NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

ANTI-COAGULATION MONITORING 2017 -18

a) Purpose of Agreement

This Agreement outlines the service to be provided by the Provider, called an Anti-coagulation monitoring service.

b) Duration of Agreement

This agreement is for a period of twelve months, commencing **1st April 2017** and ending on **31st March 2018.**

c) Background

Warfarin is being used in the management of increasing numbers of patients and conditions including patients' post-myocardial infarction, atrial fibrillation, DVTs and other disorders. While it is a very effective drug in these conditions, it can also have serious side effects, e.g. severe haemorrhage. These side effects are related to the International Normalised Ratio (INR) level, which measures the delay in the clotting of the blood caused by the warfarin. While the "normal" INR is 1, the specific range of INR values depends on the disease and the clinical conditions. Warfarin monitoring aims to stabilise the INR within set limits to help prevent serious side effects while maximising effective treatment.

d) Aims

An anti-coagulation monitoring service is designed to be one that should be available to all registered patients including those that are housebound and require domiciliary visits. Practices are required to liaise with community services to ensure there is no gap in service provision for all patients.

a) therapy should normally be initiated in secondary care, for recognised indications for specified lengths of time

b) maintenance of patients should be properly controlled

c) the service to the patient is convenient

d) the need for continuation of therapy is reviewed regularly

e) the therapy is discontinued when appropriate

e) Service Delivery

Practices can be commissioned to provide one of the levels as outlined below. The level of service should be clearly indicated on the application form.

Level	Practice Responsibility	Summary	Tariff per patient per year (excl. Level 2)
1	Prescribing Only	- Hospital Sample - Hospital Testing - Hospital Dosing - Practice Prescribing	NIL
1 (a)	Sampling and Prescribing	- Patient Administration - Practice Sample - Hospital Testing - Hospital Dosing - Practice Prescribing	£10.10 per patient per year (Patient Administration) plus £2.02 per venous sample
2	Dosing and Prescribing	- Patient Administration - Hospital Sample - Hospital Testing - Practice Dosing - Practice Prescribing	£61.65
3	Sampling, Dosing and Prescribing	- Patient Administration - Practice Sample - Hospital Testing - Practice Dosing - Practice Prescribing	£88.44
4 (a)	Sampling, Testing and Prescribing	- Patient Administration - Practice Capillary Sample - Practice Testing - Hospital Dosing - Practice Prescribing	£141.40
4 (b)	Sampling, Testing, Dosing and Prescribing	- Patient Administration - Practice Capillary Sample - Practice Testing - Practice Dosing - Practice Prescribing	£181.80

** Practices wishing to provide levels 4 (a) or (b) will need to provide capillary sampling to also provide the practice testing element of the service and therefore will incur the costs associated with Capillary Sampling including; Test Strips, NEQAS testing, Lancets and Control Solution.* ***Note*** *FP10's are not to be issued for test strips.*

Service Definitions

Patient Administration- The organisation of patient's appointments, including call and recalls etc

Hospital Sample - The process of obtaining a sample of blood to obtain an INR result through either venous or capillary methods undertaken by the hospital.

Practice Sample - The process of obtaining a sample of blood to obtain an INR result through either venous or capillary methods undertaken by Practice Employed Staff at the Practice

Hospital Testing – Obtaining an INR result through the testing of blood sample undertaken by the hospital.

Practice Testing – Obtaining the INR result through the testing of blood sample undertaken at the Practice.

Dosing - 'Doser' means any person who is suitably trained and qualified who, upon receipt of relevant information from laboratories or near patient testing equipment or otherwise, determines the appropriate anti-coagulant dosage and makes recommendations for the timing of the next INR test. If the relevant information from the laboratory does not include the dosing information then this must be determined by computer assisted decision-making equipment.

Practice Prescribing – Issuing Patient's prescription for Anti Coag therapy

f) Service outline

a) **Professional Links.** To work together with other professionals when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained.

b) **Referral Policies.** When appropriate to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist

c) **Patient Education.** To provide education to patients (and their carers and support staff when appropriate) in the management of their condition

d) **Call and Recall.** To ensure that a systemic call and recall of patients on this register is taking place either in a hospital or general practice setting.

e) **Clinical Procedures.** To ensure that all clinical information related to the service is recorded in the patient's own GP held lifelong record, including the completion of the "significant event" record that the patient is on warfarin

f) **Governance** .The governance for each step of the process sits with the organisation who undertakes the task. For instance, in level 4 (a) even though the majority of the activity will take place within the practice the hospital provide governance as they're dosing the test result.

g) **Individual management plans**. To prepare with the patient an individual management plan which gives the diagnosis planned duration and therapeutic range to be obtained (e.g. the yellow book and alert card)

All new patients prescribed warfarin must have a counselling checklist completed to ensure the patient has received all the appropriate information required. At the first appointment following transfer from secondary care, education should be reinforced. The counselling should be comprehensive to ensure that patients are fully aware of their treatment and should include:-

(i) The name of the drug and current dose,

(ii) The reason they are taking the drug,

(iii) Therapeutic goal,

(iv) The anticipated length of treatment,

(v) What to do in the event of a missed dose,

(vi) Symptoms of under/over anticoagulation and action to take if these occur,

(vii) Drug/food interactions,

(viii) Clinic arrangements and how to obtain further medicine supplies,

(ix) What to do if dental treatment/surgery is required,

(x) What to do if a surgical procedure is required/indicated,

(xi) Who to contact regarding any worries or concerns relating to their anticoagulation management.

(xii) All new patients should have a yellow anticoagulation pack, including yellow record booklet.

(xiii) All relevant information will be transferred from GP Clinical system to the relevant INR software database at first appointment. All future input of data will enable both clinical system and INR software to be updated.

h) **Record-Keeping.** To maintain adequate records of the service provided. This may include the number of bleeding episodes requiring hospital admission and deaths caused by anti-coagulants

- Patient Name
- Patient Date of Birth
- NHS number
- Indication for treatment
- Length of treatment
- Target INR
- Named medical practitioner initiating treatment
- Discontinuation date
- INR results, dosage instructions and review dates
- Missed days (i.e. a record of days when the patient has not taken their anticoagulant therapy in accordance with dosing instructions)
- Concurrent medication
- Medical conditions, hospital admissions likely to affect anticoagulation such as an increased risk of haemorrhage (BCSH Guidelines 1998)
- Bleeding episodes
- Any actions taken, as well as dosing and retest dates e.g. education, advice, whether the INR result is from near patient testing or central lab testing
- Occasions when the patient failed to attend an agreed clinic appointment
- Contact details for patient or for carers responsible for the administration of Warfarin

i) **Training.** Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so

j) **Review.** Providers must perform an annual review and make available to the Commissioner on request:

i. Local processes for compliance with CCG warfarin management guidelines - in addition to information on the number of patients being monitored

ii. information on the number of patients being monitored, the indications of anticoagulation, i.e. DVT etc, and the duration of treatment

iii. brief details as to arrangements for each of the aspects highlighted above

iv. details of any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance

v. details of any near-patient testing equipment used and arrangements for internal and external quality assurance

vi. details of any training and education relevant to the anti-coagulation monitoring service received by practitioners and staff

vii. details of the standards used for the control of anti-coagulation

Annual Clinical Audit Criteria (Statement) – based on safety indicators identified by the NPSA	**Clinical Audit standard (target standard)**
Patients established on oral anticoagulation should be within INR target more than 50% of the time (via INR Software as at commencement of repatriation of patients)	100%

The practice should be able to demonstrate appropriate action has taken place for INR 5-8, e.g. review of patient within 1 week	95%
Practices should be able to demonstrate consideration of administration of vitamin k and monitoring of patient within 2 days and/or admission for INR >8.	100%
Patients established on oral anticoagulation should be given written dosage instructions at each clinic visit	100%
Annual Service Return Criteria (Statement) – based on safety indicators identified by the NPSA	
Providers must ensure that all staff involved in providing any aspect of care under the scheme has the necessary training and skills	
Providers must have an up to date Standard Operating Procedure (SOP) for Anticoagulation	
All staff involved in providing the anticoagulation service must follow the SOP for Anticoagulation	
Patients should not be accepted on the SLA scheme without completed transfer documentation from secondary care	
Practices should have a call/recall system which captures any patient who fails to attend for follow up	
Patients established on oral anticoagulation should have their diagnosis recorded	
Patients established on oral anticoagulation should have their target INR recorded	
Patients established on oral anticoagulation should have their stop date recorded	
Patients established on oral anticoagulation should not go past their stop date	
Patients established on oral anticoagulation should be given written dosage instructions at each clinic visit	
Newly diagnosed patients should have a patient held record	
All new patients transferring in to the scheme should have the agreed documentation completed	
Providers must be able to evidence monthly calibration of all machines used to deliver the service. (A minimum of x3 NEQAS reports are to be submitted along with details on the steps taken to address any anomalies.)	
Information on the number of patients being monitored, the indications of anticoagulation, i.e. DVT/AF etc., and the duration of treatment	
Details of any training and education relevant to the anti-coagulation monitoring service received by practitioners and staff	
Details of any near-patient testing equipment used and arrangements for internal and external quality assurance	

NPSA Alert. The National Patient Safety Agency has issued guidance that must be used in conjunction with this specification. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814&q=0%c2%acwarfarin%c2%ac

g) Accreditation

Those doctors who have previously provided services similar to this service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the service shall be deemed professionally qualified to do so.

h) Untoward events

It is a condition of participation in this service that practitioners will give notification to the Commissioner clinical governance lead of all emergency admissions or deaths of any patient covered under this service, where such admission or death is or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition. This must be reported within 72 hours of the information becoming known to the practitioner. This is in addition to a practitioner's statutory obligations.

i) Activity Reporting and Payment Arrangements

- **Reporting Arrangements**

Practices are required to report the following information on a quarterly basis to capccg.enhancedservices@nhs.net by the 15th day of the following month, following Quarter end.

- The number of patients who have received Anti Coag monitoring in the relevant quarter. Submission via Practice Commissioning Statement for Local Enhanced Services.
- *For Practices undertaking the Level 4 (a) or (b) service*, Practices will also be required to submit statistics from INR Software as outlined in the quarterly report (Appendix C) and the Annual Review Self Assessment (Appendix D) at year end only.

If Practices require help or advice on clinical recording, coding and reporting, please contact The Primary Care Information team via the following email address: capccg.primarycareinformation@nhs.net

- **Payment Arrangements**

Practices will be commissioned in the first instance against their commissioned levels of activity and the indicative budget for the provision of each service for the forthcoming year. Practices will receive 12 monthly payments based on the total indicative budget for the year with any adjustments to be made at year end if necessary.

If a practice performs within their indicative budget for that service they will be paid at the full rate. However, payment for over performance will only be paid the full rate for activity above their budget if there is sufficient funding in the enhanced services cash pool.

Practices may be paid a marginal rate for activity above their budget if there is insufficient funding in the Enhanced Services cash pool to pay the full rate. The marginal rate for excess activity may be between 0-99% of the full rate depending on level of over performance across all practices.

10. Payment Verification

Practices entering into this contract agree to participate fully in the post payment verification/validation process determined by the Commissioner and LMC. Practices should ensure that they keep accurate records to ensure a full and proper audit trail is available and Practices are encouraged to utilise Practice computer systems to enable this condition to be met.

11. Performance

The CCG reserves the right to suspend the commissioning of this service where there are concerns around compliance and patient safety.

12. Safeguarding Adults

It is important that practices protect adults from avoidable harm (as defined in Safeguarding Adults guidelines) including safeguarding training, training on the Mental Capacity Act and Deprivation of Liberty. A Safeguarding lead should be identified in each practice.

13. Care Quality Commission (CQC)

The provider must meet CQC standards and where appropriate be registered with the Care Quality Commission (CQC). The standards and the relevant services are contained in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations 2014.

14. Termination

Should either party wish to terminate this agreement, a minimum period of 3 months notice must be provided in writing.

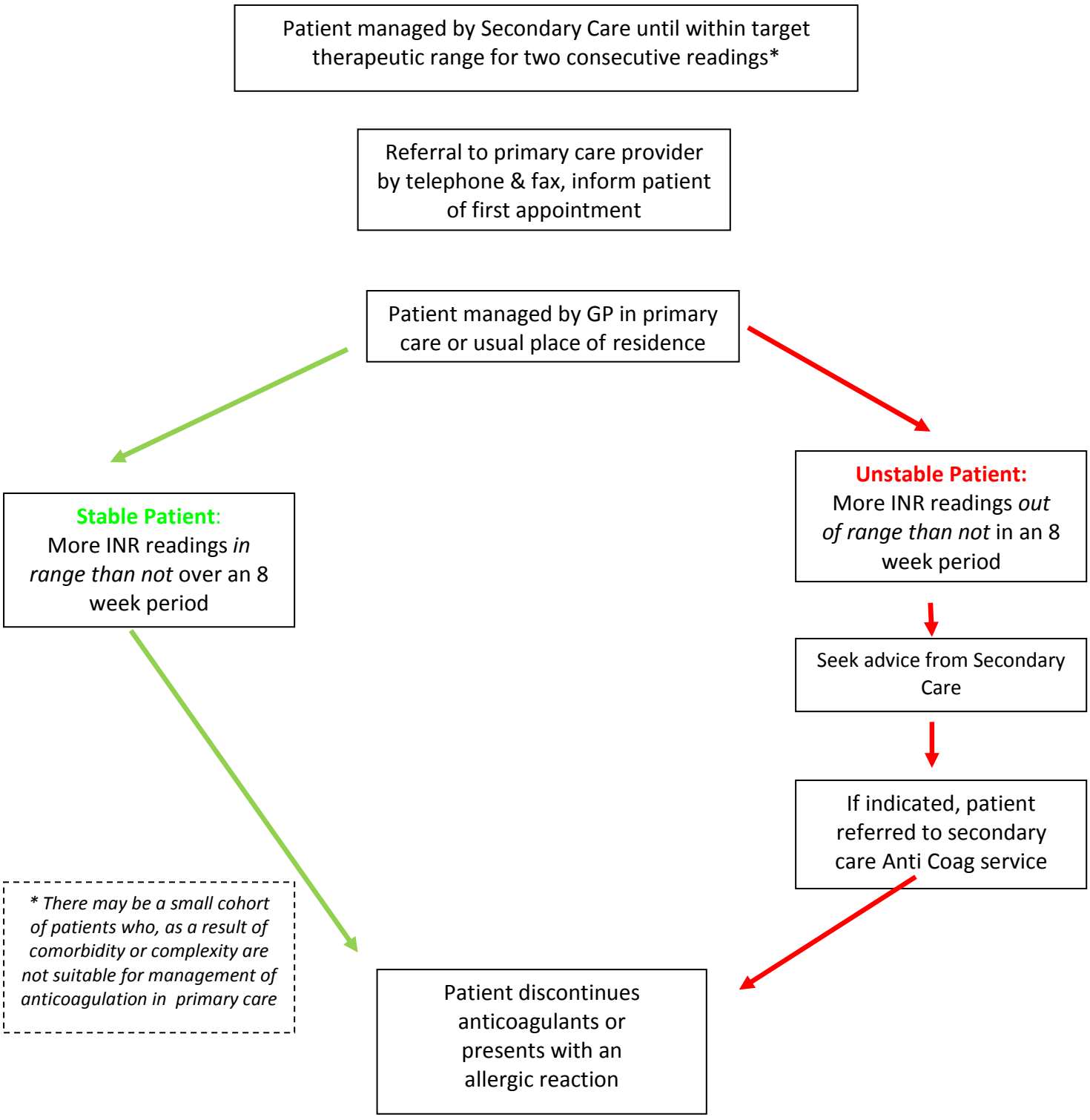
15. Signatories to the Agreement

Practices wishing to provide this service are required to complete and sign the application form, and return to the Commissioner for consideration.

Appendix B

PATIENT CARE PATHWAY

Algorithm for Initiating, Maintaining, Referring and Discontinuing Patients on Anticoagulants



Anticoagulation Monitoring – Service Level Agreement 2017/18
Accreditation Checklist for providing Level 4 (a/b) Service

This checklist should be completed by each practitioner providing the anticoagulation monitoring Service Level Agreement and submitted with the Application Form.
Please tick the appropriate boxes below.

☐ I have completed the following BMJ modules - Starting patients on anticoagulants: how to do it and / or Maintaining patients on anticoagulants: how to do it

☐ The certificates to be provided by health professional at the annual audit

☐ I have read the Standard Operating Procedures for Health Care Assistants and understand what is required

☐ I have read the Service Level Agreement and understand what is required

☐ I have read all the appropriate national and local guidelines

☐ I have read the relevant NPSA competencies 2, 4 & 6 (on link below) and declare that I meet all the requirements

http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61790

Completed by Practice	
Named Practitioner: …… Signed: ……	Clinical Lead: …… *(If different)*
Planned Service Commencement Date: ……	Date Document signed: ……

Completed by CCG Panel	
Checklist reviewed and approved by CCG Panel	YES / NO
Name:	Date:

Appendix C

Level 4 (a) / (b) Anticoagulation Monitoring Quarterly Return

All information needed for the Quarterly Reports are available from INRStar/DAWN

1. Log in to INRStar
2. Choose the '**Reports'** tab
3. Choose the '**Completed Treatments - Overview**' option in INRStar
4. Enter start & end dates for quarter then click the '**View Report**' button.
5. From the report that is generated save as an excel spreadsheet on your system in case it may be needed in future for audit purposes – give it a more descriptive name than the computer generated default so you can find it in the future. To do this click on the  icon in the middle of the page**.** Close the report to return to INRStar. **Report 1.**
6. Choose the '**Warfarin Quality Metrics (NPSA)**' option in INRStar. Enter start & end dates for quarter as before.
7. From the web page generated copy the follow
   Again save this report using the  button. **Report 2**
8. Choose the **'Rolling 12 Month TTR'** option.
9. Use the last month of the quarter as the date.
10. Record the **'TTR Band >60'** option (near the bottom of the screen).**Report 3**
11. Choose the '**External Quality Control** ' option in INRStar
12. Enter start & end dates for quarter
13. Save the web page generated the using the  button. **Report 4**
14. Return a copy of **reports 1, 2, 3 & 4** to CAPCCG.enhancedservices@nhs.net

by the 15th day of the month following quarter end.

Appendix C

Level 4 (a) / (b) Anticoagulation Monitoring Quarterly Return

Report from INRStar /DAWN

Name of Practice: _____ Locality_____

Quarter: _____

Name and email address of nominated GP Lead:	**Name and email address of Practice Manager:**
INR Variance - 'Within 1 units of target INR'	%
INR Variance - 'Within 0.75 units of target INR'	%
INR Variance - 'Within 0.5 units of target INR'	%
Patients Treated – 'Total Patients Treated'	
Test Types – 'PoCT'	
Test Types – 'Home Visits'	
Test Types – 'Self Tests'	
Percentage of INR Readings > 5.0	%
Percentage of INR Readings > 8.0	%
Percentage of INR readings < 1.0 Below Target	%
Percentage of Patients with Major Bleed in 1st Month	%
Percentage of Patients with Major Bleed in 1st Month & INR above Target Therapeutic Range	%
Percentage of Patients with Unknown Target INR	%
Percentage of Patients with Unknown Diagnosis	%
Percentage of Patients with Unknown Stop Date	%
Location – All Time TTR	%
Location – 12 Month TTR	%
Rolling 12 Month TTR - TTR Band >60	%
Date of last NEQUAS test	
PoCT INR	
Ext INR	

Please return the completed data sheets quarterly by the 15th day of the month following quarter end to your LCG via CAPCCG.enhancedservices@nhs.net

Appendix D

ANTICOAGULATION MONITORING 2017/18
LEVEL 4a / 4b SERVICE

Annual Review Self Assessment
Please return this form by 31st March 2018 to CAPCCG.enhancedservices@nhs.net

Name of Practice…… **Locality ……..**
Date:

Annual Service Return Criteria – based on safety indicators identified by the NPSA	Compliant Yes/No	Comments
Providers must ensure that all staff involved in providing any aspect of care under the scheme has the necessary training and skills.		
Providers must have an up to date Standard Operating Procedure (SOP) for Anticoagulation		
All staff involved in providing the anticoagulation service must follow the SOP for Anticoagulation		
Patients transferred from secondary care or other provider should not be accepted on the SLA scheme without completed transfer documentation		
Practices should have a call/recall system which captures any patient who fails to attend for follow up		
Patients established on oral anticoagulation should have their diagnosis recorded		
Patients established on oral anticoagulation should have their target INR recorded		
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Patients established on oral anticoagulation should not go past their stop date		
Patients established on oral anticoagulation should be given written dosage instructions at each clinic visit		
Newly diagnosed patients should have a patient held record		
Providers must be able to evidence at least monthly calibration of all machines used to deliver the service.		
Providers must be able to evidence at least quarterly external calibration (NEQAS) of all machines used to deliver the service along with the steps taken to address any anomalies		

Signed…….. Date…….

Name ……..