REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. The Heart Rhythm Society of the United Kingdom** **2. Public Health England** **3. The Secretary of State for Health, Department of Health**
1	**CORONER** I am HENRIETTA HILL, assistant coroner, for the coroner area of Inner South District of Greater London.
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 12 December 201 an investigation into the death of SANDRA HAZEL ELIZABETH HIGHAM, then aged 65 years, was opened by deputy coroner Lorna Tagliavini. On 10 June 2014 an inquest into Ms Higham's death was opened by assistant coroner Sarah Ormonde-Walsh. The inquest was adjourned. The inquest into Ms Higham's death was resumed, and concluded, by myself on 17 October 2014. The medical cause of Ms Higham's death was cerebral ischaemia, caused by atrial-oesophageal fistula, caused by ablation for atrial fibrillation. The conclusion of the inquest was a narrative conclusion, as follows: (1) Ms. Higham died at St. Thomas's Hospital, London on 7 December 2013. (2) She had undergone an ablation procedure to her heart on 17 October 2013 and this had caused an atrial-oesophageal fistula to develop. (3) This led to her suffering neurological, fever and vomiting symptoms for which she was admitted to Tunbridge Wells Hospital on 23 November 2013. A fistula of this nature is a very rare, but known, risk of the ablation procedure. (4) She was transferred to St. Thomas' Hospital, London on 24 November 2013 when two attempts were made to 'stent' her heart, but she died from the neurological consequences of the fistula, on 7 December 2013.
4	**CIRCUMSTANCES OF THE DEATH** The circumstances of the death are reflected in the narrative above.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – (1) The ablation procedure, as a method of addressing atrial fibrillation, is becoming

	more widespread (an increase of around 20-30% in recent years). (2) The development of an atrial-oesophageal fistula is a very rare, but known, risk of the ablation procedure (developing in around 0.01-0.2% of cases of percutaneous ablation and around 1-1.5% of cases of surgical ablation). (3) If an atrial-oesophageal fistula does develop, it has a very high mortality rate (reported to be 67-100%). (4) According to the literature there are no clear predictors of mortality from an atrial-oesophageal fistula, but early diagnosis, prompt surgical intervention and prolonged antibiotic therapy may be crucial for survival. (5) Diagnosing an atrial-oesophageal fistula can be difficult, especially in an acute medical setting, given its range of non-specific symptoms and duration of onset, and the lack of awareness within the wider medical profession of such a fistula being a risk of the ablation procedure.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisation has 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 29 December 2014. 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 Ms Higham, Maidstone and Tunbridge Wells NHS Trust and [redacted] 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	**3 November 2014** **Signed** ..... **Assistant Coroner**