regulation briefing update

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sonography risks appear sufficiently high to recommend that the UK Government should consider assessing the risk to determine whether voluntary registration is likely to be adequate. It is noted that the following information could help establish this.

- 1. Gathering data about the number of regulated and unregulated sonographers in the UK, both inside and outside the NHS, to inform understanding of the volume of risks.
- 2. Understanding the extent to which the number of unregistered sonographers is growing, because this may pose a risk to the public if they are not held to the same standards as registered sonographers.

In the meantime, we also recommend that the RCT updates its risk matrix including all potential risks from obstetric sonography.

 Recommendation Two: The risk matrix should be updated to identify potential risks and how specific risks associated with obstetric sonography are being mitigated.

iii. Commitment to ensuring that the treatments and services are offered in a way that does not make unproven claims or in any other way mislead the public.

The majority of RCT registrants are employed, and do not advertise their services directly to the public. Websites of individuals are not included on the RCT's register and therefore the team have not conducted registrant website checks.

We did not identify any concerns in relation to this part of the assessment. However, as set out in the full assessment the RCT was given a condition under Standard eight to review the content of its website to make sure that key information is up to date and accurate.

## 5. Impact assessment (including equalities)

We have published a full impact assessment as part of <u>renewal assessment</u> in May 2024. We have considered which are the main groups likely to be affected by renewal of accreditation of the RCT and what the main impacts are likely to be in terms of equalities, cost/markets, social and environmental impacts. This has included consideration of our duty as a public sector body under the Equality Act 2010.

The impact assessment for the RCT is published here:[RCT Impact Assessment Accreditation Renewal 2024 (professionalstandards.org.uk)

The Accreditation Panel acknowledged throughout this assessment that sonography has an impact on pregnant women. Sonographers use ultrasound scanning at Early Pregnancy Assessment Units (EPAUs) to verify the location and viability of a

pregnancy, according to the pregnancy review report. The NHS recommends that all pregnant women have at least two scans during their pregnancy, one in early pregnancy at around 12 weeks and an anomaly scan<sup>31</sup> at around 20 weeks of pregnancy to monitor the development of the embryo / foetus, examine embryological features, and identify pathologies<sup>32</sup>.

The risks associated with sonography, and the level of autonomy of the role, mean that the inherent risk of the role of sonography is high in comparison with other unregulated healthcare roles. As per SoR report, whilst many sonographers are statutorily regulated or on an accredited register in the UK, there are also sonographers working in the UK, who are not eligible to register with the Register of Clinical Technologists (RCT) as a sonographer. For this reason, although we think it strengthens public protection and therefore is in the public interest to accredit the RCT, as set out in this report we recommend that the UK Government considers whether accredited voluntary registration of sonography is likely to be sufficient.

<sup>&</sup>lt;sup>31</sup> Obstetric (Pregnancy) | BMUS.

<sup>32</sup> What is obstetric ultrasonography? - International Ultrasound Services (iuslondon.co.uk)