The Forensic Science Regulator

Response to Professor Brian Caddy's Review of the Science of Low Template DNA Analysis

7 May 2008

Foreword

The role of the Forensic Science Regulator is new, established to ensure that quality standards apply across all forensic science services to the Criminal Justice System. I operate independently from the Government but have a responsibility to advise Ministers on matters related to quality standards in forensic science. I have started on an ambitious programme of work to develop quality standards for the delivery of forensic science; I therefore welcome Professor Caddy's review which is an independent and objective view of the standards of the science used in the analysis of trace amounts of human DNA.

Professor Caddy made 21 recommendations that broadly fall into three areas: training, quality standards and research. In this response to the Review I explain how I propose to manage each of the recommendations; where possible this will be within the framework of the programme of work I have set out in my business plan.

A number of stakeholders have been consulted about the specifics of the recommendations and prior to finalizing my response members of the Forensic Science Advisory Council have given it their consideration.

Andrew Rennison
Forensic Science Regulator
7 May 2008

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1. Introduction

1.1. The Regulator

1.1.1. The position of the Forensic Science Regulator was proposed in HM Government's response to the report "Forensic Science on Trial"[1]. The creation of the position was announced by Meg Hillier MP (Parliamentary Under-Secretary of State at the Home Department) on 12 July 2007.

1.1.2. The role of the Regulator was described as follows:

> "... will be to advise Government and the Criminal Justice System on quality standards in the provision of forensic science. This will involve identifying the requirement for new or improved quality standards; leading on the development of new standards where necessary; providing advice and guidance so that providers will be able to demonstrate compliance with common standards, for example, in procurement and in courts; ensuring that satisfactory arrangements exist to provide assurance and monitoring of the standards and reporting on quality standards generally."

1.1.3. Clearly the role focuses on quality standards within forensic science. It does not deal with market or economic regulation nor does it deal with what could be considered service delivery standards. In performing this role I am supported by the Forensic Science Advisory Council (FSAC)[2].

1.1.4. Although my remit does not extend to Scotland or Northern Ireland, their respective authorities have agreed to join in the work of the Regulator and the FSAC as full partners and, accordingly, to implement the resulting standards in their own jurisdictions. This will beneficially ensure the existence of UK-wide standards in forensic science.

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1 Forensic Science on Trial, Report of the House of Commons Select Committee on Science and Technology, 2005.

2 The Terms of Reference for the FSAC are available at URL: http://police.homeoffice.gov.uk/operational-policing/forensic-science-regulator/about-the-regulator/forensic-advisory-council/

1.1.5. The scope of forensic science is, in scientific terms, vast. It covers all disciplines which could be applied to the work of the Criminal Justice System (CJS). It is impossible for one person, even supported by the FSAC, to deal in one go with the standards across this range of subjects. I am therefore establishing a number of specialist groups to advise me, and the FSAC, in relation to specific areas. These areas can be scientific (such as DNA profiling) or issue based (e.g. the requirements of validation). The specialist groups will develop:

- a model to identify risks to quality standards in forensic science – the Risk Specialist Group;
- the forensic science user requirement from the court perspective – the End-User Specialist Group;
- a protocol for the validation in forensic science – the Quality Standards Specialist Group;
- standards for forensic DNA profiling – the DNA Specialist group;
- standards for digital forensics – the Digital Forensics Specialist Group;
- standards for forensic pathology – the Forensic Pathology Specialist Group; and
- competency standards for forensic practitioners (this has been recently added to the work plan after my business plan[3] was published) – the Practitioner Quality Standards Specialist Group.

1.1.6. I will shortly be publishing, for public consultation, a manual of regulation that will detail how I propose to achieve my plans and objectives.

[3] http://police.homeoffice.gov.uk/publications/operational-policing/Forensic_Science_Regulator_3.pdf

1.2. The Review

1.2.1. In 2006 the Forensic Science Service Ltd (FSS) informed the police and the Home Office of an issue with the service it provided for analysis of low quantities of DNA. The service is known as Low Copy Number (LCN) DNA analysis. The FSS reported that the analyses could, under certain circumstances, fail to identify a DNA profile from genetic material in a sample that should reveal a profile or mixture of profiles.

1.2.2. In response to this notification the Association of Chief Police Officers (ACPO), with the Home Office, established a group to perform an operational review of the LCN forensic practices and implement such remedial investigation as was warranted[4].

1.2.3. As part of this review an assessment was made of improvements made by the FSS to the LCN method and the group were, as a result, confident to proceed with the re-analysis of samples that might have been affected by the issue reported by the FSS. This assessment also recommended a more comprehensive review of the science behind LCN.

1.2.4. My predecessor agreed to establish this more comprehensive review. In discussions with stakeholders and specialists it became clear that a number of the factors which make LCN complex result not from the specific analytical methods employed but from the fact there is very little DNA present. It follows that these factors will be encountered in other forms of DNA analysis if such low quantities of DNA are present.

1.2.5. The decision was therefore made that the review should not concentrate on LCN alone but on all methods, collectively referred to as 'Low Template DNA' (LTDNA) techniques, employed to analyse less than 200pg of DNA[5]. This figure was chosen after discussions with experts in

[4] See Written Ministerial Statement by Joan Ryan MP (Parliamentary Under Secretary of State at the Home Department) on 22 February 2007.

[5] 200pg (or 200 picograms) is 0.0000000002g.

the field, I accept there is no set boundary and others will suggest the boundary is at a lower value. I do not believe determination of the exact boundary is essential as the analytical results need to be taken on a case-by-case basis.

1.2.6. The terms of reference were therefore established as follows:

i). To examine low template DNA profiling techniques, including the LCN technique employed by FSS, and analogous processes used by other providers of DNA profiling services to the UK CJS, to generate DNA profiles from samples which would not yield useable results from the normal SGM Plus® process[6]. This is to include processes which seek to obtain profiles from DNA samples below 200pg and the application of supra-28 cycle amplification;

ii). To advise upon the scientific validity of those techniques, having regard to any novel issues raised (in comparison with accepted SGM Plus® techniques) and the variations in approach adopted by different providers, recommending best practice in the light of current scientific knowledge and opinion;

iii). To advise upon the interpretation of the results and how they should be presented to the customer and to the court in any criminal proceedings;

iv). To advise upon the creation of a national minimum technical standard for low template DNA analysis, to include extraction, quantification/dilution and interpretation criteria; and

v). To make other relevant recommendations.

6 SGM Plus® is a registered trademark of Applied Biosystems (ABI) and refers to the AmpFlSTR® SGM Plus® PCR Amplification Kit

1.2.7. In the commissioning of the review it was proposed the panel would comprise of:

- A team leader – a person of standing in the field of science, with experience of carrying out substantial inquiries in the public sector;
- Two DNA experts – each acknowledged authorities in the field of DNA profiling for forensic science purposes; at least one of whom should have practical experience gained in a UK forensic science laboratory.

1.2.8. Professor Brian Caddy was selected to lead the review. He is an Emeritus Professor of Forensic Science at Strathclyde University with a distinguished academic career and experience in conducting independent reviews over many years; including the investigation of contamination at the Forensic Explosives Laboratory[7] and more recently into the forensic science aspects of investigation into the death of Damilola Taylor[8].

1.2.9. He was supported in the review by Dr Graham R. Taylor, the Head of Genomic Services at Cancer Research UK, and Dr Adrian M.T. Linacre who is a Senior Lecturer of Forensic Science at Strathclyde University and is experienced in DNA casework.

1.3. Acknowledgments

1.3.1. My predecessor commissioned the review and appointed the expert panel and I am sure would like to join me in thanking the team for their diligence in conducting the review. The independence of the Panel and the years of experience these respected scientists brought to the review were undoubtedly an asset. I do not see the review as an end in itself but a springboard for further work based on the recommendations made by the Panel.

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7 Assessment and Implications of Centrifuge Contamination in the Trace Explosives Section of the Forensic Explosives Laboratory at Fort Halstead. Prof. B Caddy. HMSO 1996.

8 http://www.homeoffice.gov.uk/documents/damilola-taylor-review-2007

1.3.2. I would also like to endorse the thanks expressed by the Panel to those who assisted them in their work.

1.3.3. In preparing this response I have relied on the advice of the FSAC and others and I would like to express my gratitude for the valuable discussions which have had an impact on the content of this document.

2. Response to Recommendations

2.1. Police Scientific Support

Training

Recommendation 1
For SOCOs/CSIs and SIOs, there needs to be a national education programme setting out the advantages and limitations of LTDNA in order to establish a conformity of approach to crime scene work. From this should be developed national guideline documentation. It is for the Forensic Science Regulator to institute such training programs and mechanisms for the resolution of these issues.

Recommendation 2
It is for the Forensic Science Regulator to come to an agreement with all parties on what constitutes LTDNA success and to then to institute an appropriate survey.

Recommendation 3
It is for the Forensic Science Regulator to institute appropriate training programs and to set standards that will enable police forces and their crime scene personnel to have a full grasp of what constitutes LTDNA analysis, how such samples are to be collected and stored especially in relation to issues of contamination and the likelihood of success.

2.1.1. The role of the Regulator does not encompass the creation or implementation of training courses. The National Policing Improvement Agency (NPIA) is the most appropriate public body to develop or update current training programmes for police staff in England and Wales. They also deliver specialist forensic science training for Scotland, Northern Ireland and Republic of Ireland. Where forces feel this is required, NPIA will soon be in a position to provide expert advice; which is independent of the forensic science providers. The NPIA, working with ACPO (England, Wales and Northern Ireland) and ACPOS (Scotland), also has a key role in developing the doctrine for forensic science for the police service. I will work with ACPO, ACPOS, NPIA and other organisations as appropriate to address the first and third recommendations.

2.1.2. The second recommendation is addressed, in part, in this section as it is interlinked to the awareness and training. Understanding the limitations and likelihood of success for any technique would assist police staff in selecting the most appropriate strategy during an investigation. Unlike a presumptive blood test where success is a proxy measurement of the technique itself, success in LTDNA (for the frontline officer at least) is more of a measure of how well areas were targeted. This issue and the allied issue of what constitutes a useable profile are also discussed in section 2.5 on interpretation.

2.1.3. I have agreed with ACPO and NPIA that the Forensics 21 programme[9] is the vehicle for developing any police training requirements on LTDNA although it is clear to me that there are knowledge gaps throughout the CJS with regards to LTDNA. Therefore I intend to work with partners to ensure that appropriate training or material is available for the wider CJS. For example, I will work closely with the Crown Prosecution Service (CPS) to help re-write their guidance on the use of scientific evidence.

[9] http://www.npia.police.uk/en/10432.htm

I will ask the DNA and End-User Specialist Groups to look at requirements of the various parts of the CJS for LTDNA awareness advice and to identify the most effective delivery channels and partners as required, but taking advantage of the ACPO/NPIA Forensics 21 programme.

The Police Elimination Database

Recommendation 5

We have been told that there is an urgent need for the DNA profiles of all serving operational police officers and crime scene personnel to be included on the Police Elimination Database and for forensic science providers to have direct access to it as a means of eliminating irrelevant DNA profiles. While laboratory personnel can usually be eliminated from a DNA profile fairly quickly, the incomplete nature of the Police Forces DNA database is a hindrance and the Forensic Science Regulator needs to pursue this problem with ACPO. As an alternative, financial support needs to be provided to enable the DNA profiles of Police Officers and crime scene personnel involved in a specific investigation to be obtained at the same time as the suspect samples.

2.1.4. In 2003 the Police Regulations[10] mandated that all newly recruited police officers be sampled for the Police Elimination Database. Compliance is measured through external auditing by the Home Office's Police & Crime Standards Directorate (PCSD) and reported to the ACPO DNA Strategy Board. The ACPO DNA Strategy Board has agreed there is a need to pursue greater inclusion of all police staff and other personnel likely to come in contact with crime scenes or samples. I am content that recommendation 5 is implicitly included in a far wider reaching programme

[10] R19 Police Regulations 2003 S.I. 527 2003

of work by the ACPO DNA Operations Board. Therefore, I will work within this existing programme and in the meantime maintain a watching brief.

I am content that the ACPO DNA Operations Board has a comprehensive programme to review and expand the Police Elimination Database and will lend it any support required.

Laboratory Functions

Recommendation 9

Those police forces that have made the decision to carry out preliminary forensic testing by the establishment of a police forensic science laboratory must have such laboratories accredited to a standard comparable to those of forensic science providers and should comply with ISO 17025 through UKAS. The Forensic Science Regulator needs to enter into a dialogue with ACPO as to the way Police laboratories are to be integrated into the scheme of forensic science provision.

2.1.5. Police forces traditionally provided a range of laboratory based functions, such as chemical enhancement for fingermarks. The Review notes that a number of larger forces are developing the laboratory roles to cover functions more commonly/traditionally carried out by the forensic science providers (e.g. DNA searching and harvesting). This type of work is, I believe, distinct from a Scene of Crime Officer (SOCO) conducting an examination, which could have been performed at the scene, back at base in a controlled environment.

2.1.6. There are therefore different types of examination undertaken by the police – even in what could be described as laboratory conditions. It is important that the appropriate standards are identified for the various

activities and that these are applied, to the laboratory or the individual as the case may be, throughout the whole process.

2.1.7. I believe that quality standards must equally apply to laboratories within the police environment as well as those managed by forensic science providers. One of the strengths of forensic science is its independent scientific nature. Whether supplied from within a police force or from an independent supplier this independence must be maintained and demonstrated.

2.1.8. I am pleased to note that the police service recognises the need for appropriate standards to be applied to this work. This is demonstrated by the majority of fingerprint laboratories having already achieved ISO 9001: 2000, the laboratories in the National Ballistics Intelligence System working towards ISO 17025 accreditation and a number of other police laboratories are following suit.

2.1.9. The structures and processes being developed to ensure appropriate quality standards are in place are being developed with all stakeholders. Police laboratories will be involved in this work in a similar manner to commercial organisations.

The Quality Standards Specialist Group will consider the different types of laboratory work and will advise on relevant standards to apply across the board, regardless of whether a laboratory is managed by a police force or a commercial organisation.

2.2. Analytical Science: Training

Recommendation 8

It is for the Forensic Science Regulator to oversee compliance with standards of competence for LTDNA laboratory specialists and when and where appropriate to suggest modifications to such training programs and record keeping.

2.2.1. The Review notes the high standards of specialist training and record keeping observed by the United Kingdom Accreditation Service[11] (UKAS) during inspections as part of the ISO 17025 compliance regime. All current providers of LTDNA analysis have or intend to achieve accreditation to ISO 17025 standards and accreditation with the Custodian of the National DNA Database® (NDNAD) for LTDNA[12]. They already hold such accreditation for standard SGM Plus® analysis. I therefore take the view that the requirement for training and competence testing is, or will soon be, achieved.

2.2.2. I do believe there is a wider issue in relation to ensuring, and demonstrating, the competence of individual practitioners working at all stages in forensic processes. I am in discussions with stakeholders (including UKAS and the NPIA) on how to address this matter and will be establishing a specialist group to advise on ways in which appropriate measures can be implemented.

[11] The United Kingdom Accreditation Service is the sole national accreditation body recognised by government to assess, against internationally agreed standards, organisations that provide certification, testing, inspection and calibration services: http://www.ukas.com/.

[12] National DNA Database is a registered trademark owned by the Secretary of State for the Home Department.

I am establishing a Practitioner Standards Specialist Group which will review the existing standards, including those related to training, and recommend such modifications as are appropriate.

I support the work of UKAS to oversee compliance with laboratory standards and maintenance of training records as part of ISO 17025 accreditation.

I will work with UKAS and the Custodian of the NDNAD to ensure the standards applied are appropriate.

2.3. Analytical Science: Standards

Extraction and Quantification

Recommendation 4

The Forensic Science Regulator should monitor the use of DNA quantification procedures.

Recommendation 10

For all LTDNA samples and taking into account the limitations of the amount of DNA extracted from crime samples, quantification of the material extracted for analysis must be undertaken. Satisfactory commercial kits are now available for this purpose. Further research is required into the best ways of quantifying very small samples of DNA such as using repetitive DNA target. The Forensic Science Regulator must insist that as a matter of best practice a DNA quantification step is implemented for all DNA analyses submitted to the CJS and should monitor its implementation.

Recommendation 19

National minimum technical standards for extraction, quantification/dilution and interpretation criteria need to be agreed by all forensic science providers. These standards should also be agreed by the Forensic Regulator's Forensic Science Advisory Council. The Forensic Science Regulator needs to coordinate all the information already available that is associated with extraction etc. techniques and by agreement with all stakeholders establish appropriate standards.

2.3.1. I will ask the DNA Specialist Group to advise on appropriate standards for extraction methods.

2.3.2. Recommendations 4, 10 and 19 all relate to the issue of DNA quantification. DNA profiling requires a defined range of template DNA to produce optimal results, too little template DNA is likely to give incomplete results and too much template DNA may result in difficulty in interpretation or PCR failure. Recommendation 10 makes it clear that further research into the best ways of quantifying very small samples of DNA is required, and I endorse this approach. The DNA Specialist Group will be asked to look at the research requirements required to develop appropriate standards for DNA quantification, and the most effective method of closing any gaps identified.

2.3.3. I understand there are concerns that sometimes the amount of material available is so low that there may be a risk that it will be used up by a quantification test which may outweigh the risk of over amplification or PCR failure. Therefore, the DNA Specialist Group will be asked to ensure that a risk-based approach is followed when developing any DNA quantification standard.

2.3.4. Once an appropriate standard has been established, I believe it would be for UKAS to monitor compliance.

The DNA Specialist Group will develop appropriate standards for DNA extraction and quantification for LTDNA analysis.

2.4. Contamination

2.4.1. In forensic science, particularly involving trace evidence (not specifically DNA), contamination is a risk encountered in all cases. It is common practice to deal with the risk by removing the causes or minimizing the chance of contamination occurring and mitigating the impact should it occur.

Recommendation 6

A national standard needs to be established for 'DNA clean' consumables, especially in relation to crime scene recovery kits. The Forensic Science Regulator should ensure that only kits which meet such a standard should be used by police forces.

Recommendation 7

The Forensic Science Regulator should ensure the batch testing of all DNA reagents to ensure that they are DNA free prior to their use.

2.4.2. I am pleased to note the Review highlights areas of good practice around 'DNA-free' consumables[13] and reagents[14] to which recommendations 6 and 7 refer. It is important to avoid additional DNA being introduced throughout the process and this includes ensuring there is no DNA

[13] Consumables will include all disposal items employed in obtaining DNA profiles including, but not limited to, swabs, tubes and pipette tips.

[14] Reagents will include all chemicals employed in obtaining a DNA profile.

present in tubes, water or on the swabs prior to sampling. Sterile is not the same as ‘DNA-free’.

2.4.3. At the heart of DNA profiling is the Polymerase Chain Reaction (PCR) and the biotechnology industry has established standards for ‘DNA-free’ reagents for PCR applications.

2.4.4. I will ask the DNA Specialist Group to look at the issue of anti-contamination standards as a whole but with specific attention being drawn to the following questions.

- Is the PCR reagent grade appropriate for use in forensic science and in particular for 34 cycles?
- What should the requirements be for batch testing of consumables and reagents including ensuring that the testing is at the appropriate sensitivity for LTDNA and SGM Plus®?
- The extent to which “negative control” runs within the laboratory act as a measure that contamination has not occurred?
- Who should be responsible for ensuring the standards are met for the different types of consumables and reagents?

2.4.5. The Review also highlights the good practice of certain consumables suppliers in maintaining a database of production staff incorporating their DNA profile. Consideration will be given to whether this requirement should be mandatory for all suppliers of ‘DNA-free’ consumables and whether similar requirements are required for reagents when “negative controls” may serve equally well.

2.4.6. I would expect that, once agreed, the requirements will be added to the quality manuals and standard operating procedure of police forces as well as the forensic science providers and fall under the UKAS inspection regime.

I am already working with the NDNAD Custodian Unit[15] of the NPIA to develop recommendations for comprehensive standards for consumables and reagents.

I am in discussion with the NDNAD Custodian Unit over the design and operation of proficiency testing for suppliers to the National DNA Database.

The DNA Specialist Group will be asked to take responsibility for advising on these matters.

2.5. Interpretation

Recommendation 2
It is for the Forensic Science Regulator to come to an agreement with all parties on what constitutes LTDNA success and to then to institute an appropriate survey.

2.5.1. Recommendation 2 was initially discussed in relation to police scientific support training (section 2.1) to ensure the associated limitations are understood by police SOCOs so that appropriate and proportionate methods are used.

2.5.2. There are a number of possible approaches to determining a measure of success. The generation of a DNA profile of sufficient quality for use in evidence initially appears an attractive option. There would however have

[15] The National DNA Database (NDNAD) Custodian Unit is part of the National Policing Improvement Agency (NPIA), and is responsible for (a) the delivery of National DNA Database services and (b) ensuring that systems are in place to protect the integrity of the Database.

to be consideration of what would be a useable profile. Alternatively, the generation of a profile which could assist the CJS (perhaps in the investigation of crime) might be the appropriate measure. However, would that differ significantly from the first option?

2.5.3. Success rates of tests performed by the forensic science providers are currently monitored by the ACPO DNA Operations Board and supported by the Forensics 21 programme managed by the NPIA. The DNA Specialist Group could assist the NPIA in developing the measure, but it is for the NPIA to monitor and report success rates.

I will ask the NPIA to consider incorporating LTDNA monitoring under the Forensics 21 programme.

Recommendation 11

There needs to be a national agreement on how LTDNA profiles are to be interpreted especially in relation to “allele drop in and out”, stochastic effects, inhibition, and mixtures. This should be aided by regular circulation of appropriate test profiles and interpretation by ALL providers of this service and any results should be coordinated through the forensic science regulator. The Forensic Science Regulator should develop a consensus from all the forensic science providers in consultation with all stakeholders on how profiles and mixed profiles are to be interpreted. Once these criteria/standards have been agreed then the regulator should monitor their implementation. The Forensic Science Regulator should encourage openness in the availability of information that may have an impact on the way DNA profiles are interpreted in the context of a case.

Recommendation 13

Appropriate caveats should be stated in witness statements/court reports, in most instances, when LTDNA analyses have been undertaken.

Recommendation 16

Improve existing guidelines and standards. Active development of a consensus approach to the analysis of partial or contaminated DNA profiles is already underway and needs further work and an inclusive structure that takes account of all of the stakeholders. National and international providers have led the way, but this now needs to include close consultation with users. Within the UK a steering or advisory group comprising providers, users and independent legal advice, with perhaps lay representation should endeavour to develop documentation that would guide the courts in the interpretation of evidence. Educationalists and users should evaluate its comprehensibility and review it in a timely manner in the light of legal precedent and scientific advances.

Recommendation 19

National minimum technical standards for extraction, quantification/dilution and interpretation criteria need to be agreed by all forensic science providers. These standards should also be agreed by the Forensic Regulator's Forensic Science Advisory Council. The Forensic Science Regulator needs to coordinate all the information already available that is associated with extraction etc. techniques and by agreement with all stakeholders establish appropriate standards.

2.5.4. The interpretation of profiles obtained from LTDNA processes is likely to be more complex than profiles from the normal SGM Plus® process as a result of the:

- enhanced probability of detecting mixtures;
- enhanced significance of extraneous and/or contaminant DNA sources; and
- stochastic effects[16].

2.5.5. The initial scientific interpretation of results is clearly a key process. The following contextual interpretation (i.e. determining what the significance to a case is) is of no less importance.

2.5.6. I agree there needs to be an agreed approach to the interpretation of such profiles. The intention will be to produce a single proposal which addresses the issues of stochastic effects and mixture interpretation. This will include, but not be limited to, the following:

- the process by which the analytical results are interpreted to produce profiles;
- the manner in which profiles, and in particular mixed profiles, are interpreted to generate evidential weight;
- the manner in which issues around transfer and persistence of DNA are addressed;
- the manner in which issues of extrinsic or contaminant DNA are addressed;
- the way in which all of these factors are considered in relation to the circumstances of the case;

[16] For instance, the very low levels of DNA present may result in a level of randomness of the sample being drawn off containing sufficient target DNA which may result in a 'null' for that loci, unbalanced peaks or even containing only a minor component or contaminate.

- the reservations or limitations that have to be considered and how these are to be reported to the court in the light of the case circumstances; and
- the scientific and statistical basis for the approach adopted.

2.5.7. The aim will be to ensure the reported result is one which is based on sound science, supported by a sufficient body of data and that the interpretation of that result is based on a sensible model. This will ensure the CJS is informed of (a) the result, (b) the significance of the result and (c) any reservations that apply to the result and/or interpretation.

2.5.8. Any statement reporting the results of LTDNA profiling must make clear the limitations and complexities of the technique and explain any resulting issues about the evidential value of the results. Indeed this is, in England and Wales, an obligation imposed by the Criminal Procedure Rules[17] and existing case law[18]. Clearly the issues that arise will be linked to the circumstances of the case. I therefore believe a single set of caveats to be used in all cases is unlikely to be effective. Instead I will ask the DNA Specialist Group to consider whether there are a number of issues which must be considered and, where relevant, included in the expert's statement.

2.5.9. The latter part of recommendation 16 reiterates the need for the various specialist groups out lined in section 1.1 which I have formed.

[17] Part 33 Criminal Procedure Rules.
[18] R v Ward, [1993] 1 WLR 619, 96 Cr App Rep 1, [1993] 2 All ER 577

I will ask the DNA Specialist Group to draft guidance which addresses the issues of interpretation of DNA with particular reference to the increased impact of stochastic effects and DNA mixtures encountered in LTDNA analysis.

I will ask the End User Group to ensure that such guidance adequately informs the CJS of (a) the result, (b) the significance of the result and (c) any reservations that apply to the result and/or interpretation.

2.6. Research and Further Development: Validation

Recommendation 12

The Forensic Science Regulator should institute a regular program of inspections of documentation associated with all validations.

Recommendation 14

Any new methods of analysis used by a forensic science provider that will result in the presentation of evidence to the courts must be validated using appropriate and sound internationally recognised scientific principles. The details of such validation, including copies of raw data, should be lodged with the forensic science regulator before it is introduced into service. At least once a year or when the regulator decides it appropriate, such validations will be reviewed by an independent internationally recognised expert panel the composition of which will be determined by the regulator.

2.6.1. In 2005 the House of Commons Select Committee on Science and Technology stated[19]:

> "The absence of an agreed protocol for the validation of scientific techniques prior to their being admitted in court is entirely unsatisfactory".

2.6.2. I agree that this situation must be rectified, not just for the benefit of the CJS but also for the forensic science suppliers and their customers who are left without a reference point to judge what is required of a validation exercise. The issue of admissibility is covered later in this response.

2.6.3. The process for introducing new techniques or modifying existing techniques must ensure appropriate validation is undertaken. The inspection of the paperwork supporting the validation of any technique put forward for accreditation is part of the UKAS inspection and I am content that this process can deliver what is required. The point at which a change in a scientific method warrants further validation and how significant or substantial changes to processes or procedures are communicated will need to be considered.

2.6.4. As noted above there are currently no commonly accepted approaches to validation within the forensic science arena, this will also need to be addressed. Any approach will have to include the unique issues thrown up by the current forensic market – a competitive market in which suppliers will want to protect their intellectual property rights but in a context where scientific processes and the validation of such are open to disclosure in the courts. It must be recognised that the current suppliers do undertake validation to a very high standard. I will ask the Quality Standards Specialist Group to advise on these issues and assist in developing an agreed protocol.

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[19] House of Commons Select Committee on Science and Technology report "Forensic Science on Trial" 2005.

2.6.5. While recognising it is part of ISO 17025 to ensure appropriate and robust validation has been carried out, there is a place for guidelines on the path for innovation-to-market for new forensic science products and services to ensure all forensic science providers have covered the known hurdles (including the issues noted above). The FSAC and the specialist groups which assist me are appropriate to carry this forward in the first instance.

I will ask the Quality Standards Specialist Group to advise on a protocol for the validation of forensic science techniques, and how significant or substantial changes to processes or procedures are validated.

I will ensure that clear guidance on the path for innovation-to-market for new forensic science products and services is in place for all forensic science providers to follow, which will include consultation and validation requirements.

2.7. Future Developments

Recommendation 15

An independent study should be undertaken to assess the advantages and disadvantages of the two different approaches to LTDNA analysis. The Review has been informed that a scientific paper by one of the forensic science providers describing this is expected to be published soon. Whether or not this scientific paper is published the Forensic Science Regulator should provide a mechanism that, while retaining appropriate confidentiality for the researchers, enables other providers to evaluate the research.

2.7.1. The recommendation refers to a scientific paper recently accepted by the journal *Forensic Science International: Genetics* due to be published shortly and I propose to ask the DNA Specialist Group to make any further recommendations once this available.

A scientific paper on the advantages and disadvantages of the two different approaches to LTDNA analysis is expected to be published shortly and the DNA Specialist Group will review any further actions following publication.

2.7.2. The following recommendation refers to future developments of DNA profiling.

Recommendation 17

The use of STR's clearly has limitations and is essentially 15-year-old technology. The world of genetics and genome analysis has moved on a great deal since then and there may be benefits to be had from alternative technologies. For example, the world of forensic archaeology has been transformed by the use of next generation sequencers and it seems likely that these could have a huge impact on forensic DNA analysis. Furthermore PCR and other amplification technology has improved, with the development of emulsion PCR that may have substantial advantages and enable backward compatibility with the existing STR database. At present any service developments would have to be recovered as a service cost overhead. This would preclude radical advances requiring substantial funding. These developments may require high-level academic input and a competitive funding mechanism similar to those used by the Research Councils. Opportunities to tap into the international expertise of the Wellcome Trust Sanger Institute, a world leader in DNA sequencing technology, could be investigated. A UK working group focussed on such developments should develop an option appraisal. The risk of not doing this

is the stagnation and decline of standards on forensic DNA analysis, whereas a successful programme would secure a world lead for the UK.

2.7.3. The UK has undoubtedly been a world leader in the application of DNA in the investigation of crime and I believe LTDNA is just a recent manifestation of this lead. Being first to introduce innovation means being first to cross hurdles rather than waiting for consensus. I intend widening the learning from the way such “hurdles and challenges” have been addressed in the past to ensure that a clear path for innovation-to-market is available so innovation is encouraged rather than stifled by unnecessary bureaucracy.

2.7.4. My role is to ensure forensic science techniques, products and services introduced into the CJS are fit-for-purpose, it is not my role to control the direction of scientific endeavour. However, I recognise there is a need for academia, ACPO, ACPOS, NPIA, Home Office and forensic science providers to have a central conduit for commissioning research and development. Work on the Home Office Science and Technology Strategy should clarify the process.

I will ask the specialist groups to identify future opportunities and potential risks which will need managing in the context of my role.

2.8. Funding

Recommendation 18

An open funding mechanism needs to be put in place that will support an independent validation process of new developments. The Forensic Science Regulator should seek funding for independent research and validation that is open to national competition.

2.8.1. I do have an annual budget that covers the costs of specialist groups and processes necessary to achieve a model for validation. The budget will cover the exceptional cases that require my active involvement, or that of a third party. I am in discussions with the Home Office Scientific Development Branch, who have extensive experience at independent validation, about future validation of forensic science methods.

I will cover the independent validation of exceptional cases that require my active involvement, or that of a third party, on an *ad hoc* basis.

2.8.2. The following recommendation refers to financing of forensic science.

Recommendation 20

Since this matter of financing forensic science has been brought to our attention by the forensic science providers we believe it is for the Forensic Science Regulator to quantify this problem and to explore mechanisms to correct any problems his inquiry may reveal.

2.8.3. This is a reference to the current forensic procurement projects being managed by ACPO and the NPIA, and to the overall spending by the police on forensic science. It is not an issue for me unless I see a risk to quality standards linked to any changes in the procurement of forensic science services. The issue of police budget priorities is clearly beyond my terms of reference but I will work with all stakeholders to identify risks to quality standards, and will act according to the risks identified.

The Risk Specialist Group will develop a model to identify and prioritise risks to quality standards in the use of forensic science in the CJS.

2.8.4. The following recommendation was made in relation to representation of the profession.

Recommendation 21
The Forensic Science Regulator should explore the means of establishing a professional forensic science provider's organisation in order to develop mutually agreed standards.

2.8.5. When my predecessor started the work to create the position of Forensic Science Regulator and supporting structures he recognised the need for close liaison with stakeholders – including the suppliers.

2.8.6. I agree with this approach and have built good relations with individual suppliers and the Forensic Science Providers Group (FSPG). The FSPG is in the process of changing to become the Association of Forensic Science Providers (AFSP).

2.8.7. The FSPG has traditionally had a relatively selective membership but I understand the AFSP will be more inclusive and represent a wider section of the supplier community. I support this move.

2.8.8. It may be that one organisation cannot adequately represent the interests of all of the suppliers – particularly the differing concerns of the large and small suppliers. It may therefore be appropriate to establish a second representative group for the smaller organisations.

I am happy that the new Association of Forensic Science Providers already largely fulfils this requirement. Furthermore, that the Stakeholders Forum and Suppliers Forum (formed to assist me in identifying and ensuring appropriate standards are in place) completes this recommendation fully. I will monitor the developments in the Association to determine if a second organisation should be created to cover the interests of the smaller providers, particularly those involved with defence work.

3. Other Issues

Introduction

3.1.1. The Review, in a number of areas, highlights issues that, whilst not put forward as specific recommendations are worthy of further discussion/consideration. I shall address a number of these points below.

3.2. Admissibility of Scientific Evidence

Admissibility

3.2.1. The subject of validation is considered at a number of points in the Review and this discussion could be interpreted as suggesting validation

is, or perhaps should be, a condition precedent for the admissibility of scientific evidence.

3.2.2. My understanding is that, at least within England and Wales, there is no admissibility test (in relation to scientific validity) for scientific evidence. While there are cases[20] where a lack of reliability, lack of acceptance or the nature of the discipline may influence the determination of admissibility in relation to the normal tests for admissibility of expert testimony such factors normally affect only the weight attached to the evidence. In 2005 the House of Commons Select Committee on Science and Technology recommended[21] the introduction of such a test. It said:

> "The absence of an agreed protocol for the validation of scientific techniques prior to their being admitted in court is entirely unsatisfactory. Judges are not well-placed to determine scientific validity without input from scientists. We recommend that one of the first tasks of the Forensic Science Advisory Council be to develop a "gatekeeping" test for expert evidence. This should be done in partnership with judges, scientists and other key players in the criminal justice system, and should build on the US Daubert test."

3.2.3. The reference to "Daubert" is, of course, to the well known case of *Daubert v Merrill Dow Pharmaceuticals*[22] which considered the application of Rule 702 of the US Federal Rules of Evidence. This sets out an approach to determining whether evidence should be admitted.

3.2.4. The concern raised by the Select Committee was echoed by Weir J in the case of *R v Hoey*[23].

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20 Luttrell & Ors, R v [2004] EWCA Crim 1344

21 Forensic Science on Trial, Report of the House of Commons Select Committee on Science and Technology, 2005 – recommendation 55.

22 Daubert v. Merrell Dow Pharmaceuticals (92-102), 509 U.S. 579 (1993).

23 Hoey, R. v [2007] NICC 49

3.2.5. Whilst HM Government has implemented a number of the recommendations of the Select Committee (for example the formation of the FSAC) and the proposals set out in its response to the Report (e.g. establishing the role of the Regulator) it has not implemented the recommendation in relation to admissibility. The current position is, perhaps, best described by the judgment of the Court of Appeal (Criminal Division) in the case of *Harris*[24].

> "As to expert evidence generally, the evidential rules as to admissibility are clear (see for example *R v Bonython* [1984] 38 SASR 45 and *R v Clarke* (RL) [1995] 2 Cr. App. R. 425 (facial mapping)). We see no reason for special rules where medical experts are involved. There is no single test which can provide a threshold for admissibility in all cases. As *Clarke* demonstrates developments in scientific thinking and techniques should not be kept from the Court. Further, in our judgment, developments in scientific thinking should not be kept from the Court, simply because they remain at the stage of a hypothesis. Obviously, it is of the first importance that the true status of the expert's evidence is frankly indicated to the court."

3.2.6. The CPS supports the position set out in *Harris* and reviews and prosecutes cases on the basis that DNA evidence is accompanied by appropriate supporting evidence, and, together, the sum of the evidence satisfies the evidential test set out in the Code for Crown Prosecutors.

3.2.7. Although the position in *Harris* set out in paragraph 3.2.5 above may be seen as allowing unsupported hypotheses to be adduced in evidence, there are however safeguards in place. In *Harris* and in *Bowman*[25] the Court set out the duties and obligations placed upon expert witnesses.

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[24] Harris & Ors, R v [2005] EWCA Crim 1980.
[25] Bowman, R v [2006] EWCA Crim 417.

These have been codified in Part 33 of the Criminal Procedure Rules[26] (CPR).

3.2.8. In particular section 33.3 includes:

> 33.3.(1) An expert's report must—
>
> (f) where there is a range of opinion on the matters dealt with in the report—
>
> (i) summarise the range of opinion, and
>
> (ii) give reasons for his own opinion;
>
> (g) if the expert is not able to give his opinion without qualification, state the qualification:

3.2.9. These provisions, if practitioners are aware of and comply with them, will ensure the courts are advised of any reservations about a technique.

3.2.10. It is not within my remit to establish admissibility criteria for the courts and I do not seek to do so.

3.2.11. I believe that, under normal circumstances, appropriate validation should be completed before any scientific technique is employed within the CJS. This is a requirement[27] of accreditation to ISO 17025 and of normal scientific method. I do, however, recognise that cases may arise where techniques are applied at an early stage in development when validation is not completed. These cases should be exceptional.

3.2.12. In such circumstances, and in accordance with the points made above, the expert must make full disclosure of the limitations in any validation conducted.

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[26] The Criminal Procedure (Amendment No. 2) Rules 2006, S.I. 2006 No. 2636.

[27] Section 5.4.5 of ISO 17025:2005.

Validation Standard

3.2.13. This is discussed earlier in my reply, but against this background I think it is important to comment on two issues discussed within the Review.

3.2.14. The first is international acceptance of a technique. I believe it will be difficult to demand international acceptance of a technique before it can be applied within the CJS. Clearly, and perhaps simplistically, some country will always be the first to deploy a given technique. There would also be an issue, perhaps impossible to resolve, as to what amounts to international acceptance.

3.2.15. There is also a risk that the development of the technique or the applicable rules in other countries prevents its implementation.

3.2.16. However, international non-acceptance of a technique (when based on science rather than applicable law) would raise concerns which must, in England and Wales, be reported as such under the CPR Part 33 obligations and existing case law. Such non-acceptance would also highlight the risk associated with the technique and thus bring it to my attention.

3.2.17. The second is the need for scientific consensus. The term consensus is not strictly defined. Some dictionaries define it as the “majority opinion” whilst others as “an agreement or position reached by a group as a whole”. To avoid confusion I shall refer to the first as consensus and the latter as uniformity.

3.2.18. It is the nature of scientific endeavour that for any theory proposed, even when accepted by the majority, there will be dissent. Such dissent may represent a significant proportion of the community. Uniformity is a goal which is unlikely to be achieved.

3.2.19. Consensus may be achieved but I am not convinced that the opinion of the majority should automatically exclude the views of the minority from use in evidence. To do so appears contrary to the views expressed by the Court of Appeal in *Harris* and, I believe, it may not be in the best interests of the CJS.

3.2.20. As a result I do not accept consensus should be required before a technique is employed within the CJS. Certainly it should be based on sound science, have a sufficient quantity of data to support its use and have a sound interpretation model. I accept that it should be supported by a responsible body of scientific opinion but I recognise there may be a significant part of the community that hold a differing view. The fact that there is a differing opinion should be reported to the court[28].

3.2.21. These views are tentative and I may change my position when presented with the advice of the specialist group.

3.3. Reporting of Results

Reporting

3.3.1. The Review discusses, at a number of points, the interpretation of the results. Whilst not highlighted directly, the reporting of the results is the logical conclusion of the interpretative process. A number of those that I have discussed the Review with have raised the issue of suitable reporting standards.

3.3.2. The issue of reporting standards is of fundamental importance. No matter the standards applied to the generation of results, and their subsequent interpretation, if the reporting is not fit for purpose then there is a serious risk to the CJS.

3.3.3. As noted above I have established a specialist group to determine the needs of the CJS end users and to make relevant recommendations. As

[28] Part 33 Criminal Procedure Rules.

part of that exercise I shall ask the group to consider the setting of standards for the reporting of results. In particular I will ask the group to consider the following issues.

- Should reports and statements clearly state the facts that were determined as a result of the analytical process?
- Should reports and statements clearly state the matters taken into consideration when interpreting the facts?
- Should reports and statements clearly state the assumptions made in the process of interpreting the facts?
- In what manner should reports and statements set out information relied upon in preparing the report?
- In what manner should reports and statements set out any reservations or caveats about the results and interpretation?

3.3.4. There are existing requirements, such as the Criminal Procedure Rules[29], which require inclusion of certain material in reports and statements. Whilst these will act as a basis for the consideration discussed above I do not believe they should limit it. These requirements can be changed if it would be for the benefit of the CJS.

Phased Reporting

3.3.5. In recent years phased reporting[30] has been introduced and extended across a number of fields in forensic science. It has proven to be a very effective and efficient use of forensic science resources and a great benefit to the CJS.

3.3.6. I recognise that the information which can be provided in such a brief report is limited and, in a subject as complicated as LTDNA, it may prove difficult for Crown Prosecutors to make a fully informed charging decision on this information. Similarly, defence solicitors may find it difficult to

[29] Criminal Procedure Rules Part 33.3 (b)-(d).

[30] The process involves the issue of an initial (brief) report setting out basic conclusions. A full evidential statement can be issued later if the defence is not willing to agree the evidence.

assess the position of their client and establish the best course of action on the basis of a brief report on such a complex subject.

3.3.7. I will ask the End User Specialist Group to consider how the standards applied to reporting can be extended to phased reporting and ensure the best interests of the CJS are served by this process.

4. Conclusions

4.1.1. Having considered the Review and discussed its conclusions with the FSAC and stakeholders. I am content that the science underpinning the LTDNA analytical services, as provided to the CJS, is sound and that the three forensic science suppliers offering such services have properly validated their processes. There is no flaw inherent in the process which prevents its use within the CJS.

4.1.2. The recommendations set out in the Review, and points raised by members of the FSAC and stakeholder organisations, demonstrate that there are areas where the current processes can be improved. LTDNA services can be separated into three sections: collection, analysis and interpretation. I believe the key areas where improvements can be made are the collection of and, probably most importantly, the interpretation of the evidence. I have, within this Response, set out the way in which I wish to achieve these improvements.

4.1.3. The ability to improve on the current approach does not mean that the approach should not be employed within the CJS. As long as the scientist reporting the results of LTDNA analysis complies with the duties and obligations placed on expert witnesses the CJS will appreciate the nature and value of the evidence provided.

Andrew Rennison

7 May 2008

5. Annex

5.1. Summary of Responses

Grouped Recommendations	Response
Recommendation 1 For SOCOs/CSIs and SIOs, there needs to be a national education programme setting out the advantages and limitations of LTDNA in order to establish a conformity of approach to crime scene work. From this should be developed national guideline documentation. It is for the Forensic Science Regulator to institute such training programs and mechanisms for the resolution of these issues. **Recommendation 2** It is for the Forensic Science Regulator to come to an agreement with all parties on what constitutes LTDNA success and to then to institute an appropriate survey. **Recommendation 3** It is for the Forensic Science Regulator to institute appropriate training programs and to set standards that will enable police forces and their crime scene personnel to have a full grasp of what constitutes LTDNA analysis, how such samples are to be collected and stored especially in relation to issues of contamination and the likelihood of success.	I will ask the DNA and End-User Specialist Groups to look at requirements of the various parts of the Criminal Justice System for LTDNA awareness advice and to identify the most effective delivery channels and partners as required, but taking advantage of the ACPO/NPIA Forensics 21 programme.
Recommendation 5 We have been told that there is an urgent need for the DNA profiles of all serving operational police officers and crime scene personnel to be included on the Police Elimination Database and for forensic science providers to have direct access to it as a means of eliminating irrelevant DNA profiles. While laboratory personnel can usually be eliminated from a DNA profile fairly quickly, the incomplete nature of the Police Forces DNA database is a hindrance and the Forensic Science Regulator needs to pursue this problem with ACPO. As an alternative, financial support needs to be provided to enable the DNA profiles of Police Officers and crime scene personnel involved in a specific investigation to be obtained at the same time as the suspect samples.	I am content that the ACPO DNA Operations Board has a comprehensive programme to review and expand the Police Elimination Database and will lend it any support required.

Grouped Recommendations	Response
Recommendation 9 Those police forces that have made the decision to carry out preliminary forensic testing by the establishment of a police forensic science laboratory must have such laboratories accredited to a standard comparable to those of forensic science providers and should comply with ISO 17025 through UKAS. The Forensic Science Regulator needs to enter into a dialogue with ACPO as to the way Police laboratories are to be integrated into the scheme of forensic science provision.	The Quality Standards Specialist Group will consider the different types of laboratory work and will advise on relevant standards to apply across the board, regardless of whether a laboratory is managed by a police force or a commercial organisation.
Recommendation 8 It is for the Forensic Science Regulator to oversee compliance with standards of competence for LTDNA laboratory specialists and when and where appropriate to suggest modifications to such training programs and record keeping.	I am establishing a Practitioner Standards Specialist Group which will review the existing standards, including those related to training, and recommend such modifications as are appropriate. I support the work of UKAS to oversee compliance with laboratory standards and maintenance of training records as part of ISO 17025 accreditation. I will work with UKAS and the Custodian of the NDNAD to ensure the standards applied are appropriate.

Grouped Recommendations	Response
Recommendation 4 The Forensic Science Regulator should monitor the use of DNA quantification procedures. **Recommendation 10** For all LTDNA samples and taking into account the limitations of the amount of DNA extracted from crime samples, quantification of the material extracted for analysis must be undertaken. Satisfactory commercial kits are now available for this purpose. Further research is required into the best ways of quantifying very small samples of DNA such as using repetitive DNA target. The Forensic Science Regulator must insist that as a matter of best practice a DNA quantification step is implemented for all DNA analyses submitted to the CJS and should monitor its implementation. **Recommendation 19** National minimum technical standards for extraction, quantification/dilution and interpretation criteria need to be agreed by all forensic science providers. These standards should also be agreed by the Forensic Regulator's Forensic Science Advisory Council. The Forensic Science Regulator needs to coordinate all the information already available that is associated with extraction etc. techniques and by agreement with all stakeholders establish appropriate standards.	The DNA Specialist Group will develop appropriate standards for DNA extraction and quantification for LTDNA analysis.

Grouped Recommendations	Response
Recommendation 6 A national standard needs to be established for 'DNA clean' consumables, especially in relation to crime scene recovery kits. The Forensic Science Regulator should ensure that only kits which meet such a standard should be used by police forces. **Recommendation 7** The Forensic Science Regulator should ensure the batch testing of all DNA reagents to ensure that they are DNA free prior to their use.	I am already working with the NDNAD Custodian Unit of the NPIA to develop recommendations for comprehensive standards for consumables and reagents. I am in discussion with the NDNAD Custodian Unit over the design and operation of proficiency testing for suppliers to the National DNA Database. The DNA Specialist Group will be asked to take responsibility for advising on these matters.
Recommendation 2 It is for the Forensic Science Regulator to come to an agreement with all parties on what constitutes LTDNA success and to then to institute an appropriate survey.	I will ask the NPIA to consider incorporating LTDNA monitoring under the Forensics 21 programme.

Grouped Recommendations	Response
Recommendation 11 There needs to be a national agreement on how LTDNA profiles are to be interpreted especially in relation to “allele drop in and out”, stochastic effects, inhibition, and mixtures. This should be aided by regular circulation of appropriate test profiles and interpretation by ALL providers of this service and any results should be coordinated through the forensic science regulator. The Forensic Science Regulator should develop a consensus from all the forensic science providers in consultation with all stakeholders on how profiles and mixed profiles are to be interpreted. Once these criteria/standards have been agreed then the regulator should monitor their implementation. The Forensic Science Regulator should encourage openness in the availability of information that may have an impact on the way DNA profiles are interpreted in the context of a case. **Recommendation 13** Appropriate caveats should be stated in witness statements/court reports, in most instances, when LTDNA analyses have been undertaken. **Recommendation 16** Improve existing guidelines and standards. Active development of a consensus approach to the analysis of partial or contaminated DNA profiles is already underway and needs further work and an inclusive structure that takes account of all of the stakeholders. National and international providers have led the way, but this now needs to include close consultation with users. Within the UK a steering or advisory group comprising providers, users and independent legal advice, with perhaps lay representation should endeavour to develop documentation that would guide the courts in the interpretation of evidence. Educationalists and users should evaluate its comprehensibility and review it in a timely manner in the light of legal precedent and scientific advances. **Recommendation 19** National minimum technical standards for extraction, quantification/dilution and interpretation criteria need to be agreed by all forensic science providers. These	I will ask the DNA Specialist Group to draft guidance which addresses the issues of interpretation of DNA with particular reference to the increased impact of stochastic effects and DNA mixtures encountered in LTDNA analysis. I will ask the End User Group to ensure that such guidance adequately informs the CJS of (a) the result, (b) the significance of the result and (c) any reservations that apply to the result and/or interpretation.

standards should also be agreed by the Forensic Regulator's Forensic Science Advisory Council. The Forensic Science Regulator needs to coordinate all the information already available that is associated with extraction etc. techniques and by agreement with all stakeholders establish appropriate standards.	

Grouped Recommendations	Response
Recommendation 12 The Forensic Science Regulator should institute a regular program of inspections of documentation associated with all validations. **Recommendation 14** Any new methods of analysis used by a forensic science provider that will result in the presentation of evidence to the courts must be validated using appropriate and sound internationally recognised scientific principles. The details of such validation, including copies of raw data, should be lodged with the forensic science regulator before it is introduced into service. At least once a year or when the regulator decides it appropriate, such validations will be reviewed by an independent internationally recognised expert panel the composition of which will be determined by the regulator.	I will ask the Quality Standards Specialist Group to advise on a protocol for the validation of forensic science techniques, and how significant or substantial changes to processes or procedures are validated. I will ensure that clear guidance on the path for innovation-to-market for new forensic science products and services is in place for all forensic science providers to follow, which will include consultation and validation requirements.
Recommendation 15 An independent study should be undertaken to assess the advantages and disadvantages of the two different approaches to LTDNA analysis. The Review has been informed that a scientific paper by one of the forensic science providers describing this is expected to be published soon. Whether or not this scientific paper is published the Forensic Science Regulator should provide a mechanism that, while retaining appropriate confidentiality for the researchers, enables other providers to evaluate the research.	A scientific paper on the advantages and disadvantages of the two different approaches to LTDNA analysis is expected to be published shortly and the DNA Specialist Group will review any further actions following publication.

Grouped Recommendations	Response
Recommendation 17 The use of STR's clearly has limitations and is essentially 15-year-old technology. The world of genetics and genome analysis has moved on a great deal since then and there may be benefits to be had from alternative technologies. For example, the world of forensic archaeology has been transformed by the use of next generation sequencers and it seems likely that these could have a huge impact on forensic DNA analysis. Furthermore PCR and other amplification technology has improved, with the development of emulsion PCR that may have substantial advantages and enable backward compatibility with the existing STR database. At present any service developments would have to be recovered as a service cost overhead. This would preclude radical advances requiring substantial funding. These developments may require high-level academic input and a competitive funding mechanism similar to those used by the Research Councils. Opportunities to tap into the international expertise of the Wellcome Trust Sanger Institute, a world leader in DNA sequencing technology, could be investigated. A UK working group focussed on such developments should develop an option appraisal. The risk of not doing this is the stagnation and decline of standards on forensic DNA analysis, whereas a successful programme would secure a world lead for the UK.	I will ask the specialist working groups to identify future opportunities and potential risks which will need managing in the context of my role.
Recommendation 18 An open funding mechanism needs to be put in place that will support an independent validation process of new developments. The Forensic Science Regulator should seek funding for independent research and validation that is open to national competition	I will cover the independent validation of exceptional cases that require my active involvement, or that of a third party, on an ad hoc basis.
Recommendation 20 Since this matter of financing forensic science has been brought to our attention by the forensic science providers we believe it is for the Forensic Science Regulator to quantify this problem and to explore mechanisms to correct any problems his inquiry may reveal.	The Risk Specialist Group will develop a model to identify and prioritise risks to quality standards in the use of forensic science in the CJS.

Grouped Recommendations	Response
Recommendation 21 The Forensic Science Regulator should explore the means of establishing a professional forensic science provider's organisation in order to develop mutually agreed standards.	I am happy that the new Association of Forensic Science Providers already largely fulfils this requirement. Furthermore, that the Stakeholders Forum and Suppliers Forum are formed to assist me in identifying and ensuring appropriate standards are in place completes this recommendation fully. I will monitor the developments in the Association to determine if a second organisation should be created to cover the interests of the smaller providers, particularly those involved with defence work.