QUARTERLY (10 JUNE TO 10 SEPTEMBER REPORT) FROM THE MINISTRY OF HEALTH TO THE MINISTER ON THE IMPLEMENTATION OF THE RECOMMENDATIONS OF THE GISBORNE CERVICAL SCREENING INQUIRY REPORT

BACKGROUND INFORMATION

1. In response to Recommendation 46 of the Inquiry Report, the Director General has previously supplied monthly reports to the Minister. In 2002 these monthly reports were replaced with quarterly reporting. This report is the tenth quarterly report and covers the period 10 June 2004 to 10 September 2004.

COMMENT

- This quarterly report provides an update on progress against key milestones and deliverables for those areas of work that remain outstanding and relate to the following areas: the Audit of Invasive Cervical Cancer, legislative changes, NCSP operations, and the development of a Population Health Register (see also Appendix 1).
- 3. Those recommendations that have been marked as completed or implemented are attached as Appendix 2.

Cervical Cancer Audit

- 4. The draft Audit report is now out for peer review and stakeholder comment on matters of fact.
- 5. Communications planning is continuing.
- 6. The most recent multidisciplinary advisory group and liaison group meeting took place in September 2004.

Legislative Change

- 7. The NCSP Legislation Implementation project continues with good progress in all four areas Policy, Operations, Communications and Information Systems.
 - Policy Three key policies have been completed, Enrolment, Withdrawal and Re-enrolment policy, Process for Appointment of NCSP Manager and Roles and Responsibilities. It is expected that the remaining 4 policy areas which are less complex will be completed within the timeline.
 - Operations The NCSP-Register letters and forms have been finalised and will now be pretested. The colposcopy dataset has been through external consultation and finalised. Work is underway to ensure there is alignment between the colposcopy dataset and the current DHB contract monitoring reporting requirements.

- Communications The key messages for women and providers, fact sheets, and Q&A's have been agreed. A special edition of the Screening Matters Newsletter has been finalised including an article about screening issues for Māori women. The planning for the information for providers, and for the training of regional services and Independent Service Providers (ISP's) is well underway.
- Information Systems Functional requirements and a timeline have been agreed and work is progressing according to this. Development work on the information system in the key area for the enrolment, withdrawal and the re-enrolment process is underway.'
- 8. The NCSP is finalising a Health Report to accompany the general letter to all women on the Programme which is now ready for consultation with other political parties as requested and for pretesting with women.
- 9. Following the passage of the Health (National Cervical Screening Programme) Amendment Act, the Ministry of Health has consulted on the changes that should be made to the Health (Retention of Health Information) Regulations 1996 as part of the broader consultation on the Review of the Regulation of Human Tissue and Tissue-based Therapies.
- 10. The Ministry has sent the Human Tissue Review Summary of Submissions document to everyone who made a written submission or attended a consultation meeting. The document is also available on the Ministry's website. The Ministry will be meeting with key experts from the sector on 12 and 21 October to discuss the Ministry's proposed policies for therapeutic and non-therapeutic uses of human tissue. Both days will consider the Ministry's proposed informed consent framework for use of tissue in the morning and proposed regulatory frameworks in the afternoon. Sector feedback on the impact of the proposed policies will be used to inform the Ministry's policy development for the Cabinet papers.

NCSP Operations

- 11. The review of Chapter 5 of the NCSP Operational Policy and Quality Standards "Providing a Laboratory Service" is continuing. A first teleconference for the Laboratory Working Group is being organised for November. The Chair of the Royal Australasian College of Pathologists (RCPA) has agreed to lead the working group. The establishment and policy for the competency assessment of practitioners and liquid based cytology standards is being incorporated into the new chapter.
- 12. The review of Chapter 4 "Providing a Smear -Taking Service" has been scoped. This project will include involvement of the sector.
- 13. The preferred provider for an NCSP Independent Monitoring Group has now been selected and contract negotiations are underway.

Ongoing Implementation of Workforce Development Projects

- 14. The NCSP Cytology Training Group met for the final time in September 2004. The group has provided valuable oversight and leadership to the laboratory workforce initiatives in collaboration with the NSU and has completed their workplan.
- 15. The Vocational Registration Programme in Cervical Cytology (previously known as the Standard Orientation Programme in Cytology) is progressing. The printing of the logbook has been delayed due to final editing changes and late sector feed back, the log book will then be printed and distributed to Laboratories. The workbook and answer-book is undergoing revision following editorial peer review. The Clinical Training Agency (CTA) has now approved funding for up to eight new Bachelor of Medical Laboratory Science Graduates to train in cytology. Laboratories have been informed that funding will be available from 30 November 2004 and CTA report inquiries from several laboratories.
- 16. The NSU is currently consulting on a model for a competency assurance programme with an educational approach with the Royal Australasian College of Pathologists (RCPA). The Quality Assurance Programme committee of the RCPA has expressed a willingness to work with the NCSP to develop a programme for New Zealand. Wider sector consultation is planned for the New Zealand Society of Cytology Conference on 7 to 9 October 2004. This consultation and further discussions with the RCPA will delay the planned pilot by several months.
- 17. Following consultation on cytology training options document a request for proposal process has commenced. The appointed organisation will provide ongoing and updated training for all laboratory staff reporting cytology from 2005.
- 18. Three Bachelor of Medical Laboratory Science students completing the fourth year cytology option are eligible for NSU study grants. These study grants are payable on successful completion of cytology laboratory practical experience.
- 19. Very positive feedback was received from the twenty-three Anatomical Pathology registrars who attended the pre exam cytology study days in June 2004.

The New Zealand Cancer Registry Information

- 20. A number of work streams aimed at improving the accuracy and timeliness of data recorded in the New Zealand Cancer Registry continues to be progressed.
- 21. The overall status of registrations into the NZCR continues to improve and as with previous quarters more than half the annual number of cancer registrations are registered within three months of receipt.

Development of a Population Health Register (NHI Upgrade Project)

22. Work on the NHI upgrade programme continues. Activities for the past quarter include:

- The final version of the Privacy Impact Assessment Report for the programme was tabled and approved by the NHI Steering Group. The document contributes to the goal of transparency the Ministry is pursuing with respect to the NHI.
- The successful pilot of a 'web-based' application to enable the NHI to be accessed on-line has been completed and is now in production and available to the Primary Health sector for use.
- After a successful testing phase the implementation of a new NHI search engine is about to be implemented. Once implemented this will aid in the reduction of duplicate NHIs being created. Better search techniques and results returned will assist with the identification of those individuals being searched.
- The development of a training programme for health and disability support services is underway with the final version of a training package being submitted to the Programme Sponsor for approval. The training will include a number of topics including data quality, privacy and security, searching techniques and NHI user certification for registering on the NHI.
- A brochure about the NHI is currently in the final stages of approval by a consumer advisory group before being distributed to health service providers. The brochure will be a new source of information for consumer awareness covering the topics of security and privacy, to how the NHI is used and why the NHI is important for clinical safety and administrative efficiency.

Contact for telephone discussion (if required)

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APPENDIX 1.0

IMPLEMENTATION OF THE OUTSTANDING RECOMMENDATIONS AND PROGRESS AGAINST REPORTING MILESTONES FOR 10 JUNE 2004 TO 10 SEPTEMBER 2004.

Ref.	Recommendation	Reporting Milestones ¹ for 10 June 2004 to 10 September 2004.
1.	Evaluation of NCSP	Part 3 (Cancer Audit)
	The remaining two phases of the national evaluation designed by the Otago University team must proceed.	Communications planning commenced and ongoing.
		A draft report is expected to be provided to the Minister of Health in October 2004.
2.	Re-enrolment and re-screening of women.	No Reporting Milestone this period.
	If the national evaluation throws doubt on the accuracy of the current national average then the Committee recommends that all women who are or who have participated in the programme should be invited to re-enrol and offered two smears two years apart.	
4.	Operational Policy and Quality Standards & Evaluation & Monitoring Plan.	The NCSP Audit framework has now been finalised and is available on the Healthy Women Website.
	The Policy & Quality Standards for the NCSP and the Evaluation and Monitoring Plan for the NCSP must be implemented within the next 12 months.	
19.	Review of operations of ethics committees.	As part of its support role to the NEAC, Sector Policy Directorate of the Ministry of Health will continue to report to you
	There should also be a review of the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research	separately on the implementation of the outstanding recommendations relating to ethics.
	generally in New Zealand.	See also rec's 21,22,23

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¹ Reporting Milestones refer to those tasks and activities that need to be completed in the period covered by the report, against which progress on the implementation of the recommendations is measured. Recommendations where there is no Reporting Milestone against which to report for this month are marked No Reporting Milestone this period; work may however be already underway.

Ref.	Recommendation	Reporting Milestones ¹ for 10 June 2004 to 10 September 2004.
21.	Guidelines to ethics committees for observational studies. Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.	As part of its support role to the NEAC, Sector Policy Directorate of the Ministry of Health will continue to report to you separately on the implementation of the outstanding recommendations relating to ethics.
		See also rec's 19,22,23
22.	National ethics committee – multicentre studies. A national ethics committee should be established for the assessment of multi-centre or national studies.	As part of its support role to the NEAC, Sector Policy Directorate of the Ministry of Health will continue to report to you separately on the implementation of the outstanding recommendations relating to ethics.
		See also rec's 19,21,23
23.	Appeal process for ethics committee decisions. The procedures under which ethics committees operate need to be re-examined. Consideration should be given to processes to allow their decisions to be appealed to an independent body.	As part of its support role to the NEAC, Sector Policy Directorate of the Ministry of Health will continue to report to you separately on the implementation of the outstanding recommendations relating to ethics.
		See also rec's 19,21,22
24.	NCSP Complaints System. The NCSP requires its own system to deal with complaints regarding the Programme's delivery. It also needs to have in place a user-friendly system which can respond to complaints of Programme failures, such as under-reporting.	The NSU complaints process is being implemented when complaints are received by the NSU. See also rec 45.
25.	Electronic Link Cancer Register & NCSP Register. The National Cervical Screening Register needs to be electronically linked with the Cancer Register.	Processes for linking and matching data manually has been implemented and working well. (NZHIS in conjunction with the NSU) are continuing to work on a project, which will assess the feasibility of electronically linking both the New Zealand Cancer Registry and the National Cervical Screening Programme -Register
27.	Standards for the NCSP should be reviewed every two years. Standards for the NCSP should be reviewed every two years and more frequently if monitoring indicates that some of the standards are inappropriate.	The review of Chapter 5 'Providing a Laboratory Service' and Chapter 4 'Providing a Smear- Taking' Service' has commenced and are ongoing.

Ref.	Recommendation	Reporting Milestones ¹ for 10 June 2004 to 10 September 2004.
28.	The Government must ensure sufficient cytotechnologists and cytopathologists and training sites. The Government in consultation with other bodies or agencies needs to ensure that there are sufficient trained cytotechnologists and cytopathologists and that there are appropriate training sites for them. There should also be a review of the training requirements and maintenance of competence of smear test readers and cytopathologists.	Implementation of Workforce Development Strategy initiatives commenced and ongoing.
31.	Ensure electronic linkage between NCSP Register and Cytology Labs. The cervical smear test and histology histories of women enrolled on the National Cervical Screening register should be made electronically available online to all laboratories reading cervical cytology.	Work has commenced on this strategy and the pilot is underway
33.	The NCSP should develop a population-based register. The NCSP should work towards developing a population based register and move away from being the utility based register that it now is.	The NSU is represented at various levels on the Ministry's Population Register Project led by NZHIS. This project recently successfully trialled on-line Web Access to the NHI; and is now testing a new se-arch engine which is expected to assist with the further reduction of duplicates. Ā brochure aimed at increasing consumer awareness of the NHI is also presently under development.
41	All pathologists undertaking cytology should be appropriately trained. If cytology is a significant component of a pathologist's practice then he or she must participate in continuing medical education in that subject.	Implementation of Workforce Development Strategy initiatives commenced and ongoing.
45	NCSP should have a system for identifying deficiencies. The screening programme should have in place a system over and above the audit and monitoring reports, to identify deficiencies in its process. A form of survey of users so that they can be proactive rather than reactive in the delivery of the programme would be useful.	The NSU complaints process is being implemented when complaints are received by the NSU. See also rec 24

APPENDIX 2.0

RECOMMENDATIONS THAT HAVE BEEN COMPLETED OR IMPLEMENTED²

Ref.	Recommendation	Implemented or Completed
3.	Evaluation of NCSP A comprehensive evaluation of all aspects of the NCSP which reflects the 1997 Draft Evaluation Plan developed by Cox should be commenced within 18 months.	Parts 5, 6 and 8 included within the scope of Part 3 (Cancer Audit) – see recommendation 1 above. Parts 4, 7 and 10 included within scope of NCSP Statistical Reporting. Refer to recommendation 7 below.
5.	Full legal assessment of Operational Policy and Quality Standards. There needs to be a full legal assessment of the Policy & Quality Standards for the NCSP and the Evaluation and Monitoring Plan to ensure that the requisite legal authority to carry out these plans is in place.	Report provided to NSU.
6.	Legal assessment of NCSP Authority. The NCSP should be thoroughly evaluated by lawyers to determine whether or not those persons charged with tasks under the NCSP have the necessary legal authority to discharge them.	Report provided to NSU.
7.	Statistical Reporting. The NCSP should issue annual statistical reports. These reports should provide statistical analysis to indicate the quality of laboratory performance. They should also provide statistical analysis of all other aspects of the programme. They must be critically evaluated to identify areas of deficiency or weakness in the NCSP, these must be remedied in a timely manner.	Issue Annual Statistical Reports 1996-98 Report Published. 1999-00 Report in final draft The 2001 Annual Monitoring Report has been completed and is on the Healthy Women Website at healthywomen.org.nz. Work on the 2002 Annual Monitoring Report is underway.

² Ministry of Health: What Further Progress Has Been Made to Implement the Recommendations of the Cervical Screening Inquiry, As reported by the Auditor General, December 2003.

Ref.	Recommendation	Implemented or Completed
8.	Regular Statistical Information. Meaningful statistical information should be generated from both the NCSP-Register and the Cancer Registry on a regular basis. Attention must be paid not only to laboratory reporting rates but also trends and the incidence of disease, assessed by regions that are meaningful to allow some correlation between reporting profiles of laboratories and the incidence of cancer.	NSU and University of Otago consider that it is not currently possible to correlate laboratory reporting with regional incidence of cervical cancer in NZ.
9.	Minimum Standards for Cytology Laboratories. The compulsory setting of a minimum number of smears that should be ready by laboratories each year must be put in place. The proposal to impose three minimum volume standards on laboratories must be implemented. These are: each fixed site will process a min of 15,000 gynaecology cytology cases, each pathologists will report at least 500 abnormal gynaecological cytology cases, cytotechnical staff must primary screen a min of 3,000 gynaecological cytology cases per annum. This should be implemented within 12 months.	DHB and Community Laboratory Agreements incorporate minimum volume standards. Public Hospital laboratories did not meet minimum volume standards in 2002/2003 and in 2003/2004.
10	Balanced Approach for NCSP There needs to be a balanced approach, which recognises the importance of all aspects of the National Cervical Screening Programme. The emphasis on smear-taking and increasing the numbers of women enrolled on the Programme needs to be adjusted.	The Programme now has a more balanced approach.
12	Management of the NCSP The NCSP must be managed within the Ministry of Health as a separate unit by a manager who has the power to contract directly with the providers of programme on behalf of the Ministry. The programme's delivery should not be reliant on the generic funding agreements the ministry makes with providers of health services. For this purpose the unit will require its own budget.	This has been implemented.
13	Management of the NCSP The NCSP should be under the control of a second or third tier manager within the Ministry. The Manager of the unit should hold as a minimum specialist medical qualifications in public health or epidemiology. As a consequence of the programme's link with Cartwright,	

Ref.	Recommendation	Implemented or Completed
14.	Amend S74 of the Health Act 1956. The Health Act 1956 should be amended to permit the NCSP to be effectively audited, monitored and evaluated by any appropriately qualified persons irrespective of their legal relationship with the Ministry. This requires an amendment to section 74A of the Health Act to permit such persons to have ready access to all information on the NCSP-Register.	The Health (National Cervical Screening Programme) Amendment Act was passed on 7 March 2004 and will be fully implemented by 7 March 2005.
15.	Kaitiaki Regulations There needs to be reconsideration of the Kaitiaki Regulations, and the manner in which those regulations currently effect the Ministry of Health gaining access to aggregate data of Māori Women enrolled on the NCSP-Register. The Ministry of Health and any appropriately qualified persons engaged by it require ready access to the information currently protected by the Kaitiaki Regulations in order to carry out any audit, monitoring or evaluation of the Programme.	The Cabinet decision on 25 June 2002 was to retain the status quo.
16.	Legal right to access information from the Cancer Register. The present legal rights of access to information held on the Cancer Registry need to be clarified. The Ministry and any appropriately qualified persons it engages to carry out audits, monitoring, or evaluation of cervical cancer incidence and mortality require ready access to all information stored on the Cancer Registry about persons registered as having cervical cancer.	The Health (National Cervical Screening Programme) Amendment Act was passed on 7 March 2004 and will be fully implemented by 7 March 2005.
17.	Amend Health Act 1956 to enable access to medical files. The Health Act 1956 requires amendment to enable Ministry of Health and any appropriately qualified persons it engages to carry out audits, monitoring or evaluation of cervical cancer incidence and mortality to have ready access to all medical files recording the treatment of the cervical cancer by all health providers who had a role in such treatment.	The Health (National Cervical Screening Programme) Amendment Act was passed on 7 March 2004 and will be fully implemented by 7 March 2005.
18.	Change guidelines under which ethics committees operate. There needs to be change to guidelines under which ethics committees operate to make it clear that any (external and internal) audit, monitoring and evaluation of past and current medical treatment does not require the approval of ethics committees.	Guidelines updated.

Ref.	Recommendation	Implemented or Completed
20.	Provide guidelines to ethics committees regarding Privacy Act & Code. Ethics Committees require guidance regarding the application of the Privacy Act and the Privacy Health Information Code. Ethics Committees need to be informed that the interpretations of legislation relating to personal privacy is for the agency holding a patient's data to decide. They would, therefore, benefit from having at least one legally qualified person on each regional committee.	Guidelines updated.
26.	Performance Standards for NCSP Register and Cancer Register. Performance standards should be put in place for the National Cervical Screening Register and the Cancer Registry. The currency of the data on both Registers needs to be improved. The Cancer Registry should be funded in a way that enables it to provide timely and accurate data that is meaningful.	A new chapter of the NCSP Operational Policy and Quality Standards 'Providing a Regional Service' has been completed. The chapter includes performance standards for the NCSP-Register. The new chapter has been included in the DHB Agreements. Programming of the NCSP- Register for the Reconfiguration of the NCSP Regional Services has now been completed. See also recs 27 and 32 above and below.
29.	Amend Medical Laboratory Technologists Regulations 1989. The Medical Laboratory Regulations 1989 should be amended to permit only registered medical practitioners with specialist qualifications in pathology and appropriate training in cytopathology or appropriately trained cytoscreeners to read cervical smear tests.	The Health Practitioners Competence Assurance Act was passed by the House on 11 September and received Royal assent on 18 September 2003. The HPCA contains provisions that will give effect to the intent of the recommendations from the Inquiry will come into force a year after the Royal assent. That is, the establishment of new registration authorities and the development of gazetted scopes of practice. This will take place on 18 September 2004, that is, a year from the date of Royal assent.

Ref.	Recommendation	Implemented or Completed
30.	Impose Legal obligations on storage of slides. Legal obligations in addition to those mandated by IANZ must be imposed on all laboratories reading cervical cytology requiring them to 1) retain records of patients' cytology and histology results in safe storage for a period of no less than five years from the date on which the results were reported and 2) ensure that a patient's records are readily accessible and properly archived during the five year storage period.	The Health (National Cervical Screening Programme) Amendment Act was passed on 7 March 2004 and will be fully implemented by 7 March 2005.
32.	Develop Standards for accuracy of laboratory coding. Standards must be developed for ensuring the accuracy of laboratory coding and this aspect of the National Cervical Screening Register must be subject to an appropriate quality assurance process.	See also recs 26,27 above.
34.	Legal mechanisms should be in place to allow the ACC, Medical Council and the Health & Disability Commissioner to share relevant information with the Ministry's NCSP. There should be a legal obligation on the ACC, the Medical Council and the Health and Disability Commissioner to advise the NCSP's manager of complaints about the professional performance of providers to the Programme when complaints are made to those various organisations about the treatment of a patient in relation to the Programme.	The Health Practitioners Competence Assurance Act (HPCA) was passed by the House on 11 September and received Royal assent on 18 September 2003. The HPCA contains provisions that will give effect to the intent of the recommendations from the Inquiry will come into force a year after the Royal assent. That is, the establishment of new registration authorities and the development of gazetted scopes of practice. This will take place on 18 September 2004, that is, a year from the date of Royal assent.
35.	Medical Tribunal to supply information to NCSP. Consideration should be given to the addition of an express requirement in the provisions governing medical disciplinary proceedings which would oblige the Tribunal seized of the facts of any given case specifically to consider whether there are any grounds for concern that there may be a public health risk involved. If that concern is present the Tribunal should be required to inform the Minster of Health.	The Health Practitioners Competence Assurance Bill (HPCA) was passed by the House on 11 September and received Royal assent on 18 September 2003. The HPCA contains provisions that will give effect to the intent of the recommendations from the Inquiry will come into force a year after the Royal assent. That is, the establishment of new registration authorities and the development of gazetted scopes of practice. This will take place on 18 September 2004, that is, a year from the date of Royal assent.

Ref.	Recommendation	Implemented or Completed
36.	ACC & Medical Council should exchange relevant information regarding claims for medical misadventure.	Royal assent received for Injury Prevention and Rehabilitation Bill – came into effect April 2002
	There should be an exchange of information between the Accident Compensation Corporation and Medical Council regarding claims for medical misadventure and disciplinary actions against medical practitioners.	
37	Liaison with the College of Pathologists	Completed this liaison has been incorporated into the work programme of the NCSP.
38.	Information to Women. The Programme must provide women with information to enable them to make informed decisions about screening and provide them with information regarding potential risks and benefits. Until the Programme has been monitored and evaluated in accordance with the current three phase national evaluation the Programme has an obligation to inform women that the quality of the performance of some of its parts has not been tested. Women should also be informed that screening will not necessarily detect cervical cancer.	Completed. Work has been incorporated as business as usual into the work programme of the NCSP.
39.	Letters to Medical Practitioners. Medical practitioners need to be reminded that cervical smear tests are not a means of diagnosing cervical cancer. They need to be alert to signs of cervical cancer, and they should not place too much reliance on a patient's smear test results to discount the possibility of cervical cancer being present.	Letter sent.
40.	Appropriately trained personnel should do cervical screening. Primary screening of cervical smears should only be performed by individuals who are appropriately trained for that task. Consideration should be given to requiring pathologists to train as cytoscreeners if they want to function as primary screeners.	Implementation of Workforce Development Strategy commenced and ongoing.

Ref.	Recommendation	Implemented or Completed
42	Cytopathologists must participate in continuing education in cytopathology. If cytology is a major component of a pathologist's practice, it is desirable that he or she should have added qualifications in cytopathology; either a fellowship slanted towards cytopathology or a diploma in cytopathology. Consideration should be given to making this a mandatory requirement.	Implementation of Workforce Development Strategy commenced and ongoing.
43	Pathologists ought to be more openminded. Pathologists should be more open minded and critical of laboratory performance. They should be alert to the possibility that their practice or the practice of their colleagues may be suboptimal.	
44	The Medical Council should ensure that systems are in place to support the early reporting of errant medical practitioners by their colleagues. The Medical Council should ensure that systems are in place whereby medical practitioners are not deterred from reporting to it their concerns about the practice of an individual medical practitioner. Complainants should be assured that their reports will not result in them being penalised in any way.	The Health Practitioners Competence Assurance Bill (HPCA) was reported back to the House by the Health Select Committee on 16 May 2003. The Act was passed by the House on 11 September and received Royal assent on 18 September 2003. The HPCA contains provisions that will give effect to the intent of the recommendations from the Inquiry will come into force a year after the Royal assent. That is, the commencement of new registration authorities and the commencement of gazetted scopes of practice. This will take place on 18 September 2004, that is, a year from the date of Royal assent.
46.	There should be a process for monitoring the implementation of the Committees Recommendations. A process to ensure that the recommendations made by the Committee are implemented should be put in place.	Dr McGoogan's 6-Month Report released. Dr McGoogan's second and final report received in June 2003. The OAG report on further progress made (since Dr McGoogan's second and final review report) released on 8 December 2003.