UNDER THE HEALTH AND DISABILITY SERVICES ACT 1993

IN THE MATTER OF THE MINISTERIAL INQUIRY INTO THE UNDER-REPORTING OF CERVICAL SMEAR ABNORMALITIES

AFFIDAVIT OF SANDRA MARY MATCHAM

MINISTRY OF HEALTH

and

HEALTH FUNDING AUTHORITY

I, **SANDRA MARY MATCHAM** of Wellington, public servant, swear as follows:

1. My name is Sandra Mary Matcham. I have been employed as National Register Co-ordinator for the National Cervical Screening Programme (NCSP) since July 1994.

2. The evidence I am providing to the Inquiry is based on my own personal experience in the position; what I have read in files and other documentation as well as information I have gathered from others in the NCSP, specifically in the regional co-ordination sites. This evidence responds to the request for specific information about the Register from Counsel Assisting on behalf of the Inquiry Panel.

3. In particular, the evidence expands on that given by **Judith Margaret Glackin** (see Part III of her evidence in chief) in relation to the following information requested by the Panel:

   3.1 How did the 14 [regional] Registers operate in practice?

   3.1 What quality assurance measures were implemented in relation to the Register, when and who monitored/audited these?

   3.2 What steps were taken to ensure compliance with the mandatory reporting of histology after 1993?

   3.3 Brief outline of how the 14 [regional] Registers functioned against the "acknowledged requirements" of the NCSP (e.g. correlation of histology/cytology results, previous smear histories etc) including recall mechanisms.

   3.4 How many letters have been sent out, and how have they been actioned/activated?

3.5 Did the Register act as a back-stop to the recall system of the smear-taker, or how else was it intended to operate by way of recall?

3.6 Outline how ethnicity information is/was determined and entered on the Register, and how reliable that data is.

4. I have attempted to structure my brief to give an overview of the operation of the National Cervical Screening Register ("the Register") while, at the same time, addressing the specific points raised, under the following headings:

4.1 My background and role as Register Co-ordinator.

4.1 Overview of how the Register works.

4.2 Initial Register Implementation.

4.3 Register development and co-ordination.

4.4 Difficulties with the Auckland site.

4.5 Laboratory request (enrolment) forms.

4.6 Register letters

4.7 Register reports

4.8 Transferring women between sites.

4.9 Reconfiguration of the Register.

4.10 Statistical extracts and statistical reporting.

4.11 Histology.

4.12 Reliability of data.

4.13 Access to information.

4.14 How the Register works now.

MY BACKGROUND AND ROLE AS REGISTER CO-ORDINATOR

5. As with the NCSP itself, the position of National Register Co-ordinator was originally based in the Ministry of Health (MOH) until April 1998 when it moved to the Health Funding Authority (HFA). My job description is exhibit **JMP/HFA/0008** to Dr Julia Peters' evidence. This job description has not changed since I took up the position in July 1994.

6. From July 1994 until approximately July 1996, the position of Register Co-ordinator reported to the NCSP National Co-ordinator. The NCSP national team was then within the Population Health section of the Health and Disability Services Policy Support Group within the MOH. Restructuring within the MOH in November 1995 saw the Population Health section disbanded, and the NCSP moved into the newly formed Prevention Policy section of the Public Health Group. In approximately July 1996, there were substantial changes to the job description of the National Co-ordinator, and the reporting line for the Register Co-ordinator position was transferred to the Manager of the Prevention Policy section, then Judy Glackin.

7. In April 1998, the NCSP national team transferred from the MOH to the HFA. During the transition of the four RHAs into the single HFA, the Register Co-ordinator reported jointly to the General Manager of Corporate Services and the General Manager of Public Health. From October 1998, this changed so that the Register Co-ordinator reported to the Manager of Information Management within the Corporate Services group. On 13 March 2000, the position was again transferred and now I report to the Manager of the Change Management team within Public Health.

8. My background has been within the IT industry from 1969 until 1976, and again from 1987 to date. I have had experience at all levels of application programming and design as well as management of support facilities for end users. I also have experience of project management for a range of project sizes. I have eleven years experience of Unix systems and

relational databases as a project manager, software development team leader, and as a national technical support manager. I have also trained application end users and Unix and database management personnel.

9. The key skills I brought to the position were:

9.1 experience in the Unix operating system;

9.1 experience in the Ingres database management system;

9.2 experience in running a support and helpdesk facility;

9.3 experience in project management.

10. I was the first MOH employee in the role of Register Co-ordinator. Previously, the Register had been managed on contract by a consultant from Azimuth, an organisation specialising in information technology. At the time, two other staff were employed to work on the Register; a technical support person on a one year contract, and an Ingres programmer also on a short term contract. The MOH wished to employ permanent staff in all three positions and I was to advise on the recruitment of a programmer and a permanent technical support specialist.

11. We remained a team of three until October 1997, with additional staff employed on contract during the re-configuration process. Our technical support specialist resigned in October 1997. As the workload had initially reduced at the completion of reconfiguration, and knowing that we were soon to be transferred to the HFA, it was agreed between myself and my manager that we would not replace the staff member. The role previously taken by that person was split between the two remaining staff; the application programmer and myself.

12. To fulfil the role of Register Co-ordinator, it was essential that I learnt and understood the coding systems used for cytology (Bethesda) and histology (SNOMED) and the logic behind the functions of the Register as a live, operational transaction database, and I undertook to do this as soon as possible.

13. With the assistance of the two staff, my priorities were to:

13.1 maintain the 14 regional databases in an operational condition;

13.1 prepare for the “re-configuration” into a single database;

13.2 enable the Register to accept histology results and attach them to women's records.

14. In addition to these three priorities, specific tasks of the Register Co-ordinator position included:

14.1 leader of the team of programmer and technical support;

14.1 manage the helpdesk support for the regional users;

14.2 analyse problems and requests to change the Register application software;

14.3 oversee all development work and manage application upgrades;

14.4 oversee all hardware used by the regions, provide assistance where these needed replacing or upgrading;

14.5 project management of the preparatory work towards the reconfiguration of the system and subsequently the full re-configuration;

14.6 work with laboratories (when requested) who were developing systems to enable electronic download of results;

14.7 answer any questions about the coding system used within the Register and the Register's interpretation of the codes;

14.8 ensure the Register reflected the current expert recommendations for screening and management of women with abnormal smear results.

15. The two previous paragraphs outline the official responsibilities which I took on in the role of Register Co-ordinator. When I started the job, I soon

found that there was another priority which had to be considered above the others, and that was keeping the Auckland site operating. I refer to this issue later in this evidence.

16. In the six years I have been in the position, the basic tasks for the National Register team as mentioned above remain the same. We have moved away from supporting 14 remote databases, towards direct support of the central database with networked access, as the Register is now fully operational as a National database. The regional co-ordination sites no longer have the responsibility for backups, database administration or system upgrades. These are all managed centrally. This has meant additional work in systems administration, database administration and network support, but a reduction of telephone support for regional database hardware.

17. All requirements of the Register, other than regional data processing, are performed by the National Register team which comprises myself and one other staff member who does application programming as well as most of the technical support. We are now an integral part of the Change Management team within the Public Health Group in the HFA.

Overview of how the Register works

18. This is also described by Judy Glackin in paragraphs 210 to 224 of her evidence in chief. The Register is a clinical management tool for the Programme and a backup to other recall systems. It comprises information on women who have had smears or cervical or vaginal histology, the smear results and the histology results. Any woman can request that her results are not sent to the Register at the time of the smear test or the taking of histology. The laboratory forwards all other results to the Register. Any woman who has been enrolled in the Programme may request that all her information is removed from the Register if she wishes to. We prefer that these requests be made in writing to the regional co-ordination site where she is enrolled.

19. Information is entered onto the Register in two ways; on-line data entry for women's demographic information, and from floppy disks for result

information. Women's personal details are data entered by regional co-ordination site staff using information from the laboratory request form. Each woman has a unique identifier. Both cytology and histology results are forwarded on floppy disk, to the regional co-ordination site, by the laboratory which has read the smear or histology, unless requested otherwise by the woman. This information is sent to the regional co-ordination site electronically, as a file of results on a floppy disk, which is read into the database and validated, as there is no facility to directly data-enter Result information onto the Register.

20. The information on the file is validated against that already on the database. Validation is explained more fully under the heading "Reliability of Data". Each result is then attached to a woman's existing information using the unique identifier. Appropriate letters are generated, and sent to the women. As a smear-taker is the primary contact for all women, all letters for abnormal results are held at the regional co-ordination site for up to 10 working days. This is to allow the smear-taker time to speak to the woman before she receives the letter, which should be sent within 20 workings days. I am aware that there is some regional variation in this practice, depending on the time it takes the results to be sent to the regional co-ordination site and the smear-taker.

21. If the result is abnormal, a flag is set which triggers the 'follow-up' process. By a series of reports, the woman's progress through further diagnosis and treatment is followed. Once she has been confirmed as having been referred to a specialist, either by the smear-taker or clinic, she is removed from the Register recall, or "signed out". Any subsequent results that are received at the regional co-ordination site are processed, but no letters will be sent to her until treatment is completed. Once the regional co-ordination site has received confirmation either from the clinic or smear-taker, that the woman has completed her treatment, she is returned to the Register recall system.

22. If the regional co-ordination site cannot establish that the woman has been referred, or she has not turned up at a clinic, the staff will make a special

effort to track her in case she has not realised the situation, or has left the region.

23. The Register is also designed in such a way that the information stored can be made available for monitoring in a form that does not identify women.

Initial Register implementation

24. The National Cervical Screening Register was implemented as an Ingres database running on SCO Unix PCs in approximately 1990.

25. The Register application (software) was developed centrally and distributed to 14 personal computers running in the former Area Health Boards (AHB). The database design was the same on each computer. I understand that database and system backups, database maintenance and system administration were done by senior Register staff at each regional co-ordination site, to specifications provided by the MOH (previously by the Department of Health). Copies of early documentation for the Register are exhibited to this affidavit as follows:

    25.1 Compendium of Azimuth reports (October 1989-June 1990) including Standards Documentation, Technical Documentation, Data Dictionary, Index to Users Manual etc, as exhibit **SMM/HFA/0001**.

    25.1 Standards Manual (27 November 1990) as exhibit **SMM/HFA/0002**.

    25.2 User Manual (1 December 1993) as exhibit **SMM/HFA/0003**. This is the earliest version I have. The contents page of the 1990 Manual is part of the Azimuth reports exhibited above.

26. In 1993, the 14 AHBs were replaced by 23 Crown Health Enterprises (CHEs) now known as Hospital and Health Services (HHS). The regional co-ordination sites continued to be located in 14 of these CHEs.

27. At each of these sites the Register, although an IT based environment, was not the direct responsibility of the CHE Information Technology departments. The Register staff continued to take full responsibility for all work on the machines in conjunction with the National Register team (called Register support team throughout this document). Each site had a senior staff member who took the role of "System Administrator". They performed all work requested by the Register support team.

Register development and co-ordination

28. From the time the Register was first implemented, to when I started working for the Programme, several upgrade releases had been undertaken. I understand that the process employed to determine the contents and scope of each software release has not changed very much since 1990.

29. After the initial release of software, changes to the Register application functionality have been driven by suggestions and requests from regional co-ordination sites, and by the need for clinical changes specified by the National Co-ordinator. Two advisory committees, the Cytology Advisory Laboratory Committee (CALC) (later called Cervical Screening Laboratory Advisory Committee (CSLAC)) and the Cervical Screening Advisory Committee (CSAC), met regularly, and at the meetings that I attended, functionality of the Register was discussed and changes were suggested. These committees were disbanded during 1997 and 1998 respectively.

30. The National Co-ordinator met with the regional co-ordination site Programme Managers quarterly. These meetings were usually two full days each. I attended these meetings for all Register-associated items. If Register items were on the agenda, it was usually a clinical-related issue, i.e. how the Register reflected current guidelines for the management of abnormal smears.

31. Regional Systems Administrators (SAs) met six monthly with myself and the National Co-ordinator. These meetings were a full day with the following day being a joint meeting with regional Programme Managers.

The SAs interest was principally in the user interface, as well as the clinical aspects that affected them directly, especially around the reporting abilities. The SAs often discussed the processes they used that they felt worked well, to enable accurate and efficient processing. These meetings continue to be useful to this day.

32. At the meetings with the regional programme staff, my analysis of the impact of any proposed changes to the Register was discussed, and the relative priority established on a consensus basis between the site representatives. This priority was used to determine the composition and timing of software releases. At all times, any changes to Register functionality from a clinical perspective, have been at the discretion of PMs, the National Co-ordinator and recently the Manager of the Change Management team. I would be called upon only to explain whether or not the changes were feasible from a technical perspective and any implications for existing data. Each upgrade release was planned to incorporate all functionality for a specific area of the database, in such a way that the sites gained maximum benefit with minimum disruption at the time of upgrade.

33. In addition there was a continuing dialogue between myself, the National Programme Co-ordinator, laboratories and both Programme Managers and System Administrators from all regional co-ordination sites which ensured that the National Register team was aware of, and responded to, problems of both process and data in a timely manner.

34. All requests for change were, and still are, logged on the “help desk”, and those that were considered urgent were scheduled into upcoming releases of the application. This practice continues to this day, with changes and enhancements requested either by the regional co-ordination sites or the National Co-ordinator. These requests were, and still are, analysed in the same way as those discussed at meetings. The regional co-ordination site representatives request a priority which is assessed along with complexity, redundancy and other functionality requests, and scheduled accordingly.

Any 'bug' report or problem that may affect data validity or integrity is treated as the highest priority for resolution.

35. All PMs and SAs are kept informed of progress on software changes and all application releases are accompanied by full release notes describing the purpose of the change and any changes to processes that arise from the changes. Where clinical changes are to be implemented, both the National Co-ordinator and the PMs have direct input to the business requirements of the changes. Once the scope of an upgrade is determined, programming, unit and system-testing are done centrally.

36. When we had 14 databases, depending on the complexity of the release, sites would schedule the upgrades when they had sufficient spare time and resources available. Consequently, it was possible for a site to be 2 releases behind most other sites. For some releases, which required large amounts of data upgrades, Register Support staff would visit the site if required.

Difficulties with the Auckland site

37. When I took up the position of National Register Co-ordinator in 1994, the systems in use by the 11 smaller regional co-ordination sites were sufficient for their processing requirements. However the Wellington and Canterbury sites were beginning to show signs that their systems would not cope with the volume of work for much longer. The Auckland system had already reached the point where processing was very difficult for the staff, and they were progressively getting behind with the work.

38. Replacing the Auckland computer for one more powerful was not a viable option due primarily to the difficulty in obtaining a more powerful machine that was still compatible with the Personal Computers (PCs) used by the other sites. Compatibility between the hardware used by sites was essential as the software was developed centrally and sent to all sites. Even if the technology could be found, it was perceived that the cost would be prohibitive. The PCs on which the Register was based at all regions were not very powerful and there was not an obvious upgrade path. The MOH

purchased additional "memory" for the Auckland machine to assist in improving processing speed. This eased the situation slightly, but did not cure the underlying problem.

39. Thus my initial efforts were concentrated on improving the performance of the application to assist the Auckland site to function as efficiently as possible, and to enable their computer to maintain the Register until the reconfiguration of the sites could commence. All the changes made for Auckland also formed part of the performance improvements required for re-configuration. It was my responsibility to ensure that both processes could move forward at an acceptable pace, while not losing sight of the need to be able to fully process histology results. At this time, the Auckland register site implemented a two shift operation, including weekends, which allowed the computer to be in use at all times that were not otherwise required for backup and general database maintenance.

40. I believe that, in 1990, the technology platform for the Register could rightly have been seen as state of the art. A similar Ingres database on PCs was being installed in Probation Offices within the Justice Department where I was working at the time. However, by today's standards the IT environment in 1990 was primitive. It would have been technically possible to have networked the regional computer databases to a central site in 1990, but at significant cost. A much larger central computer would have been necessary. Telecommunication lines 10 years ago were many times more expensive than they are today. I expect that the increased risk of exposure of the Register to computer failure as a result of a centralised computer may have been another consideration.

Laboratory request (enrolment) forms

41. The NCSP provides forms for smear-takers to use as laboratory request forms (formerly called enrolment forms). These forms are intended to be filled in when a smear is taken for referral to the laboratory. If completed correctly, they provide all the information required to enrol a woman, or update her information, on the Register. The 3-part laboratory request

form includes a copy for the laboratory, a copy for the Register and information for the woman. It is the preferred form for the Programme. The regional site can provide a pad of forms "over-printed" with the smear-taker's information. Two examples of the form are exhibited to this affidavit as **SMM/HFA/0004** and **SMM/HFA/0005**. Exhibit **0005** is the current form, and exhibit **0004** is an earlier form.

42. Some smear-takers use forms generated by their practice computer systems. Others use the laboratory's own standard test request forms. These forms rarely contain a request for smear history or ethnicity information.

43. A further NCSP form, the Register-generated individual referral form, is available to smear-takers that request it. These forms are tailored to the individual and are generated by the Register when a woman is due for a smear and includes the woman's information currently held on the Register, including the previous smear and histology results. Regional sites have arrangements with local smear-takers as to the use of such forms. These can be generated automatically at the same time, or instead of, the recall report (referred to further under the heading "Register Reports"). The forms are expensive to produce, and can be time consuming for smear takers to file etc. An example of an unused Register-generated individual referral form and an anonymised over-printed photocopy of the form are exhibited to this affidavit as exhibit **SMM/HFA/0006**.

44. From information received from the regional co-ordination sites recently, approximately 72% of smears are requested on the standard NCSP 3-part forms; 8% use Register-generated individual referral forms which include the woman's history; 9% use a laboratory's own forms and 8% use smear-taker practice computer-generated forms. Approximately 3% of results are received without any accompanying form.

45. Where the 3-part laboratory request form is used, the part designed for the Register is sent to the local Register by the laboratory, together with a

floppy disk containing a file of results from the laboratory. If the Register generated form is used, the lower half, which records change of details information, is sent to the Register. If neither of these forms are used, the laboratory is requested to photocopy the information required for the Register from the form used.

46. Some laboratories request the previous smear history of women for whom they read smear slides. Initially, very few laboratories requested this information from the Register, but the number has increased over the years. Provision of this information was, and still is, accomplished by the laboratory sending the part of the Programme request form designed for the Register to the regional co-ordination site before the slide is read. Some laboratories now send a list of patients for whom they require histories, rather than the actual forms. The site would extract the woman's screening history information and forward it to the laboratory. Local arrangements were, and still are, in place for this to ensure an acceptable turn-round time. However, until the 14 registers were combined, the regional co-ordination site could only give smear histories of women who were enrolled in their region. Since 1997, data for the whole country can be accessed from any regional co-ordination site.

47. In November 1998, the Register was updated to comply with the updated Recommendations for Cervical Screening, and Guidelines for the Management of Women with Abnormal Smears (exhibit **JMG/MOH/0050**). The revised Guidelines took a new approach to the treatment of certain abnormalities. Previously, wherever an abnormality had been detected and treated, annual screening was recommended post-treatment. Under the revised Guidelines, following detection and treatment of low-grade abnormal cytology or histology, a six month smear is recommended and, if normal, then two annual smears. After three normal smears, the Guidelines recommend a return to three-yearly smears.

48. This change required that the Register had the history information as accurate as possible. For some women on the database, the history was stored as abnormal, but the abnormality and approximate date was

unknown. The women's smear takers were requested to provide this information. The outcome showed that many smear-takers did not appear to know the screening histories of their patients.

49. Laboratories were also encouraged to request the smear histories from the Register before processing slides, so that the correct management recommendation could be given according to the woman's previous history and current smear result. The Register is programmed to compare all result recommendations against other information on the database. If a combination of the previous history and current result would give a different recommendation according to the Guidelines, the Register will report the difference for manual checking. As I have indicated, not all laboratories request smear histories yet, but the number is increasing. Ideally, laboratories would be able to access the Register directly. Functionality for laboratory access has been available for over a year, but the technical networking requirements and issues of data access and protection have yet to be addressed.

50. Once the forms and results have been received at the regional site, the forms are used for data entry to enrol a woman onto the Register, or to maintain her information if she is already enrolled. The forms are also used as a crosscheck to ensure a result is received for every smear. Forms for smears which have been requested not to come to the Register (i.e. the woman has "opted off") are retained by the laboratory. The result information supplied on the disk is validated, and errors corrected by regional staff. The Register Protocols Manual describes the type of errors reported and what should be done to correct them. A copy of the current Manual, used by regional staff and explaining process requirements and quality/validation checks is exhibited here as **SMM/HFA/0007.** Site and Register data quality processes are described in the Data Quality document. A copy is exhibited hereto as **SMM/HFA/0008**. Once all the data for the current smear result is confirmed as valid, the result can be attached to the woman's record. This is done as a batch process once the user decides that no more errors can be fixed.

51. Any errors that cannot be corrected by the regional co-ordination site, including invalid or incompatible combinations of Bethesda codes, are reported to the laboratory. The site liases with the laboratory for these results to be corrected and re-sent. There are two methods for ensuring that no invalid results are lost or remain outstanding. One is a check of the laboratory request forms that have not been matched to a valid result. The other is by querying the database, which holds a record of all rejected results until a valid replacement is entered. A list of the outstanding information can be printed and sent to the laboratory. Frequency of this varies at each site and with the number of invalid results received. Most would check at least every six months.

52. I understand that at the beginning of the Programme, most smear-takers used local laboratories, and consequently most sites would only receive results from laboratories located within their immediate region. There was a close relationship between the regional co-ordination site and the laboratory and problems could be resolved relatively easily. However, I understand that due to some laboratories no longer processing cytology, and increasing competition between laboratories, there is an increasing trend for smears to be sent to laboratories away from the region, making liaison more difficult. This reduces the effectiveness and significance of good relationships between regional sites and their local laboratories, which have historically worked together at resolving errors and problems, and requires greater emphasis on the provision of full, accurate information by those involved at each step in the screening pathway.

Register letters

53. Result letters generated by the Register fall into different categories, some of which are only sent when the initial smear result is processed onto the Register. Other categories are sent for all results received, and others are optional, with the regional co-ordination site determining if the latter is appropriate in their region. A list of the various letters and their categories, plus examples of standard letters (anonymised) is exhibited to

this affidavit as exhibit **SMM/HFA/0009**. The letter category is the last four digits of the “phone” entry at the front of each letter.

54. General letter categories are:

53.1 Result is “normal” (500) – letter only sent on enrolment.

54.1 Result is “normal”, previous smear more than five years ago (1000) – letter is always sent.

54.2 Result is "normal", first smear on register (1500) – letter only appropriate on enrolment .

54.3 Result is "normal", there have been 3 normal smears since low grade abnormality (800 / 850) - letter only appropriate on subsequent smears.

54.4 Result is “normal”, previous abnormal history (2000 / 2500) – letter only sent on enrolment.

54.5 Result is “normal”, but smear is “satisfactory but limited” (3000) – optional.

54.6 Result shows infection or inflammation (4000 / 4250 / 4500 / 4750) – optional.

54.7 Result is ASCUS or Low Grade, no referral is required (6000 / 7000) – letter is always sent.

54.8 Result is ASCUS or Low Grade, referral is required (8000) – letter is always sent.

54.9 Result is High Grade, referral is required (8500) – letter is always sent.

54.10 Unsatisfactory smear (9000) – letter is always sent.

54.11 Three consecutive unsatisfactory smears, referral required (8900) – letter is always sent.

54.12 Welcome letter for women who have been previously enrolled with a histology result and the first smear has been received while still in treatment (9500) - letter only sent on first smear.

54.13 Letter containing no result (0) - letter only sent on enrolment

55. The Register also generates reminder letters for women with an abnormal history who are three months overdue for a smear, or six months overdue with a normal history. The system only generates one recall letter for each woman automatically, but each site can request another letter for any woman if they are notified of a change of address or if they consider a second or subsequent letter is appropriate for any other reason.

56. Once the batch process has completed attaching the results to the women's records, letters can be generated for the women. A “Welcome letter” is sent to all women when their first smear is processed on the Register. This letter usually contains the result of the smear. However, in some (rare) circumstances, when the combination of codes reported by the laboratory does not allow for the Register to give a result, the letter simply suggests that the woman should speak to her smear-taker. An example might be when an 'enrolment' smear was taken by a specialist, was not abnormal, and the laboratory has given a B2B13 recommendation code, indicating that the specialist will determine the woman's next recall and inform her of the result. The “Welcome letter” also contains the woman’s personal details held on the Register and explains how the woman can correct any missing or incorrect information.

57. Letters are also sent when the result is not completely normal, or when this result, along with previous results indicate that a referral to a specialist is indicated. These letters are not sent immediately, but are held by the regional co-ordination site for at least 10 days after the smear date, to enable the smear-taker to speak to the woman first. Some regional co-ordination sites contact the smear-taker before sending the letter. Again, the particular category of letter is determined by the Register according to protocols. The “Result” letter also contains the woman's personal details

held on the Register and explains how the women can correct any missing or incorrect information.

58. Letters for women whose results, other than the first received by the Register, are satisfactory but limited, or show infection or inflammation, are sent by some sites whilst others prefer not to send these specific letters. They are an option on the Register. In the early days of the Register, I understand that all results were always advised by letter, but this practice has ceased.

Register Reports

59. The Register can produce some 45 reports, some of which are available in different formats and giving a different range of information. A list of the basic reports is exhibited to this affidavit as **SMM/HFA/0010**. A further description of available reports is contained in section 14 of the Register Protocols manual (exhibit **SMM/HFA/0007**). A number of key reports are described as follows.

Individual Woman's Details Report

60. The Individual Women's Details Report contains a summary of the information held on the Register about a particular woman. A copy of an anonymised report is exhibit **SMM/HFA/0011** to this affidavit. The information is presented in a number of sections.

61. The first, headed "Eligible Woman Record Data", contains the latest information held on the Register.

62. The second section, "Name(s) on Data Base", contains the names which have been entered against this woman at different times. This is to ensure name changes are recorded.

63. The third section, "Addresses on Data Base", show all addresses given since enrolment and the date and time these addresses were entered on the

data base. "Domicile Code" means the coded area of the country where the woman lives. This is used to ensure her information is attached to the correct regional Programme site, and to ensure she is included in the correct local area for statistics.

64. The next section, "Nominated Smear Taker(s)/Health Centre(s)", identifies the smear taker etc by code. Each smear taker has a particular code.

65. The next section, "History of Status Codes", records the status of the woman at the date entered. "SGNOUT", or sign out, means the woman is attending a specialist for treatment. Letters will not be sent while the woman remains signed-out.

66. The next sections record the Smear Record Data for each smear. "Smear technique" is an indication of the implement used. For example, "S" is "spatula", "B" is "both spatula and cytobrush, "C" is cervix broom, "T" is spatula and cervix broom, "V" is cervix brush and "O" is "other". "Smear site" indicates the site from which the smear was taken – "R" is for cervix, "T" is for top of the vagina. "Adequacies" use the "A" codes from the Bethesda system, "Recommendation" is the "B" code and "Diagnosis" the "C" codes. "C1*" indicates infection, "C2*" reactive/repair and "C3*" abnormal.

67. A letter was sent to the woman only if the words "letter sent" and a date appear in the right hand column of the Smear Record Data section. If so, then the letter category in the left hand column indicates by category which letter was in fact sent on that date. The categories are referred to by the three or four digit number referred to above. The letter is sent to the last address recorded for the woman at the time (see third section).

68. After the Smear Record Data is recorded, the Cytology Abnormal Follow-up Referral Record Data, if any, appears. This is entered when a woman has been referred for further diagnosis and treatment.

69. An estimated "sign in" date is given so that the Register is able to check that the woman has in fact been referred. The same process applies for abnormal histology.

70. This is followed by the Histology Record Data. SNOMED codes are applied. The records show when the laboratory received the histology and when it was received at the Register. The “Register date” records the date of entry of the information on the Register.

71. Some women also have notes attached to their records. For example, for Gisborne women there might be a reference to the Sydney re-read results where the results have not yet been entered onto the Register.

Abnormal Results Not Referred Report (MF1)

72. Approximately once a month, the sites print reports of women who have had abnormal smear results more than a week ago but have not yet been referred for follow-up. A copy is attached as exhibit **SMM/HFA/0012.** These reports are used to check that all women who have a recommended referral have been given an appointment at a clinic. Sites have developed a variety of relationships with clinics and smear-takers to ensure, as far as possible, that women receive the follow-up that they require. It would be preferable if assessment information was routinely provided to the Register to assist in tracking women with abnormal results.

Delayed Sign-On Report (DSO1 / DSO2) (Women Signed out)

73. Each woman who is referred for further diagnosis or treatment is signed out, or removed from the active recall part of the Programme. Consequently, it is necessary to ascertain when the women is discharged from treatment and should be returned to the recall. Because there is no process for direct data collection from colposcopy clinics, a report is generated by each site, which shows all women who have been in treatment over a certain period. An example is exhibited as **SMM/HFA/0013**. This period ranges from three to twelve months and is set locally, depending on the waiting times for appointments in their local

clinics. Similar arrangements are in place for these reports as are used for confirming referral of women with abnormal results, referred to above.

Smear Takers Recall Reports (SRR)

74. The Register can print recall reports for smear-takers or health centres if required. These reports contain a list of women who are due for a smear in the month(s) requested. Most regional co-ordination sites liase with the health centres and print these reports for those that find them useful. Some centres prefer to use their own systems. The reports are usually printed up to three months in advance of the smear due date. An example is exhibited as **SMM/HFA/0014.**

Overdue Cervical Smear Reports (OCS)

75. Overdue reports list all women who are more than three months overdue for a smear with an abnormal history. An example is exhibited as **SMM/HFA/0015.** This report is designed to be sent to all smear-takers at least quarterly. All woman who are overdue will continue to appear on this report until either she has a smear, or the Register is informed that the smear-taker has been unable to contact her and no longer considers her their patient. The woman will then be removed from this smear-takers recall list.

76. As far as I am aware, it has always been an understanding amongst those working in the Programme that the last four reports mentioned above are the most important reports the Register produces for a woman's safety. Two are designed for tracking women with abnormalities, and the other two are for recall.

77. The Register also provides Quality of Smears reports for smear-takers, and Cytology correlation with Histology reports for laboratories. Examples of these reports are exhibited to this affidavit as **SMM/HFA/0016** and **SMM/HFA/0017** respectively. These reports are referred to later in this evidence.

78. Further samples of different reports are provided as exhibit **SMM/HFA/0018.**

Transferring women between sites

79. Prior to re-configuration of the Register, a site established that a woman had left their region in a variety of ways. This included being informed by the woman directly that she was moving regions, a message from a smear-taker while processing recall or overdue reports, or another region informing the site that a woman had moved.

80. Before re-configuration, the only way to get information from one region to another was by copying the woman's details onto a floppy disk, which could be read into the database by the other region. Her status then became “TRANS” (for “transferred”) at the original site, and she took on an “active” status at the new site.

81. As databases were merged into the central system, transfers between sites could, and can, be initiated by either the original site or the new site, and are automatic with a change of address.

Re-configuration of the Register

82. In 1994, my priority task was to combine the 14 regional registers into a single database. Before we could consider this, we had to ensure that all sites were using the data in the same way. Information that was shared by all sites, but had evolved differently, was standardised. This included a very significant task to standardise the use of smear-taker and health centre (clinic) identifiers.

83. Whilst the application was the same in each area, the way each site used some of the information had evolved differently depending on regional requirements. This was mainly in the way that the smear-taker identification was used, and the way sites worked with the providers and clinics in their region. This was all within a well understood national framework and all basic principles were complied with, but it allowed for an inconsistency in the data. For example, the smear-taker identifier had

to show both who the smear-taker was and what health centre or clinic they worked at. As many smear-takers worked at more than one health centre or clinic, coding practices had been set up so that the staff were able to group the smear-takers either by the individual, or by the health centre where they worked. This had been done in different ways, and was much easier in smaller sites, and almost impossible in larger sites due to the number of health centres required.

84. We had one major release of the Register application that was designed to convert all the smear-taker identifiers currently in use by the 14 sites into a common standard that could give us the ability to aggregate by individual smear-taker and by health centre. This enabled much tidier reports to be produced at both smear-taker and health centre level.

85. After this release, changes required to ensure that multiple sites could access a single database progressed, and in May 1996 the first site (Otago) was "cut over". Teething troubles were ironed out and in July we started merging other sites into the central system, starting with Auckland. We found considerably more duplicates, based on NHI number, between the Registers than we had originally anticipated. These were checked and all information amalgamation completed before we went on to the next site. The order of sites was determined by the size of the local database, and the perceived ability of existing hardware to continue to function.

86. By commencing the merging of sites with the larger and ending with the smaller, the greater amount of data was available centrally from the start of re-configuration. It was essential to get sites with potential hardware failures amalgamated as soon as possible. West Coast and Tairawhiti were the two smallest regions and also had computers which were functioning with no known problems. Therefore, they were chosen to be the last two sites to be amalgamated. The exercise was completed by March 1997.

87. Once re-configuration was complete, laboratory reporting pattern reports containing national averages were available to all laboratories, and quality reports containing national averages were available to all smear-takers.

Smear history information was available to any site, and consequently to all laboratories and smear-takers, for any woman enrolled on the Register. Women transferring between regions no longer had to be removed from one region and entered onto the other; a change of address and smear-taker being sufficient to transfer all their information to the new region. Women who lived in one region but attended a clinic in another region were easier to track through treatment, and all their results could be added to the system without the need to transfer to the region where the smear or histology was taken.

Statistical extracts and statistical reporting

88. Before re-configuration, monthly statistics of such things as enrolment levels and number of smears processed were run by each individual site, and forwarded to the Register support team for collation into national figures. Since re-configuration, the monthly statistics have been extracted for all sites automatically by processes set in place by the Register support team.

89. The process for extracting data for the NCSP Statistical Reports was to run a special script (a list of programming instructions separate from the Register application) at each site. It would then put the raw data onto tape, which would be sent to the Register support team. The first statistical report **(JMG/MOH/0026)** was completed before I joined the team and I do not know how that was managed. The extract for the second report **(JMG/MOH/0037)** had been planned before I joined the team, but had not at that stage been undertaken. Information was required from each site for all women enrolled up to June 1994 together with their smear results. The extract did not include information for women who had transferred out of a site, as this information was available from the receiving site. Any woman who was unknowingly enrolled in more than one site would have been included in the report twice. With hindsight, these duplications may have been extensive. Once collated, this information was made available to the statistics group in the MOH to produce the report.

90. The data for the third statistical report, covering the period up to December 1995, was extracted during the process of re-configuration **(JMG/MOH/0051)**. Information was extracted directly from the central database for those sites that were already merged. The sites that were working individually extracted their information in a similar manner to that for the previous report. This report was treated differently as, once collated, the information was forwarded to the Public Health Intelligence group within the MOH who worked to remove known duplicates before preparing the report. Consequently, this report was based on much cleaner data than the previous report. Some unknown duplicates were nevertheless included in the report.

91. From the data collected for the third report, additional "reporting patterns" statistics were provided for each laboratory against a national average. This was the first time laboratories had been given their data with a national comparison.

92. Information was extracted for the Maori statistical report somewhat later, in December 1998, covering the period up to December 1995. This information was collated in table format as defined by the MOH, and forwarded for inclusion in the report.

93. There are discrepancies between the Third Statistical Report and the Maori Statistical Report, published in 1999. These are mainly due to the timing of the extracting of the data, given the continuous updating of the Register database, and continual cleaning of data. Some information has also been presented differently. I have attempted to explain these discrepancies in a separate document, which is exhibited as **SMM/HFA/0019.**

94. In November 1999, data for the statistical report covering the period 1996 to 1998 was extracted. Preparation of this report is currently in progress.

Histology

95. Although legislation for the inclusion of histology results on the Register came into effect in 1993, when I joined the team in July 1994 the majority of laboratories were unable to process the results electronically.

96. It was anticipated that laboratories would update their IT systems in a timely manner. A document located on the HFA computer system containing relevent Ministry files and dated 10 June 1993 records the expectations and recommendations of CALC relating to laboratory compliance with the legislation. A copy is exhibited to this affidavit as **SMM/HFA/0020**. Letters were sent to all laboratories providing a cervical histology service regularly, informing them of the legislation and asking for approximate dates when their systems would be ready. Samples of letters sent, which I have been able to locate, are exhibited to this affidavit as **SMM/HFA/0021**. I am also aware that the issue was frequently raised by the local co-ordinators with laboratories in their regions, and by the National Co-ordinator with the relevant advisory committees and representatives of laboratories.

97. The Ministry organised for additional temporary staff to do SNOMED coding and data entry to enable us to get results onto a disk file for laboratories whose IT systems could not do this. The histology results were forwarded by the laboratory to the regional co-ordination sites on paper, and then forwarded to the Register support team. Until the end of 1998 two temporary staff would work for about six weeks, twice a year, to process the 'hard copy' results. We now contract an experienced person to do this extra work as required.

98. Moreover, it was not until approximately the end of 1995 that the Register was able to fully process histology results and attach them to the woman's details. The Register, as programmed in mid 1994, could accept the histology files, but not attach the results to the woman's information. One of my responsibilities was to complete the histology processing on the Register application. However, due to the other problems we were having

with the system, particularly the Auckland site, and the need to concentrate on the performance of existing functionality, completion of histology processing was delayed.

99. By the time the Register was able to fully process histology results in 1995, there was then a considerable backlog of results to be processed at all sites. Some sites did not have the backlog cleared until late 1996. The Auckland computer did not have the capacity to process or store the histology, and the majority of their histology results were not processed until after they moved to the central system in 1996.

100. Even though the majority of histology results are now sent to the Register electronically, there are still some problems with the software used by laboratories. A few laboratories still do not have software capable of sending results electronically, and some laboratory systems do not send all results electronically, so we still maintain the coding and data entry service, which is done centrally. There are currently five laboratories that do not send any results electronically. Over the last six months, two more letters have been sent to non-compliant laboratories. These are to be discussed more fully by Dr Peters in her evidence.

101. The lack of histology results affected several key areas of the Register.

100.1 Smear history reports did not include this information.

101.1 Only cytology results could be seen on their screens by regional Register staff processing or checking information. There was nothing to show that histology results should have been present.

101.2 Recall date calculation by the Register could not take into account histology results.

101.3 Receipt of histology results gave information that a woman had attended a clinic and thus confirmed that an abnormal result had been followed up. This functionality could not be used.

101.4 Correlation reports between cytology and histology reporting could not be generated.

102. Correlation reports between cytology and histology are now available for the laboratory that reads the cytology (see **SMM/HFA/0017**). This report gives details of the histology results for all women for whom the laboratory in question has read a cytology result in the previous five years. Where there has been a negative smear reported within the 5 years prior to a high grade histology result, that information is highlighted automatically by the Register when generating the report. Although this report is available for every laboratory on request, it is obviously less useful if histology in that region is not up to date on the Register.

103. Histology results are processed onto the Register in much the same way as cytology results, with the exception that letters are not sent for histology. The person managing the woman's assessment and treatment is expected to provide the woman with the appropriate information. The same checks are made as for cytology results to ensure histology information entered is as accurate as possible. It is, however, possible to have multiple results for the same biopsy, so there cannot be any checking for duplicate information.

104. Laboratories are required to send all cervical and relevant vaginal histology results to the Register, including polyps and the cervical component of a hysterectomy, unless the woman objects. However given the numbers of histology results we receive, we believe it is likely that some laboratories are not sending all the results they should. In some areas, we receive very few hysterectomy results, and in others very few polyps.

105. We also suspect that there are some histology results missing as when comparing the women who are referred to colposcopy against those with histology results on the Register, a high percentage are not matched. As we do not receive or store information relating to colposcopy attendance or processes, it is impossible to know if the lack of results is due to the

woman not attending, no biopsy being taken, or the results not arriving at the Register.

Reliability of data

106. While we recognise that some information is missing from enrolment forms (mainly screening history and ethnicity), and that the Register is dependant on the completeness of data from smear-takers and accuracy from laboratories, a combination of factors give us confidence in the accuracy of the data on the Register:

105.1 the Register application is programmed to reject any information that does not meet strict validation rules;

106.1 regional co-ordination sites do considerable manual checking to complete missing and rejected information; and

106.2 random audits and spot checks are performed both by regional co-ordination sites and centrally.

107. Information entered into the Register from laboratory disks has several validation checks, as already discussed (see Register Protocols Manual and Data Quality document, exhibits **SMM/HFA/0007** and **0008**). We have a common problem with matching the identification of smear-takers and health centres received on the result disk with that on the laboratory request form as laboratories often do not update their own records when a smear taker moves to another practice, or works at more than one practice. Errors on the laboratories systems can then be duplicated onto the result disk. These are checked by the site staff, who compare information on the disk with that on the forms they receive. If they are different, those on the disk are corrected to match the form. The Register application can do the initial check if the site wishes to use this option. Identification of the specialist on histology results is a particular problem, as the sites do not always receive forms for histology results.

108. While the Register application can cross validate any information we receive with that already in the database, and against pre-defined rules, we

have not yet been able to check the accuracy of the data as it leaves the laboratory. It is anticipated that future contractual arrangements with laboratories will provide for data audits.

109. Every woman who is newly enrolled is sent a letter asking her to check her personal details. These letters have a form on the reverse on which she can update incorrect information and return to the regional co-ordination site. Sites also receive telephone calls correcting information appearing on letters. Approximately 7% of letters sent to women result in requests to update their information on the Register.

110. It is difficult to know the extent, if any, of data missing from the Register. A woman can request that any particular smear or histology result not be sent to the Register. Any results already on the Register will remain unless the woman requests that all her information be deleted. This can lead to the appearance of a complete history for the woman on the Register, when in fact one or more results may be missing.

111. Of course there is no way of checking whether all results which a woman wishes to come to the Register are actually received.

112. If a result does not have sufficient information available to fully process it, as can happen if there is no accompanying form, it is held within the database until such a time as the information is available. In these cases, regional staff may have to contact smear-takers and wait for information to be provided. This does not hold up the processing of the majority of results. Good relationships with local laboratories have generally assisted workflow at regional sites.

113. Quality of smear reports are produced for all non medical smear-takers and for other smear-takers by request. If the information on this report is incorrect, it gives the smear-taker the opportunity to check the data with the site. Similarly, laboratory reporting patterns reports, both cytology and histology, and the correlation report give the laboratory the opportunity to check that their information matches what they expect.

114. I understand there are data audit processes at regional co-ordination sites of the data entry, but there has been no audit at a national level. The application itself will not allow incompatible information to be stored. The Register is a relational database, and continuous processing of the data requires strict adherence of all integrity rules. The integrity of the data is maintained by the Register application, which ensures that all information dependencies are managed. All regional access to the database is restricted to access using the Register application. Non application access is only available for database maintenance and audit by the Register support team..

115. The database itself is strictly managed. Twice daily backups are performed and one backup for each day is stored off site. The database is maintained twice a week to ensure no internal integrity errors occur. An audit of all data changes is taken, and these are kept for at least 12 months.

116. Periodically, spot checks of the data are carried out either by me or by the other member of the Register support team whilst acting as Database Administrator. These look at areas of the data where strict rules cannot be enforced by the database, and where anomalies could occur. Any problems are reported back to the regional co-ordination sites, and the problem is discussed to try to change processes to save further occurrences. Data is always corrected if errors have been found, and where possible, processes are tightened up at both Register and user level.

117. Approximately 10% of women on the Register have an unknown ethnicity. This is mainly because it is not filled in on the NCSP form or the question is not asked on a practice computer-generated or laboratory form. In these cases, many sites check the National Health Index (NHI) and use the ethnicity recorded there. Regional co-ordination sites have a hierarchy for recording ethnicity on the Register. If Maori is ticked (or named) with or without any other ethnicity, the Register records Maori. If any Pacific Island ethnicity is recorded with or without any other ethnicity other than Maori, the Register records either the Pacific Island generic code or the specific island group on the form. All other ethnicities take a lower

precedence. The Cancer Register uses the same hierarchy rules as the Programme Register. Even though the NHI system stores more than one ethnicity, it uses the same hierarchy as the Register when a single ethnicity is required. A copy of the ethnicity codes is exhibited to this affidavit as exhibit **SMM/HFA/0022**.

Access to information

118. Individual women's information on the Register has been, and still is, available to the woman herself, her smear-taker and the laboratory reading a subsequent slide. This has been the case since I joined the team, and I understand since the Register was first implemented. Access to unidentifiable statistical information has always required specific approval, usually from the National Co-ordinator. For the first and second statistical reports, some sites needed to get approval from their local ethical committee before the information could be extracted.

119. Prior to the re-configuration of the Register, all data requested regionally which was not from a standard report would have required a script to be able to extract the information. The regional co-ordination site would request that the Register support team provide the script with instructions on how to use it. The extracted information would normally be sent to the Register support team for formatting. I can only remember one such request for information that was not subject to further Kaitiaki/Pacific Island controls.

120. Occasionally, smear-takers have requested that their client list information be provided in electronic form to enable them to easily input it into new computer systems. Again, this is done by special scripts, and is now very rare.

121. Since re-configuration, requests are still made in the same manner, but these can now be more easily extracted as the database is available to the Register support team. All such requests have been approved either by the National Co-ordinator, or the Manager, Change Management Team, Public Health (Dr Julia Peters).

122. All requests for statistics based on Maori or Pacific Island ethnicity are referred to the Kaitiaki or Pacific Women's Data Management Groups (PWDMG) and released on their approval.

123. Data for other ethnicities can be released as long as it does not facilitate the calculation of Maori or Pacific Island figures.

124. When the Register moved from the Ministry of Health to the Health Funding Authority, responsibility for the Kaitiaki group stayed within the Ministry, whereas responsibility for the PWDMG transferred to the HFA. Arrangements were put in place whereby all requests to the Kaitiaki Group could be checked to ensure the feasibility of extracting the requested data, before this is presented to the Kaitiaki group. This has worked well in the last two years.

How the Register works now

125. While each site now has the ability to see the records for the whole country, and transfers are automatic with a change of address and smear-taker, little has changed in the functional requirements of the regional co-ordination sites since I have been involved with the Programme.

126. Women's details are still updated, and results, including histology, are still processed and attached to women's information at the regional sites. In each of the last two years over 120,000 "Welcome and "Result" letters have been generated by the register, and over 200,000 "Recall" letters have been generated. The number of new enrolments has decreased over the last two years since over 80% enrolment of women aged 20-69 was reached, but the number of smears taken per year has remained relatively stable at about 420,000 per year.

127. I believe there is still a good relationship between regional co-ordination sites and smear-takers. Reports are now quicker to produce, and some sites have devised different ways to use the reports in order to

accommodate the smear-takers preferences whilst maintaining the safety aspect of the Register.

……

SWORN by the abovenamed deponent at Wellington this day of June 2000 before me:

…….
A Solicitor of the High Court of New Zealand

INDEX TO EXHIBITS

Volume I

0001 Azimuth Report October 1989 to June 1990 (Standards Documentation, Technical Documentation, Data Dictionary, Index to Users' Manual etc)

0002 Standards Manual (27 November 1990)

0003 User Manual, 1 December 1993

Volume II

0004 NCSP three-part laboratory request form (previous)

0005 NCSP three-part laboratory request form (current)

0006 Blank Register-generated individual referral form and anonymised overprinted photocopy form

0007 Register Protocols Manual (current)

0008 Data Quality document (current)

0009 List of Register letters plus anonymised samples of standard letters

0010 List of basic Register reports

0011 Anonymised Individual Woman's Details Report (IWD)

0012 Abnormal Results Not Referred Report (MF1)

0013 Delayed Sign-on Report (DSO1/DSO2) (Women Signed Out)

0014 Smear-taker's Recall Reports (SRR)

0015 Overdue Cervical Smear Reports (OCS)

0016 Quality of Smears Reports

0017 Cytology Correlation with Histology Reports

0018 Further samples of different reports

0019 Explanation of discrepancies between Third Statistical Report and Maori Statistical Report

0020 CALC Recommendations on the Report *"Histology Requirements for the National Cervical Screening Register"* dated 10 June 1993

0021 Examples of letters sent to laboratories relating to electronic transfer of histology

0022 Register ethnicity codes