Witness Name: Karen Holland Statement No.: WITN6955001 Exhibits: WITN6955002-066 Dated: 6/4/22

# INFECTED BLOOD INQUIRY

### WRITTEN STATEMENT OF KAREN HOLLAND

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 4 March 2021.

I, Karen Holland, will say as follows: -

#### Section 1: Introduction

- Your questions relate to documents supplied to me by the Inquiry which are identified as follows: DHSC0046961\_056; DHSC0200022\_002 and DHSC0200022\_006. As requested, I have referenced these documents when responding to the questions posed. I have also referenced a file of documents which I received from the Department of Health when I was first asked about this review by the Inquiry, which are included as exhibits to this written statement [WITN6966002 - 065]. These exhibits appear to be an electronic scan of the hard copy file maintained in support of the Hepatitis C Litigation report (DHSC0046961\_071).
- 2. I have responded to your questions below but first want to set some important context regarding my ability to answer these.
- 3. I am a Group Chief Internal Auditor for the Government Internal Audit Agency (GIAA) with a 20-year career in internal audit within central government. With

the assistance of the Agency's Professional Practice colleagues, I have therefore been able to provide an overview of the procedure for internal audit of government departments (per your questions in section one of your request). This draws heavily on the Public Sector Internal Audit Standards by which I am bound. Answers draw on current practice and as the evidence base provided to me relates to 2000 it is important to note that the Standards and approach to audit have evolved over the last 20 years.

4. In 2000, when the Hepatitis C Litigation report was drafted, this was by an inhouse internal audit team (i.e. employees of the Department of Health). During 2018/19 the Department of Health internal audit team did transition into the GIAA (which was first established in 2015 following a 2013 Review of Financial Management in Government recommended pooling expertise from across government to create a single integrated audit function for the whole of government) but no members of the team were in post in 2000 and we did not inherit any paper records (these would have been used mostly at the time to record the audit teams work). Responsibility for records management and adhering to document retention rules lies with the Department who may be in a better position to answer questions posed in sections 2 and 3 of your request. I took on responsibility for delivering an internal audit programme for the Department of Health and Social Care in October 2019.

#### Section 2: Internal Audit Policy

- 1. Please set out the standard process by which the Department of Health's Internal Audit department would conduct an audit. Please include details as to what investigative work an auditor would conduct when carrying out an audit and how an audit is commissioned.
- 5. Within document DHSC0046961\_056, page 9 section 6 'Acknowledgements' the Head of Internal Audit 'gives thanks for the co-operation in helping us complete this investigation swiftly'. Page 3 Introduction of the 'Hepatitis C Litigation report [DHSC0046961\_071], Section 1.1 states that "this report follows an investigation by Internal Audit into the loss of documentation relating

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to Hepatitis C Litigation."

- 6. Investigation is a separate discipline to an internal audit, which requires different training and qualifications. Within the Government Internal Audit Agency, which currently provides internal audit services to the Department of Health and Social Care, we would expect our separate team of qualified investigators to undertake any activity framed as an investigation and not the audit team. Investigators within our Counter Fraud and Investigation team are professionally accredited and work to a strict Code of Conduct and criminal standards.
- 7. The standard, high-level process by which we currently conduct risk-based, internal audit engagements is as follows:
  - Planning and scoping of the engagement, including identification of the risks to be audited and agreement of the Terms of Reference with the customer;
  - b. Control evaluation, whereby the design of the controls in place to mitigate the risks being audited is assessed, including against the controls we might expect to find in place;
  - c. Testing *control effectiveness* of those controls considered to be effectively designed.
  - d. *Evaluating* the overall results and drawing conclusions on our work.
  - e. Reporting the results and conclusions of our work to management.
- This methodology conforms with Public Sector Internal Audit Standards (PSIAS, 2017) [RLIT0000847] and accords with good practice in the wider internal audit profession.
- 9. The standard, high-level process by which we currently conduct an investigation is as follows:
  - a. Investigation Plan / Terms of Reference produced
  - b. Evidence gathered including hard copy, electronic and witness
  - c. Investigatory or PACE interviews held where necessary
  - d. *Evidence assessed* and a *conclusion reached* on whether the evidence 3

on the balance of probabilities supports a case to answer

e. Report issued.

# 2. Please set out what steps if any, an auditor would take in circumstances where evidence necessary to form conclusions is missing.

- 10. The current version of PSIAS [RLIT0000847] requires the following:
- 11.2310 Identifying Information
  - a. Internal auditors must identify sufficient, reliable, relevant and useful information to achieve the engagement's objectives.
  - b. *Sufficient* information is factual, adequate and convincing so that a prudent, informed person would reach the same conclusions as the auditor.
  - c. *Reliable* information is the best attainable information through the use of appropriate engagement techniques.
  - d. *Relevant* information supports engagement observations and recommendations and is consistent with the objectives for the engagement.
  - e. Useful information helps the organisation meet its goals.
- 12. 2320 Analyses and Evaluations Internal auditors must base conclusions and engagement results on appropriate analyses and evaluations.
- 13. Internal auditors use a variety of recognised techniques to identify, analyse and evaluate information to obtain results and draw conclusions: inquiry, observation, examination, inspection, reperformance, vouching, tracing, independent confirmation, analytical procedures, and computer-aided audit techniques.
- 14. Where the information necessary to form conclusions to the required standard remains missing after applying the relevant techniques noted above (relevance

varies depending on the nature and scope of the engagement and of the information sought) the internal auditor would document the procedures taken to obtain the information, the outcome of the procedures and note that the missing information means that an adequate conclusion cannot be drawn.

# 3. Please set out the steps an auditor would carry out to discover this evidence or discover why this evidence is not available.

- 15.1 have outlined the techniques that may be taken to identify information to the required professional standard in my answer to question 2 above.
- 16. Often the reason for a piece of information being missing will become apparent when applying the information identification, analysis and evaluation techniques noted. If not, internal auditors may undertake root cause analysis to do so. Again, it would depend on the nature and scope of the engagement as to whether such activity occurred.

4. Please set out as far as you can, any departmental rules, policies and guidelines which prescribe what evidential basis is required, if any, for any conclusions reached in an audit report.

- 17. The requirements for identifying, analysing and evaluating information for use in internal audit activity are set out in PSIAS 2310 and 2320 [RLIT0000847], as noted in our response to question 2 above.
- 18. The Institute for Internal Auditors has also issued implementation guidance notes (IG2310 and 2320) to support internal auditors on information identification, analysis and evaluation. GIAA has incorporated this into its methodology, local guidance and training.

5. Please also set out whether an auditor must (as a matter of policy) or should (as a matter of good practice) include the evidential basis for any conclusions or beliefs set out in a final report or in the body of the report itself.

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- 19. Standard 2400 Reporting Results [RLIT0000847] requires internal auditors to communicate the results of an engagement, including the engagement's objectives, scope and results. It also requires that this must be supported by sufficient, reliable, relevant and useful information.
- 20. Within GIAA we promote the judgment, evidence, impact approach to reporting engagement results:
  - a. *Judgment* the conclusions drawn in respect of governance, risk management and the control environment.
  - b. *Evidence* the information obtained, analysed and evaluated to draw our conclusions.
  - c. Impact what this means for the customer's organisation and any recommendations we would make to address risks and issues identified through our work.

# 6. Please set out what 'quality control' measures are undertaken before a draft report is considered finalised.

- 21. Standard 2340 Engagement Supervision [RLIT0000847] requires that engagements must be properly supervised to ensure objectives are achieved, quality is assured, and staff is developed.
- 22. Within GIAA we require that at a minimum the supervisor of an engagement must review the engagement file and/or relevant document at the following stages in the audit process:
  - a. Draft Terms of Reference prior to issue to the customer for comment;
  - b. Once control evaluation completes;
  - c. Once the testing of control effectiveness completes; and
  - d. Draft Audit Report prior to issue to the customer for comment.

- 23. Where material changes to the draft Terms of Reference or Report occur after customer review, we expect the supervisor to review the updated version.
- 24. More senior internal audit staff may also perform a review at any or all of these stages, depending on the nature and subject of the engagement being conducted.

### Section 3: Internal Audit Review - Hepatitis C Litigation Final Report

7. Please describe the background to the commissioning of the Internal Audit Review Hepatitis C Litigation Final Report ('the report') (attached as DHSC0046961\_056). Please indicate who commissioned the audit, why and the terms of reference, if any, given to the auditors.

- 25.1 have only been able to answer this question through reference to exhibits WITN6955002-066 and have no other source of information from which to draw a response.
- 26. The terms of Reference for the Hepatitis C Litigation review are included in WITN6955026.
- 27.WITN6955026 includes a handwritten note indicating that the Permanent Secretary at the Department of Health commissioned the investigation following advice from M.A. Morgan from the Office of the Solicitor. A Department of Health contact sheet indicates that Marilynne Morgan is a solicitor. [WITN6955038]
- 28. An interview note in WITN6955053 records a meeting between the audit team and the DCMO (Deputy Chief Medical Officer) Pat Troop regarding the Terms of Reference. The narrative indicates that Pat would be the person who received the report of the investigation. Pat records the need 'to establish the extent to which procedures had not been followed' and that there is a need to 'ensure all that should have been done, was done (in terms of good file keeping)'.

8. Please set out as fully as you can the investigative work carried out prior to the writing of the report including:

(i) what documents and records were examined; and

- (ii) which members of staff were interviewed.
  - 29.1 have only been able to answer this question through reference to exhibits WITN6955002-066 and have no other source of information from which to draw.

#### Staff members interviewed

- 30. The Terms of Reference for the review states at section 2.4 that 'as a minimum we will need to talk to the following people, Dr Rejman, Dr. Metters and his former secretary and the person who authorised the destruction of the documents'. [WITN6955026]
- 31. The acknowledgements section of the Hepatitis C Litigation report thanks 'HSD, SOLB, SRO, the Staff Development Unit and the MEDS team for their cooperation' but there is no listing of people who were interviewed as part of the investigation. WITN6955032 contains a handwritten note headed 'interviews' which lists Dr Metters, Dr Metters Secretary, Dr Rejman and the 'destructor of the records'.
- 32. The following interview records are exhibited with this statement:
  - a. Mark Gidden SOL to discuss the background [WITN6955050]
  - b. Pat Troop DCMO to discuss the Terms of Reference [WITN6955051]
  - c. Yvonne de Samparo Secretary to Dr Metters [WITN6955052]
  - d. Anita James SOLB to discuss the background [WITN6955053]
  - e. Jill Moorcroft Management of electronic documents (MEDS)

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[WITN6955054]

- f. Steve Wells Departmental Records Officer [WITN6955055]
- g. lan Forsyth Staff Development Unit [WITN6955056]

### Documents and Records examined

- 33. The following documents are included as exhibits to this statement, but it is not clear as to what extent they were examined.
  - a. Memo to all staff on the Departmental Document Initiative and leaflet-'For the record' [WITN6955036]
  - b. Various dockets which appear to relate to files held in document storage
    [WITN6955036]
  - c. An email regarding information obtained from file store on when the ACVSB papers were destroyed [WITN6955040]
  - d. Management of electronic documents strategy and supporting cover note- [WITN6955041] & [WITN6955042]
  - e. An email to the auditor on 'Destroyed files in the GEB series' responding to a query regarding destruction dates [WITN6955044]
  - f. Health Service circular on Information management good practice including appendices on managing NHS records, retention and disposal schedules and a list of usual contacts [WITN6955045]

9. Please identify which Department(s) or office(s) were investigated as part of the audit.

(i) Please set out if all members of staff in the investigated department(s) or office(s) were investigated as part of the audit.

(ii) Please explain why Dr Rejman was not interviewed as part of the audit Process.

- 34.1 have only been able to answer this question through reference to exhibits WITN6955002-066 and have no other source of information from which to draw.
- 35. Regarding (i) see my response to question 8 above.
- 36. Regarding (ii) it is not clear from exhibits WITN6955002-066whether Dr Rejman was interviewed as part of the review. Page 6 of the Hepatitis C Litigation report states that Dr Rejman retired in 1994 [WITN6955015]

10. Please refer to the enclosed draft minute dated 3/03/2000 (attached as DHSC0200022\_006).

(i) Was the Department of Health civil servant who signed the destruction authorisation interviewed as part of the audit process?

- (ii) If not, please explain why he or she was not interviewed.
  - 37.1 have only been able to answer this question through reference to exhibits WITN6955002-066and have no other source of information from which to draw.
  - 38.On page 5 of the Hepatitis C litigation report there is reference that 'we interviewed staff members from the relevant section, but their memories of events up to 8 years ago were hazy at best, and added little to the evidence we had elsewhere'. [WITN6955015]. But it is not clear who was interviewed and whether the team did interview the civil servant who signed the destruction authorisation.

11. Please find enclosed a letter from Dr Rejman to Anita James dated 7 June 1995 (attached as DHSC0200022\_002).

(i) Please state whether examination of the formal confirmation letter ('the formal letter') referred to herein formed part of the audit process.

(ii) Please set out whether the authors of the formal letter were interviewed as part of the audit process and if not, why not?

39.1 am unable to answer this question. The exhibits that I have sight of do not provide any insight into this.

# 12. Please provide all drafts, correspondence, reports, interview records and any other documents produced during the audit process.

- 40. In order to respond to correspondence received from Sharan Sidhu, Lawyer for the DHSC in the Infected Blood Inquiry, my team asked the Departmental Records Officer for sight of any documentation relating to the Hepatitis C litigation audit.
- 41. Brendan Sheehy, Head of Records and Legacy (Departmental Records Officer) and Roseanne Pratt, Records Review & Disposal Manager at the Department of Health and Social Care forwarded the exhibits that I have attached to this statement.
- 42. This contains some information about the review undertaken but it is not logically presented, and I have no assurance that this is a complete file.

#### Section 4: The Audit's Conclusions

13. Please set out as fully as possible what evidence led to the following conclusions and

#### beliefs set out in the report:

(i) The conclusion set out in paragraph 3.1 that 'an arbitrary and unjustified decision, most likely taken by an inexperienced member of staff was responsible for the destruction of a series of files containing the minutes and background papers of the Advisory Committee on the Virological Safety of Blood (ACSVB)' [sic];

(ii) The view in paragraph 3.2 that 'the destruction of these files would have been prevented had the person marking the files for destruction, been aware of their

WITN6955001\_0011

importance'.

(iii) The conclusion in paragraph 4.5 that the decision to mark Advisory Committee on the Virological Safety of Blood papers ('the committee papers') for destruction was probably the result of 'a delegation of responsibilities without proper instruction or an assumption of responsibility without proper authorisation' during the 'upheaval of the FMR process'.

(iv) The statement in paragraph 4.6 of the report that the conclusion reached in paragraph 4.5 of the report was the most likely explanation for both marking the committee papers for destruction and marking them with short destruction dates.

(v) The belief in paragraph 5.9 that marking documents for destruction was 'authorised appropriately i.e. at the level (EO then, IP2 now) the Department considers to be appropriate'.

43.1 am unable to answer this question. The exhibits that I have sight of [WITN6955002-066]do not set out the evidence base in support of the conclusions listed in the question above.

#### Section 5: Other Issues

44. I am not able to provide any more information than that set out in my responses to questions 1 to 13 above. I do not hold any other information relevant to the inquiry. This is all held by the Department of Health and Social Care. When we enquired about the existence of an audit file in respect of the Hepatitis C litigation audit, the Head of Records and Legacy (Departmental Records Officer) provided Exhibits WITN6955002-066. Retention periods for internal audit work are such that in general documents and data that support an Audit opinion are retained for 3 years after the year the audit is completed (in certain instances e.g. audit activities that include the examination of long term contracts the retention periods are longer i.e. 6 years after the year the audit is completed in).

# **Statement of Truth**

I believe that the facts stated in this witness statement are true.

GRO-C

Signed Karen Holland

Dated 6th April 2022

#### Table of exhibits:

Date	Description	Exhibit Number
01/06/2000	Cover page and back page of the 'Department of Health's Resource Management and Finance Internal Audit & Hepatitis C Litigation (Special Review 2000/2001' Folder	WITN6955002
	Contents page on 'Reporting, Planning, Background Research, System Documentation and Testing'	WITN6955003
	Cover page stating "Reporting"	WITN6955004
20/06/1901	File Note by Laurence George; regarding: Implementing recommendations	WITN6955005
	Delegate list for the MIIA Professional Level Support Courses; The Institute of Internal Auditors UK and Ireland	WITN6955006
15/05/2000	Email chain between Department of Health officials: Andrew Cooper, Bill Burleigh, Helen Causley and Laurence George. Re: Hepatitis C Litigation	WITN6955007
11/05/2000	Memo from Alice Perkins to Helen Causley; re: Hepatitis C Litigation. CC'd to Bill Burleigh; Linda Wishart and Steve Wells	WITN6955008
13/06/2000	Interview Record 9; Audit on Hepatitis C Litigation, prepared by Laurence George. Interviewee: Steve Wells	WITN6955009
11/05/2000	Memo from Alice Perkins to Helen Causley; re: Hepatitis C Litigation	WITN6955010

19/04/2000	Memo from Marilynne Morgan to Bill Burleigh and Laurence George; re: Internal Audit Review of the Hepatitis C Litigation. CC'd to Chris Kelly and Anita James	WITN6955011
17/04/2000	Email from Laurence George to Steve Wells; re: Hepatitis C Litigation	WITN6955012
17/04/2000	File Note from Laurence George; re: Meeting to discuss an action plan	WITN6955013
10/04/2000	Email chain between Department of Health Officials: Bill Burleigh, Laurence George, Helen Causley, Martin Pitcher, Chris Kelly, Andy Cade, David Clark and Andrew Cooper. Re: Loss of papers and the Hepatitis C Litigation	WITN6955014
01/04/2000	Internal Audit Review Hepatitis C Litigation Final Report; by the Department of Health. Head of Internal Audit: Bill Burleigh; Auditor: Laurence George	WITN6955015
06/04/2000	Memo from Steve Wells to Laurence George; re: Internal Audit Review - Hepatitis C Litigation - Draft Report. CC'd to Linda Wishart, Annette Greenwood and Jill Moorcroft. Report states that "maintaining official records" is given the lowest possible profile in the core competence framework. Also mentions the quote from Steve Wells that "record-keeping is simply not taken seriously enough in the Department", asks for this quote to be revised by Laurence George.	WITN6955016
05/04/2000	Email from Laurence George to Steve Wells; re: Hepatitis C Litigation - Internal Audit Draft Report	WITN6955017
01/04/2000	Internal Audit Review Hepatitis C Litigation Draft Report; by Department of Health	WITN6955018
	Handwritten note containing Bills Comments on draft 3	WITN6955019
	Cover page stating "2" and "Planning"	WITN6955020
04/04/2000	Email chain between Department of Health officials: Sammy Foster, Bill Burleigh and Laurence George. Re: Hepatitis C Litigation - audit review	WITN6955021
03/04/2000	Email from James, Department of Social Security, to George Laurence. Re: Your audit review	WITN6955022
31/03/2000	Email from Jill Moorcroft to Laurence George; re: Reporting to the Permanent Sec	WITN6955023

28/03/2000	Email chain between Department of Health officials: Sammy Foster and Bill Burleigh; regarding the Hepatitis C Litigation: Audit review	WITN6955024
24/03/2000	Fax from Laurence George to Anita James; re: Attached terms of reference	WITN6955025
	Terms of Reference for the Internal Audit Review - Hepatitis C Litigation	WITN6955026
20/03/2000	Email from Bill Burleigh, to Pat Troop, (cc'd Laurence George and Roman Pronyszyn), re: draft terms of reference: audit investigation, loss of documents relating to hepatitis C litigation	WITN6955027
	Terms of Reference, Internal Audit Review - Hepatitis C Litigation	WITN6955028
13/03/2000	Email from Bill Burleigh, to Sammy Foster, (cc'd M.A. Morgan, Charles Lister, Pat Troop, A. James, David Clark, Flora Goldhill), re: Hep C Litigation: audit review	WITN6955029
09/03/2000	Email chain between Linda Wilson, Bill Burleigh, Sammy Foster, M.A. Morgan, (cc'd Charles Lister, Pat Troop, A. James, David Clark, Flora Goldhill), re: Hep C Litigation	WITN6955030
	Fax from David Clark/Linda Wilson, to Bill Burleigh, re: request to call David to discuss document	WITN6955031
08/03/2000	Memorandum from Marilynne Morgan, to [unknown], copied to Anita James, Charles Lister, Pat Troop, re: Hepatitis C Litigation, annotated by Sammy Foster	WITN6955032
06/03/2000	Letter from Anita James, Department of Health, to Deas Mallen Souter, re: Hepatitis C	WITN6955033
07/03/2000	Letter from Deas Mallen Souter, to The Office of the Solicitor, Department of Health, re: hepatitis generic	WITN6955034
	Cover page for Background Research, 3	WITN6955035
16/05/1994	Memorandum from G. A. Hart, to all DH Staff, re: Departmental Document Management Initiative	WITN6955036
01/11/1998	Leaflet on Record Keeping in the Department of Health, November 1998	WITN6955037
	Contact details for the Department of Health	WITN6955038
16/05/1989	Cover pages for the Advisory Committee on the Virological Safety of Blood files, 16/05/1989- 06/04/1992, volumes 4-17	WITN6955039
24/02/2000	Email chain between Charles Lister, Laurence	WITN6955040

	George, Ann Willins, Gwen Skinner, DRO File Requests, re: file requests	
01/02/2000	Management of Electronic Documents Strategy (MEDS), ISD4C Record Management Services, February 2000	WITN6955041
01/08/1999	Management of Electronic Documents Strategy: Information, Management Standards, ISD4C MEDS Team, August 1999	WITN6955042
03/03/2000	Memorandum from Charles Lister, to Anita James, (cc'd Mike McGovern and Gwen Skinner), re: HCV Litigation: Discovery	WITN6955043
31/03/2000	Email from Annette Greenwood, to Laurence George, (cc'd Roseanne Pratt), re: destroyed files in the GEB series	WITN6955044
19/03/1999	Health Service Circular HSC 1999/053, Managing records in NHS Trusts and Health Authorities, 19 March 1999	WITN6955045
	Documentation Chronology, Hepatitis C Litigation, 1988 - March 2000	WITN6955046
	Table recording when volumes were closed, sent to DRO and destroyed	WITN6955047
17/02/2000	Email from Tracy Dickens, to Paul Hiscox, Stuart Cunningham, Fred Borrows, Naresh Chohan, re: ROIS seminar	WITN6955048
	Cover page for System Documentation	WITN6955049
16/03/2000	Interview record 1 - Hepatitis C Litigation audit, auditor: L. George, interviewee: Mark Gidden, re: to arrange a meeting to discuss the background	WITN6955050
00/00/0000	Interview record 2 - Hepatitis C Litigation audit, auditors: B. Burleigh, L. George, interviewee: Pat Troop, re: To discuss and agree the Terms of	
23/03/2000	Reference for the review Interview record 3 - Hepatitis C Litigation audit,	WITN6955051
23/03/2000	auditor: L. George, interviewee: Yvonne de Samparo, re: to understand Yvonne's involvement in the search for papers	WITN6955052
28/03/2000	Interview record 4 - Hepatitis C Litigation audit, auditor: L. George, interviewee: Anita James, re: to understand the history and background to the present situation	WITN6955053
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