

**FINAL LIST OF ISSUES****Introduction****(Issues of background relevance to the Inquiry's Terms of Reference)**

A	B	C	
<p>Who were and are the parties involved in the nuclear industry?</p> <p>Which of those parties existed during the period 1961 – 1992?</p> <p>Which nuclear facilities are and were owned and/operated by which party?</p>	<p>What were the statutory and other powers and functions, relevant to the Terms of Reference, of each of the parties during the period 1961-1992?</p> <p>Did any of the functions or roles of the parties change during the period 1961 to 1992 and if so how?</p>		1
<p>What category of operations were carried out on each site 1961-1992?</p>	<p>How did the ownership or operation of the sites change during the period 1961 to 1992?</p>	<p>Which parties now hold the records in relation to those sites?</p>	2

**Issue 1: Legal and ethical framework**

**What were the legal requirements and ethical guidelines concerning the retention and testing of organs following post mortem?**

A	B	C	
<p>What was the legal position governing the retention and testing of organs following post mortem before the introduction of the Human Tissue Act 1961?</p>	<p>What was the applicable primary legislation?</p> <ul style="list-style-type: none"> <li>-Coroners Act 1887</li> <li>-Coroners (Amendment) Act 1926</li> <li>-Coroners Act 1954</li> <li>-Anatomy Act 1832</li> <li>-Anatomy Act 1871</li> </ul> <p>Were there relevant regulations?</p> <ul style="list-style-type: none"> <li>-Coroners Rules 1953</li> <li>-Coroners Rules 1956</li> </ul> <p>Is there any other applicable legislation or regulations?</p> <p>Was there any relevant case law?</p> <p>Was there any guidance available on ethics? If so what did it say?</p>	<p>Who could give authority for the removal of organs and for what purposes?</p> <p>Was the situation different for Coroners' post mortems and hospital post mortems?</p> <p>Was consent necessary?</p> <p>If so for what and from whom?</p> <p>How could consent be given (oral or written)?</p> <p>Was it necessary to keep a written record that consent was given?</p> <p>How long should any such records have been kept?</p>	<p>1</p>
<p>Was there a requirement for consent for retention and testing of organs following post mortem following the introduction of the Human Tissue Act 1961?</p>	<p>What does the Act say?</p> <p>How was the Act circulated?</p> <p>Were any formal guidelines published and what did they say?</p> <p>To what degree were any guidelines circulated?</p>	<p>Who could give authority for the removal of organs and for what purposes?</p> <p>Was the situation different for Coroners' post mortems and hospital post mortems?</p> <p>Was consent necessary?</p> <p>If so for what and from whom?</p> <p>How could consent be given (oral or written)?</p> <p>Was it necessary to keep a written record that consent was given?</p>	<p>2</p>

		How long should any such records have been kept?	
Was there any other relevant legislation between 1961 and 1992?	<ul style="list-style-type: none"> <li>-Coroners (Amendment) Rules 1974, 1977 and 1980</li> <li>-Coroners (Amendment) (Savings) Rules 1980</li> <li>-Coroners (Amendment) Rules 1983</li> <li>-Coroners Act 1980</li> <li>-Coroners Rules 1984</li> <li>-Anatomy Act 1984</li> <li>-Coroners Act 1988</li> </ul> <p>Is there any other applicable legislation or regulations?</p>	What effect on the above position did any such legislation have, if any?	3
What professional guidance on the law relating to retention and testing of organs following post mortem was available?	<p>To pathologists?</p> <p>To mortuary technicians and to mortuary managers?</p> <p>To Coroners and to Coroners' officers?</p> <p>To undertakers?</p> <p>To doctors involved in studies/programmes requiring retention and testing of organs following post mortem?</p> <p>In particular about the new HTA 1961 but also subsequent relevant legislation?</p>	<ul style="list-style-type: none"> <li>-Literature/journals</li> <li>-Royal College of Pathologists</li> <li>-Home Office</li> <li>-Ministry of Health</li> <li>-Her Majesty's Inspector of Anatomy</li> <li>-Other sources?</li> </ul> <p>To what degree was each circulated?</p>	4
What ethical considerations arising from the retention and testing of organs following post mortem were identified?	<p>Where is the ethical guidance to be found?</p> <ul style="list-style-type: none"> <li>-Literature/journals</li> <li>-Royal College of Pathologists</li> <li>-Home Office</li> <li>-Other sources?</li> </ul> <p>To what degree was each circulated?</p>	<p>To what extent did these ethical considerations change over time?</p> <p>Did ethical considerations add anything to the law?</p>	5

	<p>What was the nature of any research government apparatus which may have existed to cover studies/programmes requiring retention and testing of organs following post mortem?</p>	<p>To what extent did any equivalent research apparatus to cover studies/programmes requiring retention and testing of organs following post mortem exist within the occupational context?</p>	
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**Issue 2: Practical background prior to 1961**

**What was the custom and practice in the retention and testing of organs following post mortem prior to 1961?**

A	B	C	
<p>What evidence is available of the subjective understanding of individuals and relevant organisations of the legal requirements relating to the retention and testing of organs following post mortem prior to 1961?</p>	<p>Pathologists?</p> <p>Mortuary technicians and mortuary managers?</p> <p>Coroners and Coroners' officers?</p> <p>Undertakers?</p> <p>Doctors involved in studies/programmes requiring retention and testing of organs following post mortem?</p> <p>Employees of stakeholder organisations?</p> <p>Ethics committees?</p>		1
<p>To establish a benchmark through a sample of studies, projects or programmes prior to 1961 which included testing otherwise than at nuclear facilities on organs retained following post mortem or fetal material.</p>	<p>In respect of each:</p> <ul style="list-style-type: none"> <li>-in what circumstances were the organs obtained?</li> <li>-what consideration was given to the issue of consent and by whom?</li> <li>-was consent obtained, from whom and for what?</li> </ul>	<p>What if any guidance was specifically sought by practitioners and what was provided?</p> <p>What was the response of practitioners to the guidance?</p>	2
<p>Which studies, projects or programmes prior to 1961 included retention and testing at nuclear facilities of organs retained following post mortem?</p>	<p>Which organisations were responsible?</p> <p>Who planned and ran the studies?</p> <p>In what circumstances were the organs obtained?</p> <p>What consideration</p>	<p>What if any guidance was specifically sought by practitioners and what was provided?</p> <p>What was the response of practitioners to the guidance?</p>	3

	<p>was given to the issue of consent and by whom? What evidence is there of this? Was consent obtained, from whom and for what?</p>		
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**Issue 3 Custom and Practice 1961 – 1992**

**What was the custom and practice in programmes for the retention and testing of organs following post mortem and studies including the results of such analysis in the period 1961 – 1992?**

A	B	C	
<p>Which laboratories in the UK were capable of testing for the presence of radionuclides in organs retained following post mortem and over what periods?</p>	<p>Laboratories at nuclear facilities?</p> <p>Other laboratories under the control of stakeholder organisations in the nuclear industry?</p> <p>Laboratories outside the nuclear industry?</p>	<p>Which parties owned and/or operated any sections of such laboratories/facilities?</p> <p>Which parties hold the records relating to such sections/laboratories?</p> <p>From where did the laboratories gain their primary material?</p>	1
<p>To establish a benchmark through a sample of studies, projects or programmes which included testing otherwise than at nuclear facilities on organs retained following post mortem or fetal material during the period 1961 – 1992</p>	<p>In respect of each:                      -in what circumstances were the organs obtained?                      -what consideration was given to the issue of consent and by whom?                      -was consent obtained, from whom and for what?</p>	<p>What if any guidance was specifically sought by practitioners and what was provided?</p> <p>What was the response of practitioners to the guidance?</p>	2
<p>Which studies, projects or programmes included testing at nuclear facilities on organs retained following post mortem or fetal material during the period 1961 – 1992?</p> <p>In respect of each study, project or programme ...</p>	<p>What was the nature of the study, project or programme?</p>	<p>Which organisation had overall responsibility for the study, project or programme?</p> <p>What was the purpose of the study, project or programme?</p> <p>Which individuals were involved in the design, approval, authorisation and running of the study, project or programme?</p> <p>Did those individuals have a conflict of interest?</p> <p>Where was the research carried out?</p> <p>Which other organisations were aware of the study, project or programme?</p>	3

		<p>What was the understanding of those involved in the design and running of the study, project or programme of the relevant legal requirements relating to retention and testing of organs?</p> <p>Did they seek guidance or advice?</p> <p>If consent was considered but there was felt to be no need to obtain consent, on what basis was that decision made?</p> <p>Was consent for the retention and testing of organs a legal requirement?</p> <p>Was it practicable to include the need to consent in the study, project or programme?</p> <p>Was the possible need for consent reviewed in light of information which became available at a later date?</p> <p>What action was taken on the basis of any relevant new information on consent?</p> <p>Was ethical approval required?</p> <p>Was ethical approval sought or granted for the study, project or programme? By whom?</p> <p>To what extent was the study, project or programme made public outside medical and scientific literature?</p> <p>What consideration was there by stakeholders of publicity?</p> <p>Was there any public comment?</p> <p>In respect of fetal tissue, what was the effect of the Polkinghorne report (1998)?</p> <p>Did any individual or organisation profit financially from any project, programme, study or report or as a</p>
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		<p>result of the taking, retention and transfer of organs?</p>	
	<p>Were any projects or programmes of removal and analysis linked to any specific study?</p>	<p>What organisation had overall responsibility for the study?</p> <p>What was the name of the study?</p> <p>What was the purpose of the study?</p> <p>Which individuals were involved in the design, approval and running of the study?</p> <p>Did those individuals have a conflict of interest?</p> <p>What consideration was given at the design/ planning stage to obtaining consent for the retention and testing of organs?</p> <p>What was the understanding of those involved in the design and running of the study of the relevant legal requirements relating to retention and testing of organs?</p> <p>What guidance or advice did they seek?</p> <p>Was consent for the retention and testing of organs a legal requirement?</p> <p>Was it practicable to include the need to consent in the design of the study?</p> <p>Was the possible need for consent reviewed in light of information which became available at a later date?</p> <p>What action was taken on the basis of any relevant new information on consent?</p> <p>Was ethical approval required?</p> <p>Was ethical approval sought or granted for the study? By whom?</p>	<p>4</p>

	<p>Were the results of the projects, programmes or studies published or otherwise circulated?</p>	<p>In which publications were the results circulated?</p> <p>Were the results independently validated?</p> <p>Were they peer reviewed?</p> <p>To whom were the results of the analysis provided?</p> <p>For what purpose(s) were the results of the analysis used?</p>	5
<p>What attempts were made to set up any national autopsy register/database of workers exposed to radionuclides?</p>	<p>Why was the database seen as necessary?</p> <p>How far was any such project developed?</p> <p>If it was not successfully concluded, why not?</p>		6
<p>Were any formal or informal arrangements were put in place to identify and/or select individuals for organ retention and testing?</p> <p>Employees / Ex employees of nuclear facilities?</p> <p>Controls?</p> <p>Fetal tissue?</p> <p>Placentae?</p>	<p>Employees of BNFL and /or UKAEA?</p> <p>Coroners?</p> <p>Pathologists?</p> <p>General Practitioners?</p> <p>Trade Unions?</p> <p>Others?</p>	<p>Was there a system under which individuals were identified and/or selected for organ retention and analysis?</p> <p>If so, what was the system of identification/selection and how did the system operate in each and every regard?</p> <p>What criteria were applied, by whom, with what degree of consultation and in what circumstances?</p>	7
<p>What formal or informal arrangements for obtaining, retention, transfer, analysis and disposal of organs existed between individuals and/or organisations?</p>	<p>Employees of BNFL and /or UKAEA?</p> <p>Coroners?</p> <p>Pathologists?</p> <p>General Practitioners?</p>	<p>Attendance at post mortem?</p> <p>Post mortem procedure?</p> <p>Selection of post mortem material?</p> <p>Transportation of organs?</p> <p>Analysis of organs?</p>	8

	Trade Unions? Legal advisers? Others?	Reporting of post mortem results? Disposal of organs or residue?	
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**Issue 4 Circumstances of retention 1961 – 1992**

**Which individuals were subject to the removal, retention and analysis of organs at nuclear facilities following post mortem between 1961 and 1992 and in what circumstances?**

A	B	C	
<p>Who was subject to retention?</p>	<p>In what circumstances were organs removed?</p>	<p>By whom were organs removed?</p> <p>At whose request and on whose authority were organs removed?</p> <p>When, how, to whom and for what purpose was that authority given?</p> <p>Who was present at the post mortem?</p> <p>Was the removal linked to a Coroner's post mortem?</p> <p>Was the removal linked to a hospital post mortem?</p> <p>Was there an inquest?</p> <p>Which organs were removed?</p> <p>By what means were they removed?</p> <p>Was the amount and nature of the material removed that which was necessary for the purpose for which its removal had been authorised?</p> <p>Who was aware that organs would be/had been removed?</p> <p>Had a compensation claim been intimated?</p>	<p>1</p>
	<p>Was there any consent from the family (or advance consent from the individual)?</p>	<p>Is there any evidence to suggest that the individual consented in advance to removal and analysis of organs?</p> <p>Was consent from the family sought or obtained either directly or via their representatives?</p> <p>To what did the family consent?</p> <p>What information was given to family to obtain their consent?</p> <p>What is the evidence of consent?</p>	<p>2</p>

		Was it practicable to seek consent from either the individual prior to death or their family following death?	
	In what circumstances were organs transported and stored?	<p>What was done with the organs between removal and analysis?</p> <p>Where were the organs stored?</p> <p>How were the organs stored and over what period?</p> <p>How were the organs transported?</p> <p>By whom were the organs transported?</p> <p>At whose request were the organs transported and stored?</p>	3
	What analysis was carried out?	<p>What processes were used to prepare the material for analysis and to analyse it?</p> <p>At whose request were the organs analysed?</p> <p>By whom was analysis carried out?</p> <p>Where was analysis carried out?</p> <p>What was the purpose of the analysis?</p> <p>What were the results of the analysis?</p> <p>Were the results independently validated?</p>	4
	What were the arrangements for disposal of organs or residue after analysis?	<p>What happened to any residue after analysis?</p> <p>Who requested or gave permission for disposal?</p> <p>Were the family of the deceased consulted regarding disposal?</p> <p>Should they have been?</p> <p>Was the disposal respectful?</p>	5

		Is any tissue or residue still in existence?	
	What was done with the results of the analysis?	<p>Who had control/authority over the provision of the results of the analysis?</p> <p>Were the results given to the Coroner?</p> <p>Were either the results of the analysis or any report based upon it used for any other purpose than informing a Coroner as to cause of death?</p> <p>If there was a compensation claim, were the results used in the claim and if so how?</p> <p>Were the results published as part of any study? If so which study and where was it published?</p> <p>Was the family informed of the results of the analysis or the identity of publications in which the results had been published?</p>	6
	Where results were provided to the Coroner, what use was made of them?	<p>In what format was the information given to the Coroner?– i.e. raw data or accompanied by a report?</p> <p>When were the results/report given to the Coroner (i.e. before or after any inquest or decision not to hold an inquest?)</p> <p>Did the Coroner use the results/report to inform his (or a jury's) considerations as to cause of death?</p> <p>Who wrote any report presented to the Coroner?</p> <p>Was the writer of any report independent of the other interested parties to the Inquest?</p> <p>What standard paragraphs or templates were used in reports to the Coroner on the results of analysis?</p> <p>At whose instigation did this take</p>	7

		place and did this affect the accuracy or impartiality of the reports or prevent information being made available which might have a bearing on a Coroner or jury's decision on mode of death?	
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**Issue 5 Practice Since 1992**

**What has been the practice since 1992?**

A	B	C	
<p>Did the retention and analysis of organs at nuclear facilities following post mortem cease in 1992?</p>	<p>If the practice stopped, why was it?</p>	<p>Was the issue one of change or loss of resource, change of functions or change of need?</p> <p>Was any specific instruction given by or to any stakeholder organisation or individual to cease testing on organs obtained at post mortem?</p> <p>Was any concern raised at that time as to what had gone on before?</p>	<p>1</p>
	<p>If not then what programmes, projects or activities continued and for what purpose?</p>	<p>What consideration if any was given to the issue of consent for retention and testing of organs?</p> <p>What degree of consent was obtained for the use of the organs?</p>	<p>2</p>
<p>Was there any review of previous practice at nuclear facilities following either i) the Bristol Royal Infirmary Inquiry or ii) the Alder Hey Inquiry or iii) the introduction of the Human Tissue Act 2004?</p>	<p>If so what were the findings?</p> <p>If not, why not? Are the findings of those Inquiries and/or the requirements of the Act relevant to practice at nuclear facilities and if so, to what extent were such findings/requirements communicated?</p>	<p>What action, if any, was taken as a result of any findings?</p>	<p>3</p>
<p>What would be the requirements for retention and analysis of organs following post mortem under the Human Tissue Act 2004?</p>	<p>If there remain any organs or residue covered by the Human Tissue Act 2004, is it held in compliance with the Act?</p>		<p>4</p>