	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO: University Hospitals Birmingham NHS Foundation Trust**
1	**CORONER** I am Emma Brown Area Coroner for **Birmingham and Solihull**
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 26th June 2015 I commenced an investigation into the death of Joyce Beatrice TOZER. The investigation concluded at the end of the inquest 8th December 2015. The conclusion of the inquest was that the deceased passed away at the Queen Elizabeth Hospital Birmingham on the 12th June 2015 as a result of a reaction to contrast material injected during an interventional radiology procedure to insert bilateral nephrostomies. It has not been possible to determine whether the reaction was due to an allergic response or a response to the toxicity of the 100ml dose of omnipaque contrast solution given. The need for bilateral nephrostomies was to manage urinary leak from a conduit anastomosis placed during radical surgery on the 27th May 2015 to treat recurrent anal cancer. The medical cause of death was: 1(a) Reaction to the administration of ominpaque contrast solution 2 Recent Surgeries for the treatment and management of anal cancer.
4	**CIRCUMSTANCES OF THE DEATH** As a consequence of urostomy leakage following surgery on the 27th May 2015 Mrs. Tozer required bilateral nephrostomies. During the interventional radiology procedure to place the nephrostomies on the 12th June 2015 Mrs. Tozer remained stable until minutes after the injection through her central line of a 100ml dose of omnipaque at which time her condition deteriorated dramatically leading to cardiac arrest from which she could not be resuscitated.
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) [redacted] Consultant anaesthetist for the procedure on the 12th June 2015, gave evidence that since Mrs. Tozer's death, he has become concerned that the dose of 100ml omnipaque record in the notes as being administered by the radiologist minutes before Mrs. Tozer's sudden deterioration was well in excess of the dose recommended by the manufacturer of omnipaque (1ml/kg) especially as it was being administered through a central line rather than peripheral venous access. At this time Mrs. Tozer's weight was 52kg. [redacted] stated that he was concerned that the administration of a hypertonic solution at this dose into a central line may have affected Mrs. Tozer's heart rhythm although there was no way he could give an opinion as to whether it was the likely cause of her deterioration and death as the presentation of toxicity cannot be distinguished from an anaphylactoid reaction. [redacted] gave evidence that having made enquiries about the dose with [redacted] Lead Interventional Radiologist at the Trust, he has been told that a 100ml dose is often used. I am concerned that doses of omnipaque well in excess

	of the manufacturer's guidelines are frequently administered, sometimes through central lines, and this practice could be exposing interventional radiology patients to risks from toxicity.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you 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 10 February 2016. 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: [redacted] (next of kin). 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	 Emma Brown Area Coroner **Birmingham and Solihull** 15/12/2015