ANNEX A

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. [redacted] Secretary of State for Health & Social Care** **2. [redacted] President of the Royal College of Radiologists** **3. [redacted] Chief Executive of the Royal College of Nurses** **4. [redacted] Medical Director of Ashford & St Peters Trust Medical** **5. Family of Mrs Gillian Patricia Stokes**
1	**CORONER** I am Krestina Hayes assistant coroner, for the coroner area of Surrey
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On 15th June 2023, I commenced an investigation into the death of Mrs Gillian Patricia Stokes. The investigation concluded at the end of the inquest on 8th July 2024. The conclusion of the inquest was: on 2nd June 2023, Mrs Gillian Patricia Stokes died at the age of 74 years old from sarcoma of the right chest wall at Woking & Sam Beare Hospice, Woking. Sarcoma is a known complication of life-saving historic radiotherapy treatment for previous breast cancer in 2013.
4	**CIRCUMSTANCES OF THE DEATH** Mrs Stokes died of radiation induced sarcoma, which originated in the chest wall. She had a history of breast cancer confirmed in a referral by Woking & Sam Beare Hospice. Nine months prior to her death, Mrs Stokes had an investigation into pain in her right breast. She first attended her GP on 26th October who referred her to a Breast Clinic at Ashford Hospital. The radiation induced sarcoma was not found on an ultrasound on 10 November 2022. She attended a Breast Clinic, and her symptoms were investigated, which was said by the hospital clinicians to be in line with National Guidelines of symptomatic symptoms of patients with breast implants with suspected ALCL (Anaplastic large cell lymphoma). The guidance given on investigations, does not include what investigations need to be carried out on patients with a history of radiation with an implant to ensure the entirety of the chest wall is checked for masses. Furthermore, there is no guidance for clinicians to consider the rare diagnosis of radiation induced sarcoma, which is said by specialists at the Royal Marsden to be a growing issue, due to the increasing use of radiation combined with reconstructive surgery in the form of implants.

History of Mrs Stokes treatment

Mrs Stokes was first diagnosed with breast cancer in 2013 and was given chemotherapy and radiotherapy treatments, which included radiation of the chest wall. She also had a mastectomy followed by reconstructive surgery which included a breast implant.

Between 2013-2018 she returned to the Breast Clinic at Ashford hospital on several occasions, as she was unhappy with the implant. She had complained that it had been positioned too high, was misshapen and too large. She had a breast reduction and a further operation to remove some of the scar tissue and excess skin. Due to the multiple operations she continued to have soft tissue scarring and it remained uncomfortable, but she decided not to have any further surgery.

Mrs Stokes had 5 years of surveillance scanning following her breast cancer diagnosis in case the breast cancer should reoccur. The latency period for radiation induced sarcoma can be up to 10 years. She had an MRI scan on 7th August 2022 to investigate other issues unrelated to the breast cancer, the scan covered the area where the cancer was later found, but at that time no mass was present.

In October 2022, she reported to her GP surgery that she had a swelling in her breast area, which resulted in pain around her breast, down her right arm and armpit. She was referred to the Breast Clinic at Ashford via her GP.

As recommended in National Guidelines, the patient underwent a triple assessment for symptomatic breast disease. The triple assessment consists of 1. Clinical Examination, 2. Imaging; and 3. Biopsy of any abnormal finding. Mrs Stokes was seen at the Breast Clinic within the 2-week period of an urgent referral.

At the Breast clinic, Mrs Stokes initial clinical examination was conducted by a Nurse Diagnostician. The Nurse confirmed in evidence that her examination of Mrs Stokes chest wall was limited by her breast implant. If she had not had a breast implant, she would have been able to palpate the mastectomy area and rub it. This was not possible due to the implant.

Mrs Stokes was referred for a mammogram on her left breast, as cancer can often appear in the other breast following first diagnosis of breast cancer. This was clear.

She was also referred for an ultrasound of her right breast, this was in line with the national guidance called ABS Best Practice Diagnostic Guidelines Symptomatic Breast.

The concern by all three clinicians following Mrs Stokes Presentation at One Stop Clinic, following the clinical examination by the Nurse, an ultrasound by the Radiologist and the Surgeon, was that Mrs Stokes may have an issue regarding ALCL (Anaplastic large cell lymphoma – a fast and rare growing cancer). This was because liquid was found surrounding the breast implant. Some fluid was taken for testing and no malignant cells or makers or ALCL were found. This is in accordance with the Royal College of Radiologists Guidance on screening and symptomatic breast imaging 4th edition, breast specialists must be aware of the possibility of this rare complication of implant breast augmentation.

Radiation induced sarcoma was not considered as a possible diagnosis, as the cases that the Nurse, Radiologist and the Surgeon have experienced present with focal mass or skin change, clinically with a focal mass abnormality associated on imaging which was not found on ultrasound with Mrs Stokes.

In evidence and confirmed at the inquest, the radiologist who carried out the examination in November 2022 confirmed that the examination normally should include examination of the skin down to the chest wall (which lies posterior to the implant) for focal masses. In Mrs Stokes case, the position of the implant meant that the radiologist could not see posteriorly to the breast implant with ultrasound imaging, as the image cannot go beyond the implant and therefore not down to the chest wall.

	The Radiologist confirmed that she could see the surface of the implant and around the implant, where there was a moderate amount of fluid, but no mass in the breast tissue and no nodularity related to the surface of the implant. There was therefore in the clinicians view no suspicion of a sarcoma because no mass was visible on the surface of the breast tissue or around the implant. The implant capsule demonstrated a smooth contour with no irregularity or nodule surrounding the implant. I asked both the Nurse and the Radiologist if the fact that they could not carry out a full examination down to the chest wall was raised at MDT when deciding what management steps to take next. I was advised it was not, as it was not a consideration that there was a focal mass behind the implant. The patient wanted the implant out and she had not tested positive for ALCL. At inquest, I was told by the surgeon that they could not MRI all patients who were in this position. Furthermore, they confirmed that the guidance did not require them to. Whereas there is specific guidance for ALCL cases which are also very rare in number but can be tested by a cytology test (by taking a sample of fluid). In written evidence doctors from the Royal Marsden, who considered Mrs Stokes case at MDT after the sarcoma was diagnosed, wrote in written evidence that sarcomas are very fast growing and it is evident in this case that Mrs Stokes was as it was not present in the MRI in August 2022. I had further written witness evidence from a colleague of the Radiologist from Ashford Hospital who advised whilst they were unable to see anything on ultrasound to suggest a focal mass was present in November 2022, given the size of the mass on 27 January 2023, there is a possibility that it may have been present if an MRI scan was used in November 2023, but it is impossible to say. Royal Marsden also advised that it was not possible to say. After the One Stop Clinic following the aspiration the Nurse advised in evidence Mrs Stokes should have had a further review after two weeks, as indicated in the paperwork, but this was not followed through by the hospital and the message was not clearly communicated to the family. This would have allowed for further follow up in case the bulge had increased in size and in pain, but Mrs Stokes was not seen again until January 2023, as she was reclassed as a cosmetic case following the negative ALCL tests. Mrs Stokes attended again for an operation on 26th January 2023 and the staging CT scan on 15th March 2023 her sarcoma was classed as inoperable by Royal Marsden. Mrs Stokes was treated palliatively and passed away on 2nd June 2024. I had invited Ashford Hospital for submissions, but have not received any before completing this report.
5	**CORONER'S CONCERNS** During the inquest, the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – [BRIEF SUMMARY OF MATTERS OF CONCERN] (1) I am concerned that there is not any or insufficient guidance available to clinicians in regard to possible radiation induced sarcoma, or first line investigations for patients with breast implants to be able to see down to the chest wall. The Radiologist, Surgeon and Nurse advised that they did not have any specific guidance in relation to possible radiation-induced sarcoma,

	[redacted] from the Royal Marsden advised in written evidence, that radiation induced sarcomas are increasing in incidence as more primary breast cancer patients are now offered breast conserving surgery with wide local excision and radiotherapy, rather than mastectomy alone (previously there was no radiation). Therefore, in his view the increasing use of radiotherapy leads to increased number of patients developing radiation induced sarcomas. As [redacted] said from the Royal Marsden, diagnosis requires the treating clinician to recognise that this is a possibility. Furthermore, as [redacted] advised in his experience the difficulties in diagnosis are that they are sometimes not recognised by primary and secondary care teams who are the first to see the patient. In evidence the Radiologist confirmed that the Royal College of Radiologists do not have a protocol for patients who have had previous radiotherapy and implant. Furthermore, Nurse Diagnostician confirmed there was no protocol in the ABS Best Practice Diagnostic Guidelines for radiation induced sarcoma where a patient has had an implant. (2) I have a concern regarding the current surveillance period of 5 years provided to patients with breast cancer considering the latency period of radiation induced sarcoma is 10 years. (3) I have concerns regarding the system in place at Ashford Hospital for 2 week follow ups following an aspiration following an initial assessment at the One Stop Clinic. Following the aspiration Mrs Stokes received, the Nurse advised in evidence Mrs Stokes should have had a further review after two weeks, as indicated in the paperwork, but this was not followed through by the hospital and the message was not clearly communicated to the family. This would have allowed for further follow up in case the bulge had increased in size and in pain and could have potentially identified the need to investigate further.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you AND/OR your organisation have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 1st October 2024. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons the family of the deceased. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.

9	**8.8.24**	**Krestina Hayes**