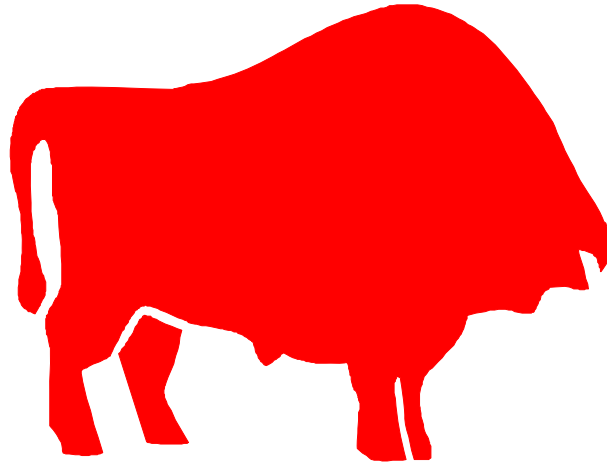


DRAFT 10

**LABORATORY CONTINGENCY
PLAN MANUAL FOR FMD
(INTERNET VERSION)**



**Institute for Animal Health
Pirbright Laboratory**

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(Only first 18 of 58 pages are available in internet version)

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1. INTRODUCTION

1.1 The Disease – A brief overview

Foot-and mouth Disease (FMD) is a serious viral disease principally affecting cattle, sheep, goats, pigs, buffalo and deer. The disease exists in 7 serotypes which are clinically indistinguishable but antigenically distinct. FMD has extreme communicability and can spread rapidly through livestock populations and across continents.

The disease has very serious consequences including: adverse animal welfare effects due to the formation of acutely painful vesicular lesions of the mouth, feet and udder and fatalities in immature livestock. FMD has both direct and indirect economic effects. These include: loss of productivity of meat and milk, mortalities, loss of national trading status and markets for live animals and animal products; interference with agriculture and tourism and the costs of applying control measures. These can encompass movement standstill orders, slaughter and disposal of animals, cleaning and disinfection, compensation and vaccination. An additional cost is that of conducting the required serological surveillance after an outbreak in order to prove that both the disease and the virus have been eliminated.

Laboratory testing of suspect FMD samples is essential in order to confirm the clinical diagnosis, to determine the serotype and origin of the virus and to enable testing towards the selection of the most appropriate vaccine strain(s) to use against the spread of the disease.

The UK is currently free of the disease and holds the Office International des Epizooties status of a country “free from FMD without vaccination”. Past UK outbreaks have varied greatly in their extent, ranging from a single animal on a single premises (Isle Of Wight 1981) to hundreds of thousands of animals on thousands of premises (England, Scotland and Wales 2001). However, most outbreaks in the last 50 years have been relatively small in their geographical extent and the number of animals involved. The contingency plan is designed to cover a range of scenarios, including the worst case so far encountered.

Vaccination has never yet been practised in the UK and control has traditionally been by the slaughter of diseased and in-contact animals and associated zoosanitary measures. The most recent incursion of FMD was in 2001 when a massive epidemic occurred lasting 7 months with eradication involving the slaughter of some 400,000 animals at a cost of 1.75 billion pounds sterling. Following the 2001 outbreak there have been changes to both the approach and the legislation relating to the control of FMD in Europe, making it more likely that vaccination may be applied against any future outbreaks in the UK.

1.2 Contingency Planning for FMD in the UK.

Under European Union and United Kingdom law and in accordance with EU Council Directive 2003/85/EC of 29th September 2003, the UK is obliged to maintain contingency plans to deal with an outbreak of FMD. In the UK the lead agency responsible for the overall control of an outbreak is the State Veterinary Service within the Government Department for the Environment, Food and Rural Affairs (Defra). Defra maintains the national contingency plan which deals principally with the management of the disease in the field. Responsibility for the confirmation of diagnosis and other specified FMD related duties is contracted by Defra to the Institute for Animal Health, Pirbright Laboratory, which is also the UN-FAO World Reference Laboratory for FMD and an OIE Reference Laboratory for FMD.

Pirbright provides 24 hour cover for the diagnosis of FMD throughout the entire year and operates under SAPO Category 4 conditions of biocontainment. Pirbright is also responsible for serological surveillance during and after an outbreak. However, in the event that surveillance requirements exceed 8,000 serum samples per week, then the main bulk of such testing is to be transferred to the Veterinary Laboratories Agency laboratory at Weybridge, also under contract to Defra. In this event Pirbright will assist with the supply of expertise, staff and reagents as necessary. Consistency must be ensured between the contingency plans of all three parties.

In terms of laboratory engagement, the most demanding outbreak of FMD so far experienced in the United Kingdom occurred in 2001. During and after the seven month epidemic the laboratory investigations included the testing of 15,400 samples for the presence of FMD virus and 3,073,500 sera for the presence of antibodies to the virus. Contingency planning for FMD in the UK must at least cater for laboratory testing on a similar scale.

1.3 The Pirbright Contingency Plan for FMD

This document details the contingency plan at Pirbright for FMD, setting out the resources required, the responsibilities involved and the actions to be implemented to ensure preparedness for the threat, or the actual occurrence, of an outbreak of foot-and-mouth disease in the United Kingdom.

The plan is based on four alert levels, A, B, C and D. These levels are outlined in the following table and check lists for actions at each level are given in **Appendices 1A, 1B, 1C and 1D.**

ALERT LEVEL	STATUS
A	<i>No additional threat is recognised of the introduction of FMD into the UK</i>
B	<i>An outbreak or epidemic of foot-and-mouth disease is confirmed in a member country of the European Union, other than in the United Kingdom.</i>
C	<i>An outbreak of foot-and-mouth disease is confirmed in the United Kingdom</i>
D	<i>Foot-and-mouth disease attains, or is considered likely to attain, epidemic proportions in the United Kingdom.</i>

The plan is in two parts.

Part 1 describes the essential operational aspects of the plan, including listings of all relevant documentation.

Part 2 includes Appendices which provide further background and detailed information.

The Head of the Department of Control of Vesicular Virus Diseases at Pirbright is responsible for the overall management and maintenance of the plan. (See Crisis Job Descriptions. **Appendix 6.**)

The plan is practiced, reviewed and if necessary revised, at least annually to a set timetable.

1.4 DISTRIBUTION, ACCESS AND MAINTENANCE OF THE MANUAL

The Pirbright Laboratory Contingency Plan Manual for Foot-and-Mouth Disease is maintained electronically in two versions:-

1. An **outline form** of the manual is maintained on the Institute for Animal Health, Pirbright Laboratory, Website at

<http://www.iah.bbsrc.ac.uk/virus/Picornaviridae/Aphthovirus/index.html>

with free Internet access. The outline shows the structure of the plan without the details of documentation, the names of Pirbright staff concerned in management and the contents of the Appendices.

2. The **complete manual** is maintained on the Institute for Animal Health Intranet with access for all IAH staff at

<http://www3.iah.bbsrc.ac.uk/FMDpirbright>

under the heading of “FMD Contingency Plan”

3. **Electronic copies of the complete manual are also supplied to:-**

- The UK Department for the Environment Food and Rural Affairs (Defra) and the UK State Veterinary Service (SVS).

The Head of Veterinary Exotic Diseases Research and Official Controls Division

and

The Chairperson, UK FMD National Expert Group

- The UK Veterinary Laboratories Agency (VLA).

[The Chairperson of the Disease Emergency Response Committee (DERC)]

These individuals and organisations are automatically advised electronically when the plan is revised. The named individuals in Defra, SVS and VLA are responsible for any further distribution within their organisations.

2. Flow Chart showing the step-wise sequence of events at Pirbright for suspect FMD samples from the United Kingdom, together with a listing of the corresponding procedural documentation

NOTES:

1. The sequential actions are listed in the upper box at each step in the flow chart.
2. The relevant documentation listed in the lower box at each step in the flow chart is given in full on the IAH Pirbright Intranet.
3. The following acronyms are employed in the flow chart and are listed here in alphabetical order

CSU	Central Service Unit
DIN	Desk Instruction
DPR	Data processing and Recording
ELISA	Enzyme Linked Immunosorbent Assay
FLO	Flow Sheet
FMD	Foot-and-Mouth Disease
LIMS	Laboratory Information Management System
MEG	Molecular Epidemiology Group
NSP	Non Structural Protein
PRO	Protocol
QUA	Quality Assurance
SAU	Serum Assay Unit
SOP	Standing Operating Procedure
STARS	Sample Tracking and Reference System
VDG	Vesicular Diseases Group.
VNT	Virus Neutralisation Test
WRL	World Reference Laboratory

2.1. IAH Responsibilities to Defra under the Contingency Plan for FMD

The contract between Defra and IAH for the supply of exotic disease reference laboratory facilities including test capabilities, turn around times and scale up (Appendix 2)

[FLO 002](#). Statutory testing related to notifiable exotic viral diseases: sample receipt, and reporting



2.2. Defra contacts IAH Pirbright about the suspicion of an outbreak of FMD in the United Kingdom

List of Defra contact details (Current listing at Appendix 5. Updated as notified by Defra)

A0231. Access control, deliveries and collection

[DIN 110](#). Arrangements with Defra for the notification of IAH Pirbright Laboratory of incoming diagnostic samples from suspect cases of OIE List A diseases in Great Britain

[QAU Form 242](#) - FMD on-call rota

[QAU Form 243](#) - FMD on-call telephone list

[DIN 130](#). On-call officers for out of hours receipt and testing of samples in connection with Suspect cases of OIE List A diseases



2.3. The Head of the Laboratory and the Head of the Department of Control of Vesicular Diseases activate the components of the contingency plan at level C

Check Lists for alert levels A, B, C and D (given in Appendices 1A, 1B, 1C and 1D).



2.4. The sample is received and transported to the restricted area

[DIN 120](#). Procedure for receipt and onward transfer of OIE List A disease samples by gatehouse staff at IAH, Pirbright Laboratory
[WRL 001](#). Receipt of samples into the World Reference Laboratory for Foot-and-Mouth Disease and reporting results



2.5. The sample is unpacked, details are recorded and a unique identifier label affixed in the World Reference Laboratory (WRL) or the Serum Assay Unit

.... Finalised, redesigned submission forms (Appendix 5)
.....Recording of sample details. Computerised record and hard copy back up (SOP for STARS Manual)
.....
WRL FMD Day Book (sample acceptance book)
WRL FMD Field Sample Card (STARS can produce)
WRL FMD Diary
[DPR 008](#). Unpacking of diagnostic serology samples for SAU
[DPR 012](#) Departmental booking in of samples to ISIS LIMS. Printing worksheets. Edit,look-up, validation and report printing in the laboratory.. Foot and mouth serology: Registering submissions for



2.6. The sample may be transferred between laboratories at Pirbright

[WRL 019](#). Internal transfer of viruses and sera within IAH Pirbright



2.7. The assay methods are selected

[DIN 140](#). Selection of appropriate tests for FMD diagnosis
[DIN 150](#). Selection of appropriate tests for SVD diagnosis



2.8. Suspect material for virus detection is processed and tested in the WRL

- [WRL 002](#). Processing field samples for diagnosis and growth of vesicular viruses
- [WRL 004](#). Probang testing to demonstrate absence of vesicular viruses
- [WRL 005](#). Miscellaneous sample testing to demonstrate absence of vesicular viruses
- [WRL 006](#). FMDV and SVDV antigen detection ELISA
- [WRL 021](#). Ribonucleic acid (RNA) extraction from field samples (and cells) submitted to the WRL for FMD using TRIzol reagent or lysis/binding buffer
- [WRL 022](#). First strand synthesis of RNA (reverse transcription) from vesicular and related viruses
- [WRL 023](#). Polymerase chain reaction of cDNA samples from vesicular and related viruses
- [WRL 024](#). Electrophoresis of PCR DNA arising from vesicular and related viruses
- [WRL 025](#). Nucleic acid extraction and reverse transcription from vesicular and related viruses using MagNA Pure LC automated programmes
- [WRL 026](#). TaqMan procedures for diagnosis of vesicular and related viruses
- [WRL 031](#). Procedure for using the Molecular Diagnostic Suite within the Epidemiology building
- MEG 001. RNA extraction
- MEG 002. One-step RT-PCR
- MEG 003. Agarose gel electrophoresis of DNA
- MEG 004. Purification of PCR products using Wizard PCR prep purification kit (Promega) and 'ExoSAP-IT'
- MEG 005. Automated electrophoretic analysis and sequence documentation with the Beckman Coulter CEQ™ 8000 Genetic Analysis System
- MEG 006. Data processing



2.9. Serum samples are tested in the Serum Assay Unit (SAU)

NOTE: when the number of serum samples for serological surveillance exceeds 8,000 per week, the main bulk of such testing will be transferred to the Veterinary Laboratories Agency at Weybridge. Particular diagnostic serological testing will continue at Pirbright.

- [SAU 011](#). Detection of antibody to foot-and-mouth disease virus by solid-phase competitive ELISA (SPCE)
- [SVD 008](#). 5B7-monoclonal antibody competition (MAC) ELISA for the detection of antibodies against SVD virus
- [SAU 003](#). Growth and titration of viruses, and registration of viruses and antisera for use in ELISA and VNT
- [SAU 004](#). Detection of antibodies against vesicular and related viruses by the virus neutralisation test (VNT)
- SAU 004-VNT Appendix 3a-c Control & Screening Test Plate Layouts
- [SAU 005](#). Liquid phase blocking ELISA (LPBE) for detection of antibodies against, and strain characterisation of, foot-and-mouth disease virus (FMDV)
- SAU 005 LPBE SAU Appendix 3
- [SAU 008](#). Two dimensional virus neutralisation test (VNT)
- [SAU 010](#). Identification of antibodies to FMDV non-structural proteins using CEDI test

FMDV-NS kits



2.10. The results are recorded and the test validated

[SAU 011](#). Detection of antibody to foot and mouth disease virus by solid-phase competitive ELSA (SPCE)

[DPR 012](#). Departmental booking in of samples to ISIS LIMS, printing worksheets, edit, lookup, validation and report printing in the laboratory (will be replaced by STARS)



2.11. The results are reported

[DIN 160](#). Reporting of test results for FMD, other vesicular diseases and Rinderpest



2.12. The sample is stored

[WRL 003](#). Storage of field samples and field isolates
[VDG MS7](#). Storage and recording of virus samples by the Vesicular Diseases Group.
[SAU PRO 002](#). Receipt, storage and disposal of serological samples in SAU
[DIN 140](#). Selection of appropriate tests for FMD diagnosis
Storage record book
WRL for FMD - Green Books
Storage record book
Field Samples stored at -20°C



2.13. The sample may be transferred to an external laboratory

[WRL 020](#). External transfer of viruses and sera from IAH Pirbright
[SAU PRO 002](#). Receipt, storage and disposal of serological samples in SAU



2.14. Samples are safely discarded

[WRL 002](#). Processing field samples for diagnosis and growth of vesicular viruses
SOP required for disposal of serum samples

3. Documentation related to the Contingency Planning Manual for FMD in the UK at the IAH Pirbright Laboratory

including:-

- 3.1 United Kingdom Department for the Environment, Food and Rural Affairs (Defra) Generic Exotic Animal Disease Contingency Plan. See Defra website at :-**

www.Defra.gov.uk/animalh/diseases/control/contingency/index.htm .

- 3.2 Contract between Defra and IAH Pirbright for the Supply of Exotic Disease Laboratory Services**

Extracts shown in **Appendix 2** of this document

- 3.3 VLA Weybridge Contingency Plan for FMD Sero-Surveillance**

(to be supplied)

- 3.4 Disease Emergency Committee (DERC) Terms of Reference**

See **Appendix 3** of this document

- 3.5 Disease Emergency Committee (DERC). Contingency Planning Template**

See **Appendix 4** of this document

- 3.6 European Union Council Directive 2003/85/EC of 29th September 2003 on Community measures for the control of foot-and-mouth disease. Repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC. See EU website at:-**

http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_306/l_30620031122en00010087.pdf

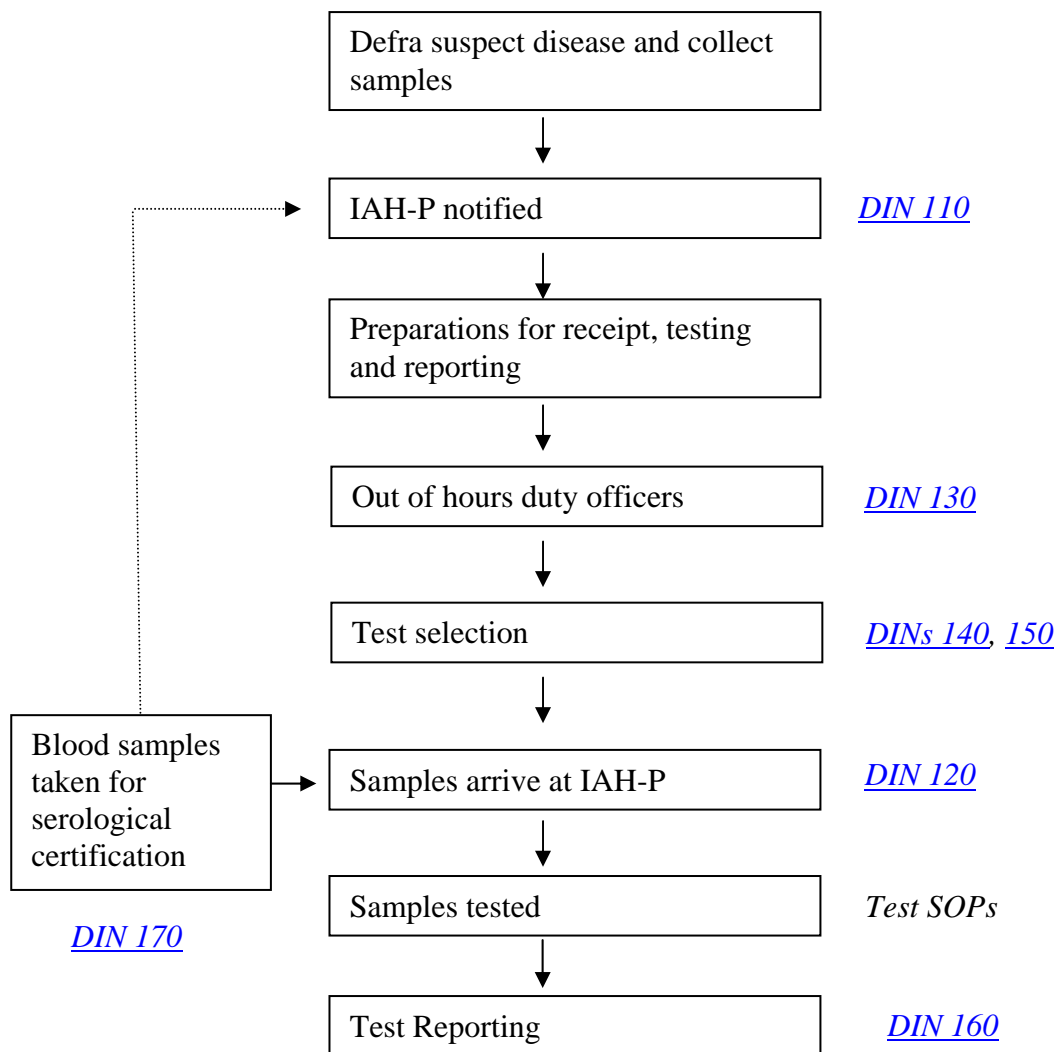
- 3.7 IAH Pirbright Quality Assurance System Manual**

- 3.8 The IAH scope of registration to ISO 9001:2000**
as contained within the IAH Quality System Manual accessible at:-

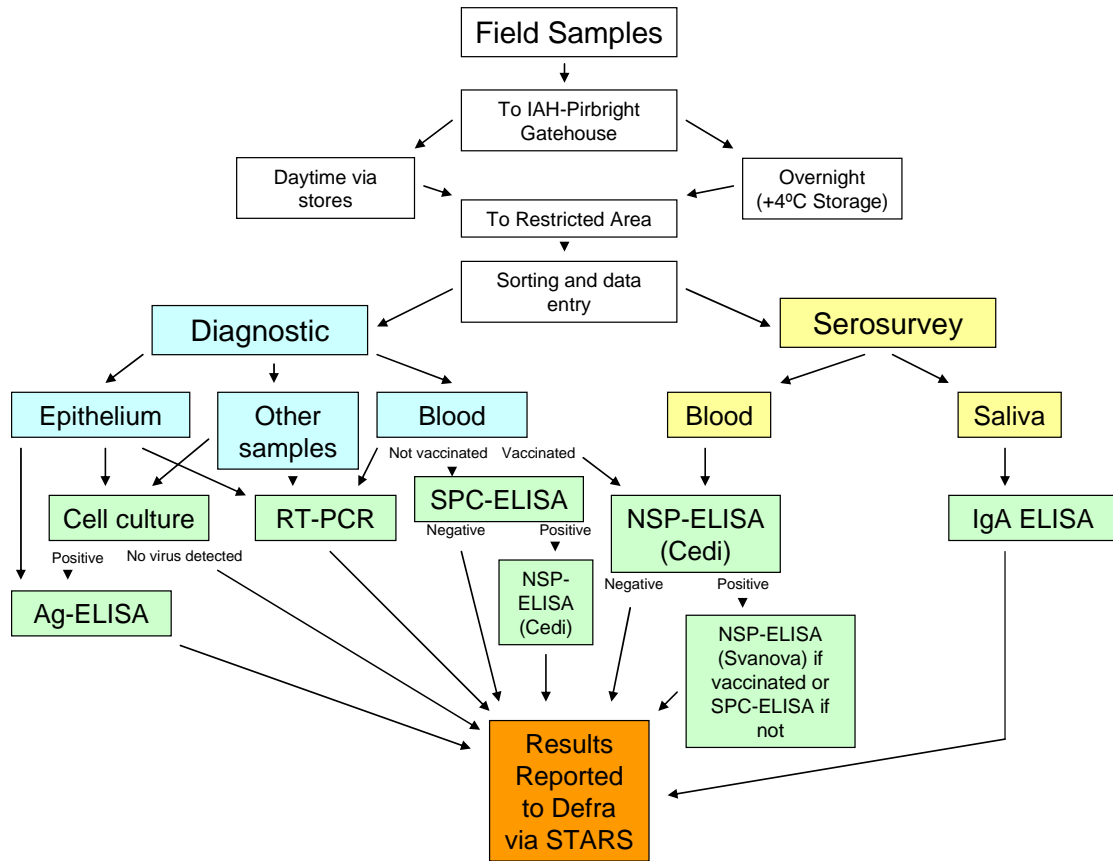
<http://www3.iah.bbsrc.ac.uk/QMS/Manuals/Manuals.htm>

- 3.9 IAH Pirbright Disease Security Manual**

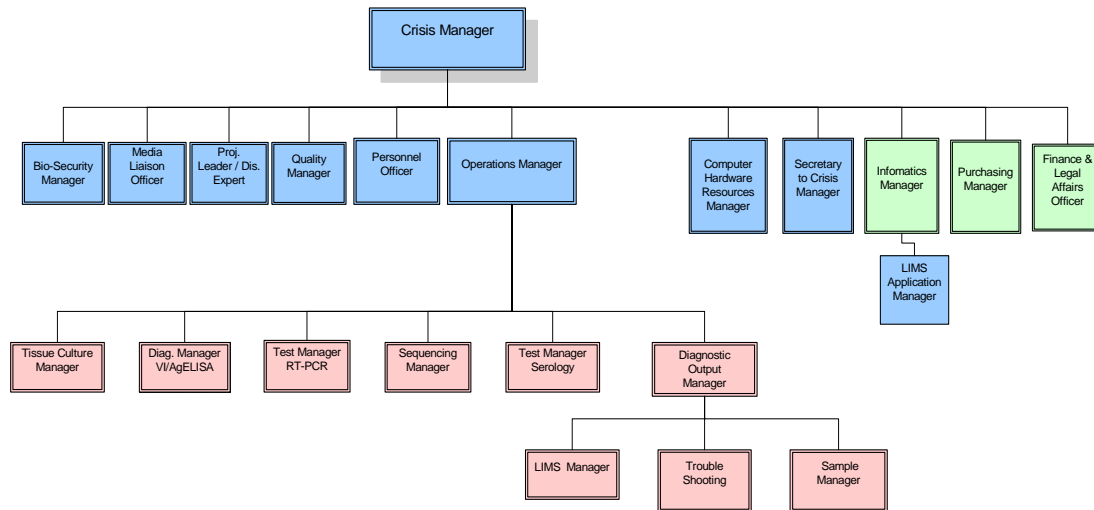
4. Flowchart to illustrate how desk instructions relate to sample receipt, test selection and result reporting (FLO 002-07-02-05)



5. Diagram illustrating the sequence of testing for FMD field samples at Pirbright



6. Organogram showing the membership of the FMD Outbreak Team



IAH Pirbright
FMD Outbreak Team
 20/01/2006