INTERIM REPORT FROM THE IMPLEMENTATION REVIEW GROUP ON THE SYSTEM FOR BSE TESTING OF CATTLE AGED OVER THIRTY MONTHS

Executive summary

1. This paper draws to the attention of the Board the interim report of the Implementation Review Group set up by the Agency to oversee implementation of the BSE testing system for its first 12 months of operation and the report by DNV Consulting of an independent review of the first 6 months of operation of the BSE testing system.

2. The Board is invited to:

   - **note** the conclusion of the Implementation Review Group's Interim Report that to date the implementation of the testing system in UK abattoirs has proceeded satisfactorily and there is sound evidence that the system advised by the Independent Advisory Group is being effectively and consistently implemented. No ineligible animal has entered the food supply;

   - **note** the conclusion of the independent review of the first 6 months of operation of the BSE testing system carried out by DNV Consulting that an effective and robust BSE testing system has been implemented in the UK to allow OTM animals to be slaughtered for human consumption, which should continue to provide a high level of assurance to the consumer;

   - **agree** that, on the basis of the above, the FSA should advise Ministers that implementation of the testing system in UK abattoirs has proceeded satisfactorily and that there is sound evidence that the "robust" system advised by the Independent Advisory Group is being effectively and consistently implemented.

TSE Division

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INTERIM REPORT FROM THE IMPLEMENTATION REVIEW GROUP ON THE SYSTEM FOR BSE TESTING OF CATTLE AGED OVER THIRTY MONTHS

Issue

1. The interim report from the Implementation Review Group on the system for BSE testing of over thirty months (OTM) cattle slaughtered for food.

Strategic Aims

2. This work links to the Agency's aim to protect consumers by implementing and enforcing proportionate and effective BSE controls.

Background

3. With effect from 7 November 2005, BSE testing for OTM cattle slaughtered for food[1] replaced the previous over thirty months (OTM) rule which banned the entry of all such animals into the UK food supply.

4. In deciding that the OTM rule should be replaced by BSE testing, Ministers agreed that the FSA should report to them on the first 6 months of implementation of testing following the change. In order to inform such a report, the FSA commissioned DNV Consulting to provide an independent review of the operation of the BSE testing system during that period. DNV Consulting's report is at Annex C. The official response to the issues raised by the report is at Annex D.

5. As agreed by the Board, an OTM testing Implementation Review Group (IRG), chaired by the FSA, has been set up to oversee implementation of the BSE testing system for its first 12 months of operation and to report. The Group involves all the UK Government Departments concerned and includes representatives of the MHS Board, consumers and the meat industry. IRG's terms of reference are at Annex A and its interim report, which takes into account the findings of DNV Consulting's independent review, is at Annex B.

Current Position on Implementation of BSE Testing

6. The implementation and performance of the BSE testing system has been under close scrutiny since the move to testing took place. DNV have carried out a thorough review, which included audit of a broad representative sample of abattoirs approved to slaughter OTM cattle throughout the UK and testing

[1] from 7 November 2005, cattle aged over 30 months have been permitted to enter the food supply provided they have received a negative result from a BSE test, except for cattle born before August 1996 which remain subject to a permanent ban

laboratories in both GB and NI. The operation of the testing system in each approved abattoir has been closely monitored by MHS or DARD veterinary staff and any exception to correct procedure has been reported up the line for appropriate action to be agreed. MHS and DARD internal auditors have carried out an intensive programme of audit at approved abattoirs. IRG has kept a close watch on the flow of data and reports from this monitoring and audit activity and has provided independent scrutiny of the management of the system.

7. As a result of all this work, IRG concludes that to date the implementation of the testing system in UK abattoirs has proceeded satisfactorily and there is sound evidence that the system advised by the Independent Advisory Group (IAG)[2] is being effectively and consistently implemented. No ineligible animal has entered the food supply. IRG's conclusion is supported by the conclusion of the review carried out by DNV Consulting that an effective and robust BSE testing system has been implemented in the UK to allow OTM animals to be slaughtered for human consumption, which should continue to provide a high level of assurance to the consumer.

8. The only issue on which IRG expresses concern is the continuing consignment of cattle born or reared in the UK before August 1996, that remain ineligible for the food supply, to abattoirs slaughtering for human consumption. On this, IRG concludes that the performance so far of the controls on such cattle indicates that they are effective but that nevertheless there remains a need for vigilance and continued pressure on the industry to reduce the number sent to fresh meat abattoirs.

Risk

9. Given IRG's findings that the system advised by IAG is being effectively and consistently implemented, and that IRG will continue to monitor the system's performance until November, the risk of a systematic failure in the testing system must be considered low. An individual failure that could lead to an ineligible animal entering the food chain cannot be ruled out, although IRG notes that the system has stood up well to the challenge posed by the relatively few incidents of non-compliance that have occurred to date.

10. If such an individual failure were to occur, for example if a pre-August-1996-born animal were allowed into the food supply, there remains a significant risk that confidence in the meat industry's ability to manage the system could be harmed. In that event, the main damage would be felt by the industry itself in terms of the potential effect on the acceptability of the product from OTM cattle to manufacturers, consumers and export markets. The FSA's reputation could also be affected, because of its role in advising Ministers that the testing system would

[2] independent group appointed by the FSA to specify the requirements for a robust BSE testing regimen

be reliable. The adverse impact on the FSA would be compounded if the MHS were implicated in the failure.

11. It is becoming increasingly clear, however, that even a significant failure in the testing system would have little or no impact on the safety of OTM beef. A public health benefit from BSE testing is derived only when a positive animal is identifed and removed from the food supply. Even then, the benefit is small because specified risk material controls remove almost all of the potential risk from an infected animal. So far no BSE positive has been identified in the 160,000 OTM cattle that have slaughtered for human consumption in the UK since testing began. This lack of positives is not entirely unexpected given that, for the reasons explained in IRG's report, very few cattle subject to emergency slaughter (the population in which the large majority of BSE positives is found) are currently entering the food supply.

Review

12. The European Commission's "TSE Roadmap", its strategy discussion paper issued last year, includes as a strategic goal reduction in the numbers of tests of bovine animals, while continuing to use testing to measure the effectiveness of the measures in place with a better targeting of the surveillance activity. As part of the discussion on the roadmap, a review of the testing programme is likely in the medium term (end of 2006/start of 2007). The Commission has made clear that any change to the BSE controls would need to be scientifically justified and that EFSA will be consulted.

Board Action Required

13. The Board is invited to:

- **note** the conclusion of the Implementation Review Group's Interim Report that to date the implementation of the testing system in UK abattoirs has proceeded satisfactorily and there is sound evidence that the system advised by the Independent Advisory Group is being effectively and consistently implemented. No ineligible animal has entered the food supply;
- **note** the conclusion of the independent review of the first 6 months of operation of the BSE testing system carried out by DNV Consulting that an effective and robust BSE testing system has been implemented in the UK to allow OTM animals to be slaughtered for human consumption, which should continue to provide a high level of assurance to the consumer;
- **agree** that, on the basis of the above, the FSA should advise Ministers that implementation of the testing system in UK abattoirs has proceeded satisfactorily and that there is sound evidence that the "robust" system advised by the Independent Advisory Group is being effectively and consistently implemented.

ANNEX A

OTM TESTING IMPLEMENTATION REVIEW GROUP

TERMS OF REFERENCE AND MEMBERSHIP

Purpose of the Group

To oversee implementation of the BSE testing regime applied to cattle born after July 1996 aged over 30 months and slaughtered for human consumption; to scrutinise and comment upon the operational aspects taken forward by Defra and MHS in GB, and DARD in NI, to secure effective implementation, compliance and enforcement of that testing regime in accordance with the recommendations of the FSA Board at their meeting on 15 August 2005[1]; and to ensure public health and consumer interests are protected in a proportionate manner in accordance with FSA's general statement of objectives and practices[2].

Frequency of meetings

Monthly. Group to be wound up one year following introduction of OTM testing.

Terms of Reference

1. To develop performance criteria, establish performance measurement information required and reporting mechanisms

2. To review information and reports received (including audit reports) and agree action where appropriate

3. To agree and review action in response to Independent Advisory Group recommendations

4. To refer matters which are relevant to the Meat Hygiene Service to, and receive reports from, the MHS Board.

5. To report regularly to the FSA Board, alerting the FSA Board immediately if serious problems with implementation are encountered

6. To consider ongoing communications requirements for consumers and other stakeholders

7. To consider reports received from the audit and review of the first six months of implementation and subsequent on-going audit and review by the FSA, make recommendations to the FSA Board and oversee follow-up action.

[1] www.food.gov.uk/news/newsarchive/2005/aug/boardupdateaugust2005
[2] www.food.gov.uk/multimedia/pdfs/sgop.pdf

MEMBERSHIP

Food Standards Agency	Head of TSE Division – Alison Gleadle (Chair) Veterinary Director- Alick Simmons TSED Veterinary Adviser – Adrienne Conroy TSED Head of OTM Branch – David Carruthers FSA NI – Kirsten Dunbar
MHS Board	Celia Bennett
Consumer Representative	Diane McCrea
Meat Industry Representative	Duncan Pullar, MLC[3]
Department of Health	Eileen Lawrence
Defra	Stuart Roberts
Department for Agriculture and Rural Development in Northern Ireland (DARD)	Kate Davey George Byrne
Scottish Executive	Martin Morgan
National Assembly for Wales	Jo Glenn

OBSERVERS

Meat Hygiene Service	Colin Pearson, Craig Kirby

SECRETARIAT

Food Standards Agency	TSE Division, OTM Branch – Jill Wilson

[3] replacing the late Mike Attenborough

OTM TESTING IMPLEMENTATION REVIEW GROUP

INTERIM REPORT: 4 July 2006

Summary

1. This report presents the Implementation Review Group's views on the effectiveness of the implementation and functioning of the BSE testing system to date, taking into account a report of an independent review of the first 6 months of operation carried out by DNV Consulting. The Group's conclusions are that:

    - to date the implementation of the testing system in UK abattoirs has proceeded satisfactorily and there is sound evidence that the system advised by the Independent Advisory Group is being effectively and consistently implemented. No ineligible animal has entered the food supply;
    - the sampling and testing part of the system is working well. The level of "no test" results, though relatively low, imposes an avoidable cost on industry, but has not given rise to any risk to consumer safety;
    - the abattoir controls on processing OTM cattle for human consumption are working effectively and so far there has been 100% compliance with the rule that OTM cattle must receive a negative BSE test result before being allowed into the food supply. No bovine born or reared in the UK before August 1996 has entered the food supply. The system of checks and audit provide assurance that this good level of performance can be maintained;
    - the performance so far of the controls on cattle born before August 1996 indicates that they are effective but that nevertheless there remains a need for vigilance and continued pressure on the industry to reduce the number of such animals sent to fresh meat abattoirs;
    - overall, incidents of non-compliance have been relatively few. Nevertheless, the system has been challenged by these incidents and it has stood up well to the test;
    - the effect of the changes referred to in paragraph 29, in reducing the numbers of emergency slaughter cattle that might potentially have entered the food supply, is likely to have been beneficial in reducing the BSE risk in OTM cattle entering the food supply.

Background

2. On 7 November 2005, the ban on cattle aged over thirty months (OTM) from the food supply, which had been introduced in 1996 as a key measure to protect public health from BSE, was replaced by a system of BSE testing OTM cattle slaughtered for human consumption. Cattle born or reared in the UK before August 1996 remain permanently excluded from the food supply.

3. Before the move to BSE testing took place, the FSA had been advised by an Independent Advisory Group (IAG) on the requirements for a regime for BSE testing that would operate effectively provided it is fully implemented and monitored[1].

4. The Implementation Review Group has been asked by the FSA to oversee implementation of the BSE testing system for its first 12 months of operation and to report. The Group has monitored implementation of the testing system over a period starting October 2005, just before the implementation date.

Work programme

5. The Group has met each month since October 2005 to oversee implementation of the system for BSE testing of OTM cattle slaughtered for human consumption. During that period the Group has:

    - reviewed and agreed the actions taken in response to the recommendations of the IAG;
    - developed performance criteria and established the performance measurement information required and reporting mechanisms for the testing system;
    - reviewed regular reports from officials in Defra and DARD[2], who have operational responsibility for the testing system, on the implementation and performance of the system;
    - reviewed reports on issues that have arisen in relation to the operation of the system that could potentially give rise to a failure and the official responses to those issues;
    - examined reports of audit of the testing operation by Meat Hygiene Service (MHS) Verification and Audit Team (in GB) and DARD Veterinary Service (VS) audit unit (NI) and the report of the independent review of the operation of the first 6 months of the BSE testing system by DNV Consulting;
    - kept the requirement for communications with consumers and other stakeholders on implementation of the testing system under review.

Current position on implementation of the testing system

(a) implementation of the testing system

6. Ten abattoirs in GB and one abattoir in NI were approved to slaughter OTM cattle for human consumption from the start date for BSE testing and the numbers of approved abattoirs have steadily increased since then. As at end June 2006, 56 abattoirs in GB and 9 abattoirs in NI had been approved. No problem of too few approved abattoirs or a lack of approved slaughter capacity for OTM cattle has existed in any part of the country since BSE testing began. More than sufficient approved slaughter capacity currently exists to meet expected future peak demand for OTM slaughter.

7. The numbers of OTM cattle slaughtered for human consumption each week started low but then built up steadily in both GB and NI. The weekly total of OTM cattle

[1] Report to the FSA on the development of a system for BSE testing of over thirty months cattle at http://www.food.gov.uk/multimedia/pdfs/fsa050802a.pdf

[2] Department of Agriculture and Rural Development, Northern Ireland

slaughtered for human consumption is currently running at around 5,000 in GB, which is at the level of the Meat and Livestock Commission's forecast slaughter estimate, and 1,500 in NI. By 26 June the cumulative totals of OTM cattle slaughtered for human consumption since testing began were 129,000 in GB and 32,000 in NI.

8. The Group is encouraged to note the findings of the DNV review that

    - guidance for enforcement staff, provided in MHS and DARD VS instructions, was accurate and adequate;
    - requirements that all MHS staff working at OTM plants attend a one-day training course and pass a competency test have been effective in ensuring an appropriate level of competence in the staff deployed. In NI, the OVS and a Senior Meat Hygiene Inspector from each abattoir had attended a one-day training course and cascaded the training to all members of the meat inspection team;
    - all RMOPs (Required Methods of Operation) were found to meet the requirements of IAG and to exhibit a high level of consistency between plants; and
    - the testing regime implemented in the UK has taken account of the issues highlighted by the Wall Report[3] and that strenuous efforts have been made to ensure that the system is effective and robust.

9. The Group concludes that to date implementation of the testing system in UK abattoirs has proceeded satisfactorily and that there is sound evidence that the system advised by the Independent Advisory Group is being effectively and consistently implemented. No ineligible animal has entered the food supply.

(b) sampling and testing

10. As yet no animal slaughtered for human consumption has tested positive for BSE. All tests carried out so far have produced a negative result, apart from a relatively small number of samples (less than 1 in a thousand samples taken) which for a variety of reasons have been of an inadequate quality for testing and have been given a "no test" result.

11. EU rules require "no test" results to be treated as if they were positive, with the consequence that the carcase and body parts of the animal before and two animals following the "no test" animal on the slaughter line must be removed and destroyed. The Group has been assured that the correct procedure has been followed in all cases in which a "no test" result has occurred and that there have been no failures by laboratories to return results within the timescale required by industry.

12. The Group has reviewed the laboratory quality systems in place and arrangements for monitoring test and laboratory performance by the Veterinary Laboratories Agency (VLA) in its role as National Reference Laboratory for BSE testing. For added assurance, the Group invited the VLA to give a presentation of the systems and procedures in place to minimise errors in testing. The Group also takes note of DNV's finding that a high level of assurance was provided in terms of the integrity of systems in place for rapid laboratory testing from the activities observed in both GB and NI and that sample identification and tracking systems were found to be robust.

[3] report on investigation into testing failures published 11 October 2004 at http://www.food.gov.uk/news/newsarchive/2004/oct/wallreport

13. The Group concludes that the sampling and testing part of the system is working well. The level of "no test" results, though relatively low, imposes an avoidable cost on industry, but has not given rise to any risk to consumer safety.

(c) checks and audit

14. The Group has been given assurances by MHS and DARD that their checks on the operation of the testing system indicate that no OTM bovine without a negative test result and no animal born or reared in the UK before August 1996 has been allowed into the food supply. The Group has also noted that a cross-check carried out retrospectively between slaughter data on the Cattle Tracing System and data on the test result of each animal tested has confirmed that no such failure occurred in GB up to the end of March 2006. Such a retrospective check is not required in NI, as the the Animal and Public Health Information System (APHIS) enables "real time" checks on the eligiblity of cattle at slaughter[4].

15. The Group has examined the results of audits of the MHS and DARD controls on slaughter of OTM cattle for human consumption by the MHS Verification and Audit Team and DARD VS respectively. MHS auditors conclude that the audits carried out to date provide assurance that MHS staff are applying the controls as required. DARD auditors conclude that the system of approved RMOPs, trials, supervision and audit has provided a system with a high rate of compliance and a very low risk that unfit material from OTM cattle will enter the food supply.

16. The DNV review found that the arrangements for audit of the testing regime by MHS and DARD veterinary staff and by the respective internal audits provided a good level of assurance.

17. In addition to these arrangements, the FSA is assuming ongoing responsibility for audit of the entire testing system now that DNV have concluded their review. The Group is pleased to note that, in the light of its concern that the entire control system including audit should be subject to independent scrutiny, the FSA has agreed that the FSA audit should undergo a third-party verification.

18. The Group concludes that the abattoir controls on processing OTM cattle for human consumption are working effectively and that so far there has been 100% compliance with the rule that OTM cattle receive a negative BSE test result before being allowed into the food supply. No bovine born or reared in the UK before August 1996 has entered the food supply. The system of checks and audit provide assurance that this good level of performance can be maintained.

(d) exceptions

19. The Group has examined all non-compliances with the control system which, while not leading to any ineligible meat entering the food supply, increase the risk that such a failure could occur.

20. The most common non-compliance has been the consignment of cattle born or reared in the UK before August 1996 to abattoirs slaughtering for human consumption, which is a breach of law and poses a risk that such an animal might bypass the controls and enter the food supply. Up to 25 June, the numbers of pre-August-1996-born cattle presented at a fresh meat abattoir had reached 114 in GB

[4] APHIS is programmed to highlight any animal born before August 1996 before slaughter and prints a list of all animals entered for slaughter by each producer, separating them into age categories, i.e. under thirty months, OTM and pre-August 1996, thus helping to avoid inappropriate slaughter. The information is available "real time" at each abattoir.

and 11 in NI. A small number continues to be found each week, although numbers have declined relative to overall throughput of OTM cattle.

21. The Group has been most concerned about the continual consignment of ineligible animals to fresh meat abattoirs. The Group has looked into the reasons for this and has concluded that the main ones are lack of awareness of the rule and human error, rather than deliberate attempts at fraud. The Group has taken a keen interest in and worked with Defra and others on initiatives to get the message across to the industry that such consignment of ineligible animals is illegal and will result in the loss of the animal, and is satisfied that a considerable effort has been made to do so.

22. In almost all cases, the ineligible animals have been identified by the operator's own controls before slaughter and voluntarily surrendered for disposal. The Group regards this as an example of good co-operation with the controls by industry. On the few occasions on which an over-age animal was not detected by the operator's controls it was identified by the official (in these cases MHS) controls and destroyed.

23. The Group concludes that the performance of the controls on over-age animals so far indicates that they are effective but that nevertheless there remains a need for vigilance and continued pressure on the industry to reduce the number of over-age animals sent to fresh meat abattoirs.

24. The Group has reviewed other instances of non-compliance that, if not dealt with correctly, could have led to a break down in the controls (summary at Annex A) and has examined why in each case the additional controls in place were effective and able to ensure that there had been no actual failure. The Group has also ensured that any lessons learned from these incidents have been logged and applied across the system more generally to avoid future occurrences.

25. It was notable in many cases that, because of the layers of control in place, although the requirements of one part of the system had not been followed, a check at a later stage had ensured that no break-down in control occurred. For example, a number of cases of incorrect labelling of sample pots were identified and resolved by checks built into the abattoir system or, failing that, the laboratory system.

26. The Group concludes that, overall, incidents of non-compliance have been relatively few. Nevertheless, the system has been challenged by these incidents and it has stood up well to the test.

(e) Communications

27. The Group has kept the need for communications with consumers and other stakeholders under review as implementation of the testing system has progressed. The Group has also agreed the types of incident or failure in the testing system that would warrant communication and the priorities and mechanisms for reporting these.

28. The Group reviewed the communications work leading up to the transition to testing and noted that there had been good coverage of the change in the national and regional media at the time, but that media interest in the subject then subsided. As implementation of testing has subsequently proceeded satisfactorily and without incident of any significance, the Group has to date not seen a need for any further public communication on this issue.

Impact of the change in the rules on emergency slaughter

29. The Group has monitored the impact of recent changes on the numbers of animals reported as emergency slaughter and fallen stock. The changes involved are:

- the replacement of the OTM rule by BSE testing (from 7 November 2005);
- the change in the conditions for eligibility of livestock for emergency slaughter on-farm for human consumption (from 1 January 2006). Following this change, only otherwise healthy cattle that are slaughtered on-farm having suffered a genuine accident may be accepted for human consumption. Cattle suffering from an ongoing condition are no longer eligible;
- replacement of the over thirty months scheme (OTMS)[5] by the Older Cattle Disposal Scheme (OCDS) (for cattle born before August 1996) from 23 January 2006 and the full application of the new eligiblity conditions for emergency slaughter to cattle entering OCDS.

30. The IAG were concerned about the high numbers of emergency slaughter cattle entering the OTMS, as these cattle would in principle have been eligible for human consumption following OTM rule change and most of the cattle testing positive for BSE were in this population. In the event, the changes noted above have driven a dramatic decrease in the number of animals subject to emergency slaughter. The numbers of such cattle that are currently entering fresh meat abattoirs each week are only around 10 in GB and 0 to 3 in NI. These figures compare with weekly average numbers of cattle subject to emergency slaughter in November 2005 of over 2,300 in GB and 450 in NI (all but a handful of which would have entered OTMS). A graph illustrating the change in GB is at Annex B.

31. The Group concludes that the effect of the above changes, in reducing the numbers of emergency slaughter cattle that might potentially have entered the food supply, is likely to have been beneficial in reducing the BSE risk in OTM cattle entering the food supply.

[5] the previous cull scheme under which OTM cattle ineligible for the food supply were purchased for destruction

Annex 1

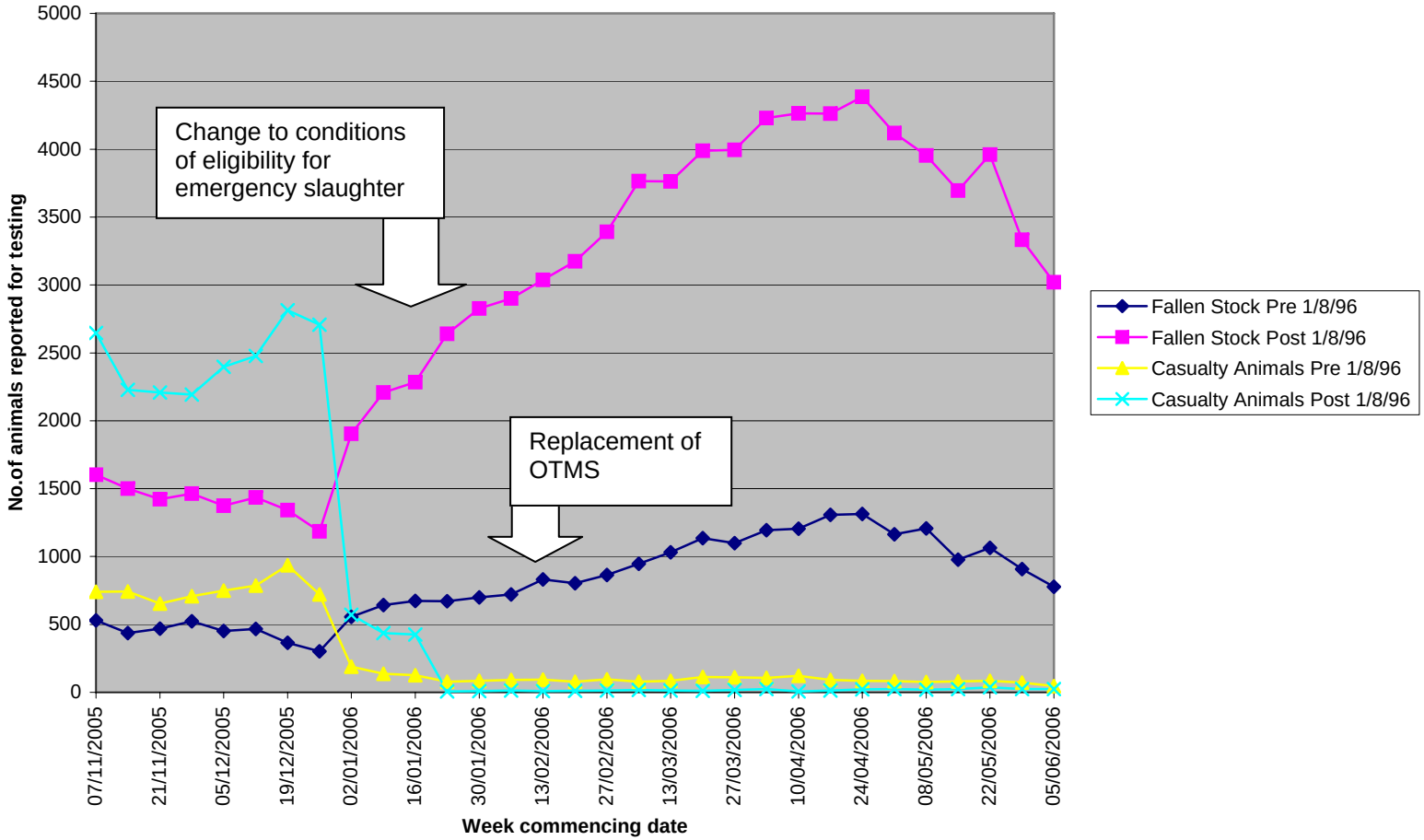
Exception Reports (Summary)

Exception type	Number of reports
Suspension of approval trials because of poor controls/ inadequate facilities	4
Failure to segregate OTM cattle from cattle aged under 30 months at slaughter	7
OTM bovine slaughtered at non-approved abattoir	1
Cattle born or reared in the UK before August 1996 slaughtered	3
Errors in sample pot labelling/result reporting	9
Carcase that should have been disposed of under “1 before 2 after” rule allowed to enter cutting room before it was identified and disposed of	1
Exceptions on consignments of OTM carcases containing vertebral column (broken seals/incorrect or missing paperwork etc.)	9
Blue stripe label applied to OTM carcases	1
Absence of OVS during part of abattoir approval trial	1
Exceptions on retained carcases (breakage of seals/non-storage in kill order)	3
Small piece of spinal cord in OTM carcase[6]	2
OTM animal not sampled, as a result 4 carcases and all offal and by-products of kill disposed of	1
OTM carcases sent to stand-alone cutting plant without notification of OVS	1

[6] these are SRM failures rather than failures of the BSE testing system

Annex 2

Animals reported as fallen stock and emergency slaughter in Great Britain.



DNV CONSULTING

OTM Rule Replacement: Independent Review of BSE Testing System:

Final Report to the Food Standards Agency
Report No. 22312319-02 rev 2, 3rd July 2006

OTM Rule Replacement: Independent Review of BSE Testing System
for

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Report No.: 22312319-02 rev 2 Subject Group:

Indexing terms: BSE Testing, OTM, Audit, FSA, MHS

Summary: An independent review of the first six months of operation of the BSE testing system in the UK has been undertaken. The audit has shown that an effective and robust BSE testing system has been implemented in the UK to allow OTM animals to be slaughtered for human consumption, which should continue to provide a high level of assurance to the consumer.

Prepared by: *Name and position*
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Approved by: *Name and position*
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Date of issue: 3rd July 2006

Project No: 22312319

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Executive Summary

An independent review of the first six months of operation of the BSE testing system in the UK has been undertaken. An audit protocol has been developed to provide a consistent structure for the audits of the slaughterhouses and cutting plants and the basis for the opinions of the audit team. The audit was intended to test the system and procedures in place, rather than the detailed implementation in every plant.

The audit has included the MHS offices in York, DARD in Belfast, two BSE testing laboratories, 18 slaughterhouses (14 with co-located cutting plants) and 7 stand-alone cutting plants. Plants were chosen to be included in the audit schedule so that the audit included plants of different type and size and from different parts of the country. The 18 slaughterhouses audited represent 30% of those approved for OTM slaughter in the UK by end May 2006.

No significant non-conformities have been identified in the audit of the first six months operation of the BSE testing system in the UK. In general all the facilities have demonstrated robust controls in accordance with the requirements for allowing OTM animals to be slaughtered for human consumption as set out by the Independent Advisory Group (IAG) led by Professor Wall.

The auditors were required to provide opinions on a number of specific issues as set out in the study objectives (Section 1.2). These are addressed below:

1. ***Guidance for enforcement staff, provided in staff instructions and the MHS and VS-VPHU Operations Manuals.***
   The sections of the Operations Manuals and staff instructions that relate to the slaughter of OTM animals for human consumption were reviewed and found to be accurate and adequate. Copies of Manuals were present at each facility.
2. ***Training and deployment of enforcement staff, and the training of abattoir personnel.***
   All MHS staff working at OTM plants (i.e. both OVSs and MHIs) have been required to attend a one day training course and pass a competency test. This has been a new development for the MHS and has proved effective in ensuring an appropriate level of competence in the staff deployed. In Northern Ireland, the OVS and an MHI from each abattoir had attended a one day training course and had cascaded the training to all members of the MHI team. Resource planning for enforcement staff as recorded in the day book and/or on resource planning sheets at each plant was reviewed and found to be thorough and effective. All abattoir personnel involved in brain stem sampling had been trained and records kept. In Great Britain training was either by VLA staff or by previously trained staff and the names of those trained are entered on a central register. In Northern Ireland plant staff had been trained by DARD staff and each plant holds a list of those trained and approved to take samples.
3. ***Review of RMOP documents***
   All RMOPs were found to meet the requirements as set out by the Independent Advisory Group. There was a high level of consistency between the RMOPs at different plants.
4. ***The level of assurance of the testing regime provided by existing audit arrangements of MHS by the MHS internal audit team.***
   All OTM additionally approved slaughterhouses are audited routinely by the AOVs using a compliance checklist. In addition, a number of audits of OTM additionally approved slaughterhouses have been carried out by MHS internal audit and OTM issues will become part of their regular audit programme. The overall audit arrangements were considered to provide a good level of assurance.

5. ***The level of assurance provided by existing audit arrangements of VS-VPHU operations by the VS-VPHU internal audit team.***
   All plants handling OTM material had been audited by DARD, and it was planned to carry out audits about once a month for first 6 months of operation. In addition, the Divisional Veterinary Officer for OTM makes regular visits to all plants. The audit arrangements provided a good level of assurance.
6. ***The level of assurance provided by existing arrangements for quality assurance and audit of testing laboratories.***
   A high degree of assurance was provided in terms of the integrity of the systems in place for rapid laboratory testing for BSE from the activities observed. The systems had been automated to a high degree, reducing the potential for human error and standard kits and reagents were being used. The sample identification and tracking systems were found to be robust and backed by effective IT platforms. Furthermore, additional assurance is provided by the extensive internal and external audit programmes undertaken by UKAS and VLA.
7. ***An assessment of the extent to which the issues highlighted by the external review into casualty animal test failures (The Wall Report) have been addressed.***
   The testing regime implemented in the UK has taken account of the issues highlighted by the Wall Report and strenuous efforts have been made to ensure that the system is effective and robust. In particular, the introduction of the AOV with direct supervision of the plant OVS has addressed some of the key issues. However, some of the issues highlighted by the Wall Report relate to broader issues for the MHS, such as the contract arrangements for supply of OVSs. Proposed changes to veterinary supervision arrangements within the MHS are presently under discussion and the subject of a public consultation.

In conclusion, the audit has shown that an effective and robust BSE testing system has been implemented in the UK to allow OTM animals to be slaughtered for human consumption, which should continue to provide a high level of assurance to the consumer.

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Appendix I – Definitions and Acronyms

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1.0 Introduction and Objectives

1.1 Background

In September 2005 the Government announced that it had accepted advice from the FSA Board that a reliable BSE testing system had been developed to test cattle that were over thirty months (OTM) old and born on or after 1st August 1996, so that they could once more be allowed to be used for human food. On 7th November 2005 a system of BSE testing for OTM cattle was introduced. DNV Consulting were commissioned by the Food Standards Agency in November 2005 to carry out an independent review of the first six months of operation of the BSE testing system in the UK and to report to the Implementation Review Group (IRG) and the FSA Board.

1.2 Objectives

The overall purpose of this assignment is to provide an independent review of the first six months of operation of the BSE testing system in the UK.

The review will provide the following assessments and opinions:

- An assessment of the effectiveness of guidance for enforcement staff, provided in staff instructions and the MHS (in Great Britain) and VS-VPHU (in Northern Ireland) Operations Manuals.
- An assessment of the effectiveness of the training and deployment of enforcement staff, and the training of abattoir personnel.
- An assessment of the extent to which individual RMOP documents, agreed between plant operators, AOV's and the MHS (VS-VPHU in NI) are consistent and meet requirements.
- An opinion on the level of assurance with regard to MHS enforcement of the testing regime provided by existing audit arrangements of MHS by the MHS internal audit team.
- An opinion on the level of assurance provided by existing audit arrangements of VS-VPHU operations by the VS-VPHU internal audit team.
- An opinion on the level of assurance provided by existing arrangements for quality assurance and audit of testing laboratories.
- An assessment of the extent to which the issues highlighted by the external review into casualty animal test failures (The Wall Report) have been addressed.

1.3 Det Norske Veritas (DNV)

DNV is an independent foundation, established in 1864, with the objective of safeguarding life, property and the environment. DNV is an independent, autonomous and self-owned foundation and is among the world's leading companies in managing risks in areas of safety and the environment for today's industrial and societal settings. Throughout its history DNV has had a rule-setting function and/or determined conformance and compliance to Rules, Standards and Regulations. DNV undertakes third party services requiring high technical expertise and carries out that work with the utmost integrity in all respects.

This study has been undertaken by DNV Consulting, the risk management consulting business of DNV.

1.4 Acknowledgements

The DNV audit team gratefully acknowledges the help and support we have had from the many people we have had dealings with in the course of this project. This has included personnel from the enforcement agencies, the official veterinarians at the plants and the staff at the plants we audited. There has been a very positive response to the audit and we have had an excellent level of support.

2.0 Audit Approach and Plan

2.1 Audit Approach

An audit protocol has been developed to provide a consistent structure for the audits of the slaughterhouses and cutting plants and the basis for the opinions of the audit team. The protocol has drawn on work already done by the FSA and the audits carried out during the development of the testing regime. The protocol, which is given in full in Appendix II, was reviewed with both the FSA and the MHS OTM Veterinary Advisor and trialled during an initial audit in December 2005.

The DNV audit team was made up of three experienced auditors all of whom had experience of the meat industry. Initial trial audits were held on the 19th and 20th December at one slaughterhouse and one cutting plant. These involved all three of the DNV auditors and provided an opportunity to review the audit protocol and ensure a common approach between the three auditors. The MHS OTM Veterinary Advisor was also present at these initial audits.

A full day was allowed for each slaughterhouse audit. Where there was a co-located cutting plant this was included within the day. Audits of stand-alone cutting plants required about half a day.

2.2 Audit Plan

The plan for the project included the following elements:

- Audits of the MHS HQ at York and the VS-VPHU of DARD in Belfast;
- Audits of two of the BSE testing laboratories
- Audit of slaughterhouses and cutting plant; it was planned that a total of 18 slaughterhouses, 6 stand alone cutting plant and 6 co-located cutting plant should be carried out.

2.3 Work completed

Work on the study started with a Kick Off meeting held in Aviation House on the 15th November. Work on the development of an Audit protocol started immediately, during which a visit was made to an abattoir and cutting plant that had participated in the testing trials. This provided the team with an overview of how the testing system was working in practice.

The detailed audit schedule was developed as the study progressed in collaboration with the MHS OTM Veterinary Advisor. Early in the study (December 05) there were 26 slaughterhouses approved for OTM slaughter in GB plus 4 in NI, of which only 15 were active at that time. The take up rate in GB was somewhat slower than had been expected and the start of the main audit programme was delayed slightly until February 2006 to allow more plants to come on line. At the end of the first six months in May 2006, 61 slaughterhouses and 94 cutting plants had been approved in the UK.

Plants were chosen to be included in the audit schedule so that the audit included plants of different type and size and from different parts of the country. The audit covered 18 slaughterhouses, 14 of which had co-located cutting plants, and 7 stand alone cutting plants as shown in Table 1. These included 2 plants in Northern Ireland, 3 in Scotland, 6 in the North region, 5 in the Central and 8 in the South and West. The one plant chosen in Wales ceased trading before the audit took place. The plants included some of the small facilities with low

throughput as well as some of the largest abattoirs. The audit included plants within the responsibility for each of the AOV's.

The 18 slaughterhouses audited represent 30% of those approved for OTM slaughter in the UK by May 2006 and the 21 cutting plants 22% of those approved. All planned audits were completed by 19th May. A greater number of co-located cutting plants than originally planned was audited due to the fact that many of the slaughterhouses chosen for audit had co-located cutting facilities.

Table 1: Summary of Audits Completed

Type of Facility	Number of audits planned	Number completed
Head Office (MHS & DARD)	2	2
BSE Testing Laboratories	2	2
Abattoirs	18	18
Co-located cutting plant	6	14
Stand alone cutting plant	6	7

3.0 Summary of Findings

No significant non-conformities have been identified in the audit of the first six months operation of the BSE testing system in the UK. In general all the facilities have demonstrated robust controls in accordance with the requirements for allowing OTM animals to be slaughtered for human consumption as set out by the Independent Advisory Group (IAG) led by Professor Wall.

3.1 Meat Hygiene Service, York

Two meetings were held at MHS offices in York with the OTM Project Director and the OTM Veterinary Advisor. The first meeting was early in the project and the second near the end to review issues raised during the audits. The main areas covered were:

3.1.1 Approval of Slaughterhouses and Cutting plants

The procedures for approval of slaughterhouses and cutting plants were reviewed and a number of the relevant documents examined. The approval process included the review and approval of an RMOP document for each facility. The process appeared to be robust and well maintained. At the initial meeting it was recognised that there was a need to establish a system for updates to the RMOPs and document control.

3.1.2 Area Official Veterinarians

The process for the selection, appointment and training of the AOVs was reviewed. The AOVs were given 4 weeks training (as a group), that covered training and audit skills as well as OTM specific issues. A copy of the training programme was inspected. The whole process was thorough and had been well thought through.

3.1.3 Training of MHS staff

The IAG had stated that the enforcement bodies would need suitably trained and competent staff for the OTM system. All MHS staff working at OTM plants (i.e. both OVS and MHIs) have been required to attend a one day training course and pass a competency test. At the time of the meeting, 1089 individuals had been trained and about 14% had failed at the first attempt. Candidates are allowed a second attempt following review and the overall pass rate is 95%. The competency test has in general been well received.

3.1.4 SLA, Monitoring & Audit

A copy of the SLA with Defra for OTM testing was reviewed. The primary audit of the plants handling OTM animals for the MHS is provided by the AOVs. The AOVs complete a checklist compliance review each time they visit a plant noting any corrective actions required. The checklist covers the compliance areas required by the IRG. The reports from these visits are given to the plant OV and copied to the MHS OTM Veterinary Advisor. Any corrective actions are reviewed at the next plant visit. MHS Internal Audit provides a secondary level of audit for these facilities. Their role is to provide assurance to the Chief Executive and it is planned that OTM issues will become part of the normal audit programme. The MHS Internal Audit procedures were reviewed with the Verification and Audit Manager.

3.2 DARD

A meeting was held at DARD offices in Stormont on the 24th January 2006, with the official responsible for the TSE section in DARD, the Divisional Veterinary Officer for OTM implementation in NI and other members of the TSE section. DARD is responsible for both the policy and enforcement of BSE testing in NI. Everything is therefore under the control of the one agency. The Divisional Veterinary Officer (DVO) for OTM combines the role of the MHS OTM Veterinary Advisor and that of an AOV and is responsible for the implementation of the BSE testing system in NI and works directly with the OVS's at the meat plants.

3.2.1 Meat Plants in NI

There are 10 fresh meat abattoirs in NI; 9 of these are now approved for slaughter of OTM animals for human consumption, of which 7 have co-located cutting plants. There are 5 stand alone cutting plants approved to take OTM carcasses but none had done so at the time of the audit visit.

3.2.2 AOV Selection and training

With only a single position being required in NI there was not the need for the formal recruitment and selection process required by the MHS. An experienced DVO, who had been involved with similar types of approval process for the Date Based Export Scheme for which RMOPs are also used, was appointed as the most appropriately qualified person for the role.

3.2.3 Plant Approval Process

The plant approval process is very similar to that in GB. This was reviewed and copies of the signed RMOPs, which are held by DARD, were examined. The process seemed to have worked effectively.

3.2.4 Audit

All plants handling OTM material have been audited by DARD and it is planned to carry out audits about once a month for first 6 months of operation. At the time of the meeting, hand written audit reports on a standard checklist were viewed, but these had not yet been written up formally. Feedback had been given verbally to the plant and OVS after each audit but no further reports sent and there had been no formal follow up of audit recommendations. The DVO for OTM also plans to visit each plant once per month.

No major non-conformities had been identified in the audits completed, which would have been followed up immediately. Any minor non-conformities would be followed up at the next audit. A system is now in place to issue formal reports immediately following the audit.

3.2.5 BSE Testing

A number of training sessions have been held by DARD for plant operators. DARD has a record of those trained (via signed sheets from training sessions) but there is no central register of personnel approved to take samples. Each plant holds a list of those trained and approved to take samples.

3.2.6 Training of DARD staff

DARD has run a number of one day courses for the reintroduction of OTM animals for human consumption. It was stated that the OVS and one of the MHI team (normally the senior MHI) from each abattoir had attended this training. The OVS and MHI would then have cascaded the training down to all members of the MHI team. The kind of training programme set up in GB for MHS staff was not considered appropriate in NI, where OVS's are all permanent staff and where there is a very low turnover. The NI training programme had been discussed with the IRG.

3.2.7 Procedure failure follow-up

Information on a failure that led to the temporary withdrawal of approval from one of the NI plants was provided, including a set of documents. These provided a record of the incident itself and demonstrated that appropriate follow up action had been taken.

3.3 Audit of Slaughterhouses and Cutting Plants

As indicated in Section 2, a total of 39 plants was audited over the course of the project. A summary of some of the observations from these visits is given below. The summaries from each of the audit reports are given in Appendix III. A set of the full audit reports has been given to the FSA and the GB reports to the MHS OTM Veterinary Advisor and those for NI to the DVO for OTM.

On all the plants audited the systems and operations have demonstrated robust controls in accordance with OTM human consumption requirements and the associated approved RMOP for each plant. No significant non-conformities were identified.

Four minor non-conformities were raised (three at one plant) and observations regarding opportunities for good practice improvement were also made at a number of sites.

At one plant it was recommended that the company should review the hygiene practices between brain stem sampling as there was potential for cross contamination with the current practices. The sampler was not washing his hands sufficiently nor wiping them dry in accordance with the company RMOP. This was causing slight blood and water contamination of the outer packaging which contained the blue plastic spoons/scoops. This was identified as a minor non-conformity but the risk was assessed as being low.

At another plant inadequate use of personal protective equipment at the brain stem sampling point was noted as the operator was not wearing a visor. A visor had been provided for use by the sampling operative and was required by the company RMOP. At the same operator the disposal system for brain stem sampling equipment breached Environment Agency rules with regard to clinical waste. In addition, some discrepancies in the records inspected were noted (e.g. missing ante mortem records, incomplete forms). These points were identified as minor non-conformities.

Where plants had had a no-test earlier in the scheme, and this applied at a number of sites during the "learning curve" phase, effective actions had been taken to remedy the problems. This had also provided an opportunity to check that the one before and two after procedure had worked effectively. There have been no positive test results in OTM animals slaughtered

for human consumption, emphasising the very low prevalence of BSE in animals born after August 1996.

In most of the plants seen, hides were retained on the premises until receipt of the test results and the retention and traceability of hides at these premises was reviewed as part of this audit. However, at some of the plants in GB the hides were dispatched daily to a hides premise, before test results were received. The auditors noted that at these plants a separate protocol had been agreed between the abattoir, the hides premise and the Meat and Livestock Commission (MLC) who are responsible for controls at hides premises. However, these separate controls were not covered by this audit.

It was noted that some training certificates of authorised brainstem sampling personnel were not dated on the certificates issued by VLA.

Some general issues have been raised in respect of the operation of MHS protocols relating to the OTM HC system:

1. It was questioned whether there is a formal process and definition of responsibility/authority relating to concessions on operational matters; e.g. acceptance of an unlabelled sample as negative on the basis of additional information/evidence provided by the plant to MHS HQ and resulting consultations that took place.
2. Certain documents, such as OVS contracts and training records, were not kept on site for confidentiality reasons. The specific contracts and records noted at site visits were reviewed and confirmed at the meeting with the MHS in York on 19 May.
3. It was suggested that an effective date of implementation be identified for any RMOP amendments agreed. It was also suggested that the version number of the RMOP should be included in the internal document control system.

3.3.1 Seal issues on OTM containers

At two of the audits issues were raised regarding the seals on containers of OTM material moving from an abattoir to a cutting plant. In one instance there had been an error and a seal had not been applied, and in another the container arrived with no seal.

In the first instance the issue was referred to the MHS OTM Veterinary Advisor and to FSA HQ in London and a decision taken to unload the container under MHS supervision and scrutiny. Following this the decision process was passed down to AOV/VA level to make the decision to unload or not in relation to similar issues. In such cases, where the seal is not present, it would be normal for the container to be unloaded with 100% inspection from the MHIs on site to match eligibility records from the plant that sent the container with tags on the sides in the container.

A lorry driver has a legal right to open the container to check his load. It is therefore likely that seals will be removed from time to time, especially on containers travelling a long distance which may be shunted or picked up by several different tractor units.

3.4 Review of RMOPs

The RMOP at each abattoir or cutting plant was reviewed as an integral part of each audit. The RMOPs varied in detail, reflecting the differences between the plants and different approaches to meeting the requirements, but there was a high level of consistency. All RMOPs were found

to meet the requirements as set out by the Independent Advisory Group. Consistency between RMOPS was helped by the model documents provided by the MHS and DARD as part of the application pack and the fact that all the RMOPs were reviewed and signed off by the MHS OTM Veterinary Advisor for plants in GB and the DVO for OTM in NI.

3.5 BSE Testing laboratories

LGC (Runcorn) and the Department of Agriculture and Rural Development (Belfast) were visited on 1 and 2 February 2006 respectively. The objective was to gauge the degree of assurance provided by the testing systems / methodologies and associated support systems in place (including internal, VLA and UKAS audit programmes) relating to the TSE rapid laboratory testing programme. This was not intended to duplicate either the detailed audits conducted by United Kingdom Accreditation Service (UKAS; both facilities have methods accredited against ISO 17025), or the inspections conducted annually by the Veterinary Laboratories Agency (VLA) as the TSE reference laboratory, but rather to gain an overview as to how the process was conducted and controlled in the context of the wider OTM testing programme.

A management system relevant to the work was in place in both laboratories and the work processes were accredited to ISO 17025. This was clearly at least partly responsible for the high degree of rigour and comprehensive tracking mechanisms in place. Work processes in both laboratories were found to be well documented, with extensive recording and traceability systems. Systems to eliminate the potential for sample transcription and translation errors were in place, and opportunities for introduction of human error had been minimised.

A high degree of assurance was provided in terms of the integrity of the systems in place for rapid laboratory testing for BSE from the activities observed. The systems had been automated to a high degree, reducing the potential for human error and standard kits and reagents were being used. The sample identification and tracking systems were found to be robust and backed by effective IT platforms. Furthermore, additional assurance is provided by the extensive internal and external audit programmes undertaken by UKAS and VLA.

4.0 Audit Conclusions

No significant non-conformities have been identified in the audit of the first six months operation of the BSE testing system in the UK. All the facilities have demonstrated robust controls in accordance with the requirements for allowing OTM animals to be slaughtered for human consumption as set out by the Independent Advisory Group (IAG) led by Professor Wall.

The auditors were required to provide opinions on a number of specific issues as set out in the study objectives (Section 1.2). These are addressed below:

1. ***Guidance for enforcement staff, provided in staff instructions and the MHS and VS-VPHU Operations Manuals.***
   The sections of the Operations Manuals and staff instructions that relate to the slaughter of OTM animals for human consumption were reviewed and found to be accurate and adequate. Copies of Manuals were present at each facility.
2. ***Training and deployment of enforcement staff, and the training of abattoir personnel.***
   All MHS staff working at OTM plants (i.e. both OVSs and MHIs) have been required to attend a one day training course and pass a competency test. This has been a new development for the MHS and has proved effective in ensuring an appropriate level of competence in the staff deployed. In Northern Ireland, the OVS and an MHI from each abattoir had attended a one day training course and had cascaded the training to all members of the MHI team. Resource planning for enforcement staff as recorded in the day book and/or on resource planning sheets at each plant was reviewed and found to be thorough and effective. All abattoir personnel involved in brain stem sampling had been trained and records kept. In Great Britain training was either by VLA staff or by previously trained staff and the names of those trained are entered on a central register. In Northern Ireland plant staff had been trained by DARD staff and each plant holds a list of those trained and approved to take samples.
3. ***Review of RMOP documents***
   All RMOPs were found to meet the requirements as set out by the Independent Advisory Group. There was a high level of consistency between the RMOPs at different plants.
4. ***The level of assurance of the testing regime provided by existing audit arrangements of MHS by the MHS internal audit team.***
   All OTM additionally approved slaughterhouses are audited routinely by the AOVs using a compliance checklist. In addition, a number of audits of OTM additionally approved slaughterhouses have been carried out by MHS internal audit and OTM issues will become part of their regular audit programme. The overall audit arrangements were considered to provide a good level of assurance.
5. ***The level of assurance provided by existing audit arrangements of VS-VPHU operations by the VS-VPHU internal audit team.***
   All plants handling OTM material had been audited by DARD, and it was planned to carry out audits about once a month for first 6 months of operation. In addition, the Divisional Veterinary Officer for OTM makes regular visits to all plants. The audit arrangements provided a good level of assurance.
6. ***The level of assurance provided by existing arrangements for quality assurance and audit of testing laboratories.***
   A high degree of assurance was provided in terms of the integrity of the systems in place for rapid laboratory testing for BSE from the activities observed. The systems had been automated to a high degree, reducing the potential for human error and standard kits and reagents were being used. The sample identification and tracking systems were found to

be robust and backed by effective IT platforms. Furthermore, additional assurance is provided by the extensive internal and external audit programmes undertaken by UKAS and VLA.

7. ***An assessment of the extent to which the issues highlighted by the external review into casualty animal test failures (The Wall Report) have been addressed.***

The testing regime implemented in the UK has taken account of the issues highlighted by the Wall Report and strenuous efforts have been made to ensure that the system is effective and robust. In particular, the introduction of the AOV with direct supervision of the plant OVS has addressed some of the key issues. However, some of the issues highlighted by the Wall Report relate to broader issues for the MHS, such as the contract arrangements for supply of OVSs. Proposed changes to veterinary supervision arrangements within the MHS are presently under discussion and the subject of a public consultation.

In conclusion, the audit has shown that an effective and robust BSE testing system has been implemented in the UK to allow OTM animals to be slaughtered for human consumption, which should continue to provide a high level of assurance to the consumer.

Appendix I – Definitions and Acronyms

Definitions	
Non-conformity	a "non-conformity" is an audit finding demonstrating either that the protocol does not include something germaine to the operation or that something in the protocol is not being carried out in the manner laid down.
Closed out	Corrective action in response to a non conformity has been completed to the satisfaction of the audit body.
Acronyms	
AOV	Area Official Veterinarian
BSE	Bovine Spongiform Encephalopathy
CAR	Corrective Action Report
DARD	Department of Agriculture and Rural Development (Northern Ireland)
DVO	Divisional Veterinary Officer
GB	Great Britain
IAG	Independent Advisory Group
IRG	Implementation Review Group
MHI	Meat Hygiene Inspector
MHS	Meat Hygiene Service (Enforcement agency in GB)
NI	Northern Ireland
OVS	Official Veterinary Surgeon
RMOP	Required Method of Operation
TSE	Transmissible Spongiform Encephalopathy
VA	Veterinary Advisor
VLA	Veterinary Laboratories Agency
VS-VPHU	Veterinary Service, Veterinary Public Health Unit (of Northern Ireland)

Appendix –II
Audit Report Template and Checklist

Copy of Audit report template and checklist to be added as a separate document.

Appendix –III
Audit Report Summaries

This appendix contains the Audit Summaries from each of the Audit reports produced for the study. These summaries reflect the findings at the time of audit. A set of the complete audit reports has been provided to the FSA separately.

Plant	Audit Summary
a)	**Abattoir (19th December 2005)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. The following matters were raised in respect of operation of MHS protocols relating to the OTM HC system: 1. In respect of concessions. Is there a formal process and definition of responsibility/authority relating to concessions on operational matter? E.g. acceptance of unlabelled sample as negative on the basis of additional information/evidence provided by the plant to MHS HQ and resulting consultations that took place. 2. In respect of removal of hides from the tannery stock in the event of a +ve or no-test. Verification of disposal arrangements appears to be outwith currently agreed independent audit arrangements. 3. Training certificates of authorised brainstem sampling personnel were not dated on the certificates issued by VLA. 4. Certain matters included on the checklist were unable to be verified on-site, although the information was said to be available at MHS HQ. Examples include OVS contract, OVS training records (at the closing meeting this was said to be available via access by authorised staff to the MHS internal computer system).
b)	**Abattoir with co-located cutting plant (24th January 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. There were no issues raised in relation to VS-VPHU or Plant systems and their implementation.
c)	**Abattoir with co-located cutting plant (25th January 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP on the whole. The following minor issues were raised at the closing meeting: The company should review the hygiene practices between brain stem sampling as there was potential for cross contamination with the current practices although deemed low risk. Records of cleaning around the sampling area could be improved, in particular, for the sample table which could be a cross contamination point although this is once again considered low risk. The current practice of the DARD staff crossing off carcases identified as acceptable to be withdrawn on the RN2 due to non TSE reasons, but with no reason detailed on the record, is misleading to a third party auditor and should be changed.
d)	**Abattoir (22nd February 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP.

	No operational nonconformities in connection with the plant operator or Meat Hygiene Service activities were observed during the audit. All documents and records inspected had been properly completed. Only 11 OTM cattle were killed on the day of the audit and these were all observed through the process of killing and dressing and brain stem sampling. (Of the OTM cattle killed, 7 were TB reactors). The site had experienced one "no test" since it began slaughtering OTM for human consumption. This was immediately clear to the operator before the carcase was split and so, after consultation with the OV and AOV, it was detained and split separately. In this case there were no 1B2A carcases to be disposed of. All details of this were fully recorded in the MHS day book.
e)	**Abattoir with co-located cutting plant (2nd March 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. Offal is usually individually identified but a breakdown on the offal line meant that all the red offals for this day had to be treated as a single batch. The following matters were raised in respect of operation of MHS protocols relating to the OTM HC system: 1. The OVS contract was unable to be verified on-site, although the information was said to be available at MHS HQ. 2. Training records for OVS's not available for inspection on site (kept in personnel files at MHS regional offices). Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. This was established through discussions with the Boning Hall Manager and inspecting records as there was no boning of OTM during the audit.
f)	**Abattoir with co-located cutting plant (3rd March 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. Edible Offals treated as 2 batches during the OTM slaughter. Hides retained on site until test results through. All other by-products leave site as SRM. This site has had an MHS audit and the report had been received although there had been a delay between the audit and the receipt of the report. Issue with receipt of information from DEFRA in relation to confirmation of samplers on DEFRA register. Letter sent from plant on 31/10/05 no reply yet. This plant had a no test early on in the scheme and effective action recorded as taken. The following matters were raised in respect of operation of MHS protocols relating to the OTM HC system: 1. As with some previous audits the OVS contract was unable to be verified on-site, although the information was said to be available at MHS HQ. 2. Training records for OVS's not available for inspection on site (kept in personnel files at MHS regional offices).

	Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. This was established through discussions with the Boning Hall Manager and inspecting records as there was no boning of OTM during the audit.
g)	**Abattoir with co-located cutting plant (8th March 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. No operational nonconformities in connection with the plant operator or Meat Hygiene Service activities were observed during the audit. All documents and records inspected had been properly completed. During the course of the audit a local electrical power cut occurred lasting several minutes. When power was restored the IT system in use for collection and recording brain stem sampling resumed without any apparent loss of data as soon as the local area wireless network was re-established. Following discussion with the plant operator's Technical Manager it was not clear whether this was because the information was retained in the notebook computer memory used in the plant (with its own battery power available) or whether the information is held on the server. It was recommended that the security of the system in preventing data loss in the event of power cut or similar events be evaluated. The small cutting operation, where VC removal is carried out on a few of the cattle slaughtered, was also audited. There were no nonconformities identified in this operation and controls appeared to be properly implemented.
h)	**Abattoir with co-located cutting plant (13th March 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. Red offals for human consumption treated as single batch during the OTM slaughter. Individually tagged hides retained on site until test results through. Lungs, livers and trachea put into separate OTM bins for petfood and all other by-products leave site as SRM. This plant had a no test early on in the scheme and effective action recorded as taken. This site has had an MHS audit and although the report had been received and actions taken on site they had not documented their actions as they had not been sent a CAR form from the auditors in accordance with the MHS internal audit procedure. This meant that the audit findings could not be verified and closed out by the auditors. (In subsequent review with the MHS it was learnt that this was an early audit using new protocols, and that the system is now working as planned). Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. This was established through discussions with the Boning Hall Supervisor, inspecting records and observation of the boning of OTM during the audit.
i)	**Abattoir (15th March 2006)** Plant systems and operation were well implemented and all controls reviewed were in accordance with the OTM HC requirements and the associated approved RMOP. The latter had been reissued on 1 March 2006 for minor changes in respect of blood tank security changes and update of form numbers. Edible offals are treated as a single batch during the OTM slaughter. Hides are despatched

	daily to the tannery before test results are received but MLC controls are in place to quarantine these. The site has had two MHS audits and the report was reviewed for the most recent. All recommendations for action had been implemented. Samplers are on the DEFRA register but no confirmation has been received by the company to confirm this. The plant has had one "no test" result early in the scheme and effective corrective action had been recorded as having been taken. An issue had arisen on 27 February with regard to an unsealed load despatched to a cutting plant. This appeared to have been a genuine mistake owing to a communication error – paperwork for the despatch reflected the lack of sealing. Full information regarding the material on this load had been supplied to the MHS staff at the cutting plant so that all concerned were satisfied that the beef concerned could be used. The company and the MHS staff on site had implemented a tighter control over this aspect by way of corrective action which appeared to be satisfactory. Recommendations were made re minor observations of the system: 1 It was suggested that it would be good practice to have a fridge located in or adjacent to the sampling area for keeping brain stem samples chilled prior to freezella application and dispatch in summer months 2 HCIP document should include revision control date to indicate status 3 Recent minor changes to the RMOP should have been signed off with a new "back page" to indicate agreement by original signatories.
j)	**Abattoir with co-located cutting plant (7th April 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. Edible Offals treated as single batch during the OTM slaughter. Hides retained on site until test results through. All other by-products leave site as SRM. This site has had an MHS audit and the report had been received. Only minor business related issues raised. This plant had a no test in February and effective action recorded as taken. Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. This was established through discussions with the Technical Manager, MHS staff and inspecting records as there was no boning of OTM during the audit.
k)	**Abattoir with co-located cutting plant (12th April 2006)** Plant systems and operation were well implemented and all controls reviewed were in accordance with the OTM HC requirements and the associated approved RMOP. The latter had been reissued on 25 January 2006 for minor changes in respect of red offal handling (change from traceability for each animal slaughtered to a part day batch defined by meal breaks) . Hides are despatched daily before test results are received but MLC controls are in place to quarantine these. The site has had one MHS audit and the report was not available as it had been returned in annotated form to cover corrective actions. Whilst it was indicated to me that all recommendations for action had been implemented it was suggested that a photocopy

	should be held on site in this eventuality. Samplers are on the DEFRA register and had been trained by cascade by the Technical Manager. The plant has had two or three "no test" results early in the scheme and effective corrective action had been recorded as having been taken. Recommendations were made re minor observations of the system: 1 It was suggested that it would be good practice to have a fridge located in or adjacent to the sampling area for keeping brain stem samples chilled prior to freezella application and dispatch in summer months 2 The generation of bar code labels for the sample pots at the lairage office has been set up using in-house developed software to produce three labels for each animal. In reality only two are required – one for the pot and one stuck to the record form. It was suggested that the software should be adapted so that a third label cannot be produced: such "spare" labels could be a recipe for confusion or mislabelling at some point.
l)	**Abattoir with co-located cutting plant (12th April 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. Offal and hides are individually identified. Hides sent off site at end of each day (i.e. before receipt of BSE test results) and approved hide movement protocols in place. The following matters were raised in respect of operation of MHS protocols relating to the OTM HC system: 1. The OVS contract was unable to be verified on-site, although the information was said to be available at MHS HQ. 2. Training records for OVS's not available for inspection on site (kept in personnel files at MHS regional offices). Observation raised in that the current approved RMOPs did not state how the plant handled schedule 19 animals which are brought into the plant on odd occasions. Observation raised in that the current dentition check records for checks carried out by both plant and MHS on odd occasions show discrepancies. Note these discrepancies had no impact on risk relating to OTMHC scheme. Observation raised in relation to quality of the tweezers delivered to plant in sample box kits from LGC. The sample operative was having difficulty using them due their poor quality. Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. This was established through discussions with the Boning Hall Manager and inspecting records as there was no boning of OTM during the audit.
m)	**Abattoir with co-located cutting plant (12th April 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. No operational nonconformities in connection with the plant operator or Meat Hygiene Service activities were observed during the audit. One recommendation was made to the OV to avoid the use of correction fluid when making corrections in records. One

	recommendation was made to the Plant Operator to maintain a record of each collection made by the clinical waste disposal company. The site had not experienced any "no tests" since it began slaughtering OTM for human consumption.
n)	**Abattoir with co-located cutting plant (26th April 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. Red offals for human consumption treated as single batch during the OTM slaughter. Individually tagged hides retained on site until test results through. This plant had a 2-3 no tests early on in the scheme and effective action recorded as taken. The following matters were raised in respect of operation of MHS protocols relating to the OTM HC system: From 3-5-06 SRM protocols change in that it will be a requirement to remove the VC from cattle 24-30 months (EU harmonisation) and the 24-30 month carcasses will not have a blue stripe label applied. As it will be possible to send these carcasses to a non approved OTM cutting plant even a butchers shop (as no brain stem sampling is required) there will be no visual differentiation between these carcasses and the OTM carcasses. The blue stripe label will be applied to the under 24 month cattle carcasses. Site MHS could record the corrective actions or responses to recommendations from MHS internal audits even if they are deemed low priority issues to formalise the process. It is not clear in the plant operators manual how to handle a 6 tooth UTM carcase although there is a verbally approved protocol of the options available to the plant. Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. This was established through discussions with the Technical Manager and inspecting records as there was no OTM boning during the audit.
o)	**Abattoir with co-located cutting plant (28th April 2006)** Plant systems and operation were well implemented and all controls reviewed were in accordance with the OTM HC requirements and the associated approved RMOP. The latter had had three annexes issued subsequent to original approval for reasons of (1) definition of cutting plants and blood handling control as Cat 1 SRM, (2) Handling of "6 toothers" and (3) Sampler discretion regarding non-viable stem samples. Hides are despatched daily to a merchant in Kent i.e. before test results are received but MLC controls at the merchant are in place to quarantine these. The site has had one MHS audit and the report was not available as it had been returned in annotated form to cover corrective actions. Whilst it was indicated to me that all recommendations for action had been implemented it was suggested that a photocopy should be held on site in this eventuality. Samplers are on the DEFRA register and one additional sampler had been trained by cascade by the Utilities Manager.
p)	**Abattoir with co-located cutting plant (28th April 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP.

	Red offals for human consumption identified individually during the OTM slaughter. Individually tagged hides retained on site until test results through. This plant is relatively new on the scheme i.e. started 14-3-06 and have not had any no tests since they started. The following matters were raised in respect of operation of MHS protocols relating to the OTM HC system: VA had not signed the original RMOP (internal MHS issue only). Suggested that the MHS record in their day book when the Trading Standards Animal Welfare Officer releases 6 tooth UTMs. Eg the day book recorded when a 6 tooth UTM was detained on the 20-3-06 pending Welfare Officer decision but there was no record to say what happened to it. Plant HICP document requires updating to reflect current practices. Plant could make it clearer in the RMOP that the tongues are labelled to ensure correlation of offals to sample/kill number. Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. This was established through observing the VC removal during the audit, discussions with the Management and MHI and review of records.
q)	**Abattoir (5th May 2006)** Plant systems and operation demonstrated mainly suitable controls in accordance with OTM HC requirements and the associated approved RMOP. No practices were observed that would appear to jeopardise the integrity of the traceability of carcases or other body parts or the integrity of the brain stem sampling or testing. The sample of records examined supported this. However, three nonconformities were identified during the audit. Two of these related to the Plant Operator (Food Business Operator, FBO) and concerned the inadequate use of personal protective equipment by the operator taking brain stem samples and the lack of a formal system for disposal of used brain stem sampling equipment as clinical waste. The third nonconformity related to a number of errors in documentation used by the MHS. A further recommendation was made to the FBO in relation to maintaining records to show that cleaning takes place when there is a switch from OTM to UTM or horses. The site had experienced two “no tests” since it began slaughtering OTM for human consumption and the records indicated that the proper isolation and disposal procedures had been followed in these cases. Non conformities: 1. Sampling operative was not wearing visor when brain stem sampling commenced. RMOP requires operator to wear adequate protective clothing according to health and safety instructions issued by plant management. A visor had been provided by management for the purpose of sampling. The matter was rectified when pointed out to the Plant Manager by the auditor. 2. There was no formal system in place for separate disposal of equipment as clinical waste and no record of this. 3. On the sample of records inspected discrepancies were noted as follows: • 2 or 3 ante mortem records for April 2006 were missing from the file • TSE 6/9 (MHS check at sampling) sheets were often incomplete in respect of number of samples submitted (i.e. numbers killed)

	• One instance of a seal not recorded as removed • A transfer permit form had been amended/corrected without any signature/date/reason for amendment • Copies of OV monthly reports to MHS York were not available on site
r)	**Abattoir with co-located cutting plant (19th May 2006)** Plant systems and operation demonstrated robust controls in accordance with OTM HC requirements and the associated approved RMOP. Only 7 OTM HC cattle were killed on the day of the audit. No operational nonconformities in connection with the plant operator or Meat Hygiene Service activities were observed during the audit. One recommendation was made to the OV to avoid the use of correction fluid when making corrections in records. The site had not experienced any "no tests" since it began slaughtering OTM for human consumption.
s)	**Stand alone cutting plant (20th December 2005)** Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. Single recommendation made in relation to the site records to show the time that cleaning takes place when there is a switch from OTM to UTM cutting during the working day.
t)	**Stand alone cutting plant (23rd February 2006)** Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. Both Operator and MHS systems appeared to be well managed and operator system in particular appeared to be very efficient. No non conformities were identified. Two recommendations made in relation to document control. It was suggested that an effective date of implementation be identified for any RMOP amendments agreed. It was also suggested that the version number of the RMOP should be included in the internal document control system.
u)	**Stand alone cutting plant (10th March 2006)** Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. No non conformities were identified. No suggestions or recommendations were made. From records, one instance of an unsealed vehicle containing OTM HC carcases (with otherwise correct transfer documentation) received 27 February 2006 was noted. Incident was dealt with by identifying each carcase against traceability records obtained from abattoir, including eligibility record and BSE test results from LGC. Information concerning this was passed to DNV Auditor in advance of his planned audit of the abattoir.
v)	**Stand alone cutting plant (14th March 2006)** Onsite plant and MHS systems for controlling OTM Vertebral column removal were seen to be effectively implemented and compliant with the MHS (non statutory) protocols. No issues raised against plant or on site MHS procedures.

	Concern with MHS protocols in relation to containers seals. Plant has had 3 incidences relating to seal issues on incoming containers. 1st issue – Trailer arrived unsealed and with a copy of the Transfer permit. FSA HQ London allowed the load to be unloaded under MHS supervision and scrutiny. 2nd Issue – The Transfer permit had been locked in the container i.e. could not be checked before breaking seal. 3rd Issue – Which occurred today during the audit – The container turned up with a copy of the transfer permit (not original) and there was a wrong seal number on the permit. In this case there were 2 seals on the container one from the MHS on the left hand door and one from the company on the right hand door (which is the first opening door). It was the company seal number which was incorrect. Decision taken at VA and AOV level to unload the container with 100% inspection from the MHIs on site to match eligibility records faxed through from abattoir with tags on the sides sent through in the container. Following the first issue the decision process was passed down to AOV/VA level to make the decision to unload or not in relation to similar issues. Further complication to this is the fact that containers travelling long distances may be shunted or picked up by up several tractor units and the driver has a legal right to open the container to check his load before moving off. This is what happened in the first issue above when the container arrived without seal because one of the tractor drivers had removed it at some point.
w)	**Stand alone cutting plant (20th March 2006)** Onsite plant and MHS systems for controlling OTM vertebral column removal were seen to be effectively implemented and compliant with the MHS (on-statutory) protocols. No issues of non-conformity were raised against plant or on-site MHS procedures. An OVS visits the plant every 5 months on an audit basis. The OVS contractor also provides relief meat inspection staff as required under the contract – but no copy of this is held on site. (A recurring theme on these visits) No incidents of concern had arisen in the period since operation to the scheme commenced in November 2005. The point was made by both the plant Technical Manager and by the MHS staff that thwe Transfer Permit document does not contain a line or “box” in part A for the insertion of a date by the despatching abattoir MHS staff. I concur with their view that whilst in general it is obvious, on the day, to which date the document on hand refers, review of archive documents can be confusing. Part B of the form contains a “date box” and it may be that this was an oversight in the form design. Amendment is recommended to remove one more (albeit very minor) weak link in the chain of traceability.
x)	**Stand alone cutting plant (11th April 2006)** Onsite plant and MHS systems for controlling OTM vertebral column removal were seen to be effectively implemented and compliant with the MHS (on-statutory) protocols. No issues of non-conformity were raised against plant or on-site MHS procedures. OVS visits the plant every 5 months on an audit basis. The OVS contractor also provides meat inspection staff as required under the contract – but no copy of this is held on site.

	Noted that the contracted MHI, had been trained (12 December) re the OTMHC Scheme and VC removal, but no record available at site, neither does she hold a copy of such a record. It is recommended that these records should be made available to appropriate audit parties and not just held at York. No incidents of concern had arisen in the period since operation to the scheme commenced in November 2005. MHS Audit of the plant dated 15 March 2006 had not raised any findings of significance re the OTMHC scheme and rated the operation "excellent" on most counts.
y)	**Stand alone cutting plant (24th April 2006)** Onsite plant and MHS systems for controlling OTM vertebral column removal were seen to be effectively implemented and compliant with the MHS (on-statutory) protocols. No issues of non-conformity were raised against plant or on-site MHS procedures. OVS visits the plant every 5 months on an audit basis. The OVS contractor also provides meat inspection staff as required under the contract – but no copy of this is held on site. Noted that the contracted MHI, had been trained re the OTMHC Scheme, but no record available at site. It is recommended that these records should be made available to appropriate audit parties and not just held at York. No incidents of concern had arisen in the period since operation to the scheme commenced in November 2005. No MHS Audit of the plant had been carried out to date.

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MANAGING RISK

OTM Rule Replacement: Independent Review of BSE Testing
Site Audit Report

AUDIT DETAILS

Audit Details			
Name of Auditing Company: DNV Consulting			
Auditor: Craig Whitehouse	Audit Date:		EC Plant No.
Plant Occupier/Company Name:			
Occupier Address:			
Postcode:	Tel. No.		
Registered Company Address:			
Postcode:	Tel. No.		

Key Personnel			
Name/Job Title	Present at Audit (✔)		
	Opening Meeting	Site & Procedures Inspection	Closing Meeting
	✔	✔	✔
AOV -			
OVS -			

Plant Activities

OVERVIEW OF PERFORMANCE AGAINST THE OTM REQUIREMENTS

SUMMARY

NON-CONFORMITIES SUMMARY SHEET

List of Non-Conformities		
No.	Requirement ref.	Detail of Non-conformity

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SLAUGHTERHOUSE CHECKLIST/REPORT

1. PRE-REQUISITES			
PROCESS	**PURPOSE**	**Comments/ Objective evidence**	**Conforms Y / No**
1. MHS/VS-VPHU to establish that pre-requisites are in place	**Checks to verify that**: Adequate staff on site to do tasks and training and competency of staff to the required level of competence, i.e. that qualifications and training records are correct, complete and up to date for all plant operatives and MHS/VS-VPHU staff.		
1.1	OVS staffing levels and facilities adequate for OVS to undertake extra responsibilities at ante-mortem.		
1.2	Contracted OVSs aware of priorities associated with the OTM BSE testing. Level of service defined in contract?		
1.3	The plant has sufficient lairage/slaughter capacity, do they allow segregation of OTM cattle requiring testing (also includes Over 24 month casualty animals).		
1.4	Suitable sampling facilities are available, (separation to prevent cross contamination). Staff taking the samples on the DEFRA register		
1.5	Appropriate, secure and sufficient chiller space is available for holding the carcasses and other animal parts pending test results,		

1.6	Plants have a secure and efficient means of receiving test results, eg fax, e-mail		
1.7	An adequate "Hazard Identification and Control Plan – HICP) for the testing is in place.		
1.8	Satisfactory MHS internal audit processes in place		
1.9	H&S addressed for operators (ref ACDP guidance)		
1.10 RMOP	Each plant has an RMOP which has been approved by the AOV and HQ OTM VA, (approved by HQ VS-VPHU, DVO in NI). RMOP signed by OVS and plant operator Robust traceability system established to match up samples to carcase and body parts. OTM & UTM differentiation ie UTM – blue striped labels. USE RMOP CHECKLIST – ATTACHMENT 1		
1.11. Testing assessment	That appropriate procedures are in place to ensure that any non-compliance with approved procedures are identified and rectified immediately and there is an effective mechanism for notifying the FSA of any serious violations.		
1.12. MHS/VS-VPHU Ops Manual	MHS/VS-VPHU operations manual instructions and amendments are up to date.		
1.13. Trials	2 day trial carried out with MHS & AOV assessment Approval letter available from MHS. Was AOV present on day 2 of OTM processing		

SLAUGHTERHOUSE: SCOPE OF REVIEW			
PROCESS **2.** Pre-Audit checks	**PURPOSE** To ensure enforcement protocols in place before operator undertook OTM work **KEY CHECKS** **Document checks to verify:**	**Comments**	**Conforms** **Y / No**
2.1	Name of plant occupier / limited company / address of occupier / registered company address, plant licence number **-** licence details are correct/appropriate for activities undertaken.		
2.2	RMOP is relevant, comprehensive and has been agreed by all relevant parties i.e. the prior approval process was carried out satisfactorily and there is confidence that the abattoir meets the requirements of the BSE testing scheme.		
2.3	That critical controls in relation to BSE testing are satisfactory and comprehensive.		
2.4	That any relevant enforcement or corrective actions are clearly identified.		
2.5	Useful information from any relevant audit report by internal MHS/VS-VPHU is assessed together with relevant information gained from other MHS/VS-VPHU documentation.		

2.6	**MHS documentation**: (Note all will have new references from Jan-06) - MHS 34 (Ante-mortem inspection record) - MHS 42 (Transfer permits for sheep/goat/BAS carcasses) - MHS 47 (Daily SRM record) - MHS 46 (Monthly SRM record) - MHS 50 (Bovine eligibility record)		
2.7	**VS-VPHU documentation**: - Ante-mortem records - SRM 35 (transfer permit for bovine carcasses containing SRM) - SRM checklist (auditor) - SRM checklist (inspector) daily SRM record - MT20 (daily slaughter report)		
2.8	Documentation of action resulting from laboratory feedback on the quality of brain stem samples received and transmission/receipt of results laboratory testing, to show negative, positives and "no test" results.		
3. RMOP, HACCP and HICP systems	**Purpose** To ensure that all relevant activities are satisfactorily covered and that requirements are carried out in practice for each step of the process. *Mostly covered in pre-audit documentation review (RMOPS etc)*		

4. Identity and age of animal checks	**Purpose** To ensure all OTM cattle are correctly identified and presented for testing To ensure animals born before 1st August 1996 excluded from food chain. **Physical, document checks and interview of operatives to ensure**:		
4.1	That reliable ante-mortem checks on animal identity are carried out on arrival/in lairage as appropriate. Passport/ID and ear tag correlation procedures robust.		
4.2	Check compliance with RMOP requirements to ensure identification of all eligible animals to be tested i.e. a) born on/after 1 August 1996; b) over 30 months old; c) over 24 months accompanied by schedule 18/19 certificates and any appropriate action taken; d) over 24 months displaying abnormalities at ante-mortem inspection;		
4.3	Check compliance with RMOP requirements for dealing with on-farm slaughtered animals		
4.4	Check compliance with RMOP requirements for dealing with animals exhibiting abnormalities		

4.5	Check compliance with RMOP requirements to ensure any over-age cattle excluded from food chain		
4.6	That the MHS 34 and 50 form data correlates (In NI , that ante-mortem and MT 20 data correlates		
4.7	MHS lairage OTM & UTM checks carried out. 10% min check of passport/ID against ear tag numbers		

5. Slaughter schedule	**Purpose** To ensure all OTM cattle are correctly identified and presented for testing and there is no risk from cross contamination		
5.1	All OTM cattle identified? OTM and UTM in separate batches? Is it detailed when OTM cattle will be slaughtered? Correct procedures in place for casualties?		
5.2	Agreed RMOP ensures no cross-contamination, at least from:. Equipment used for eligible cattle; Operatives who handled eligible cattle; Splashing from eligible cattle; Inadequate space between carcasses.		
5.3	MHS cross check passport/ID, ear tag and dentition for **ALL** OTM & UTM animals – Forms completed?		

6. Sampling procedures in abattoirs	**Purpose** Verify the provision of suitable facilities with separation from slaughter line Verify the traceability of the obex sample and carcass. **Physical and document checks to ensure:**		
6.1	That sampling areas are clearly defined and are being supervised by OVS. Compliance with RMOP procedures on identification, sampling, traceability i.e.		
6.2	Sampling carried out by trained operatives? Records kept by occupier of all operatives trained in brain stem removal? MHS do not undertake any sampling where there are trained operatives? Sampling operatives wear appropriate protective clothing? MHS Staff supervise sampling?		
6.3	All testing equipment disposed of as clinical waste? Procedures for disposal of clinical waste? New equipment used for each sample? Sampling carried out hygienically under FM & TSE Regs?		
6.4	If samples not despatched, chilled in fridge at 4°C? (Up to 4 days) Storage of brain stem sample pots or freezella packs does not allow cross- contamination of food/meat for human consumption?		
6.5	Samples submitted for analysis of adequate quality? Dressing methods used (such as hide pullers) do not damage brain stem?		

6.6	MHS staff ensure sample pots are identified and correlated to animals to be tested? (according to the following guidelines which are non-prescriptive ie modify as per ops manual) < 10 animals slaughtered per day – 100% > 10 but < 50 – 20% > 50 but < 100 –10% Operator correlates sample pots to head, carcase and detained body parts?		
6.7	Splashes of blood on outside of sample pots are avoided? Lid is screwed securely and tightened and checked before packed?		
6.8	Samples sent to LGC with movement card? (Unless details sent electronically) If no Movement card, photocopy of passport used with barcode sticker?		

7. Controls on carcasses in abattoirs	**Purpose** To ensure traceability of carcass and parts **Physical and document checks to ensure:**		
7.1	There are appropriate arrangements for chiller storage of carcasses, including weekend/public holiday storage and security.		
7.2	That both carcass sides can be correlated with red offal, Animal By-Products, blood and hide and can be linked to brain stem sample.		
7.3	Carcasses detained in chillers comply with relevant hygiene regulations (From Jan 06 new Hygiene regs)		
7.4	If a batch correlation system adopted, whole batch disposed of as SRM by incineration, if positive result?		
7.5	Blood and other by-products retained unless disposed of as SRM by incineration, before results received?		
7.6	Non OTM carcasses ie not detained in chillers should be (not compulsory) segregated, to assist in ease of locating OTM carcasses.		
7.7	Chillers used for "tested" carcasses awaiting test results are secure and sealed (either rail or chiller) n.b. in event of positive or no-test the carcase of the preceding animal plus the carcases of each of the 2 following animals (1b2a) are also removed.		

7.8	Locks or seals only opened by OVS/MHI? Chiller control processes recorded in day book or appropriate form, i.e. when locked/sealed, by whom and when opened/seal broken, by whom?		
7.9	Offal for human consumption retained in a chiller used exclusively for animals pending test results: Is chiller sealed and under official control?		
7.10	Offal for human consumption retained in a chiller where non-tested carcases and offal are stored: Is a secure system of retention of offal in place. Is there adequate separation from other meat intended for h/c? (Tagging, labelling so can be correlated to carcase?)		
7.11	Arrangements in place to ensure SRM removed from carcasses is disposed of immediately, i.e. appropriate supervision of identification and disposal arrangements for SRM.		
7.12	Arrangements in place to ensure unfit meat identified at post mortem is promptly disposed of as SRM		
7.13	Green Offal, unfit for human consumption, disposed of by incineration as SRM?		
7.14	Green Offal not classified as SRM, disposed of by incineration as SRM, if no negative result, or securely retained avoiding cross-contamination?		
7.15	Arrangements in place for dealing with hides:		

7.16	MHS Staff have ensured that hides are retained under official control within the abattoir until results received? (Unless delivered to hide market under official control)		
7.17	One system in place? (Individual or batched) If hides are individually identified in the abattoir, are any positives disposed of by incineration as SRM? (1b2a applies to positive test results but does not apply to a no-test result)		
7.18	Batches containing hides awaiting results, retained in hide room? (Unless sent to hide market under official control) Batch clearly labelled "Pending test result"? Label includes No of hides and slaughter date?		
7.19	If batched and +ve result, whole batch disposed of by incineration as SRM? (1b2a as per 7.17)		
7.20	If +ve and despatched, does operator ensure hide is pulled back and disposed of by MLC staff at hide market/tannery?		
7.21	Blood retained separately pending test result, unless disposed of by incineration		

8. Test results, health marking and dispatch	**Purpose** To ensure traceability of obex sample and carcass To ensure traceability of carcass and parts. To ensure no unfit meat enters the food chain. To ensure correct disposal of unfit material. **Operative interviews and document checks to ensure:**		
8.1	Procedures in place in abattoir for receipt of test results and correlation of the obex sample results with the relevant carcass		
8.2	Procedures in place for plant operator to bring test results to attention of MHS/VS-VPHU. Recording and archiving of test results.		
	Action by OVS in the event of <u>positive test result:</u>		
8.3	OVS confirms identity of: Positive carcase One before & two after Offals (which may be a batch) Hide (which may be a batch) Blood (which may be in a sealed tank and under official control)		
8.4	All parts of positive animal (or whole batch) and 1b2a dispatched for disposal of by incineration as SRM?		

8.5	Hides stored in hide room disposed of by incineration as SRM under MHS inspection? 1b2a does not apply to hides		
8.6	MHS inspects staining of SRM?		
8.7	Operator ensures accurate records are maintained of weight disposed of by incineration as SRM?		
	Action by OVS in the event of a <u>"no test" result.</u>		
8.8	Carcase and all parts (including blood) and all batched material, stained and disposed of by incineration as SRM? (1b2a does apply except for hides)		
8.9	OVS supervises carcase and all parts disposed of as SRM?		
8.10	Operator ensures accurate records are maintained of weight disposed of by incineration as SRM?		
	Action by OVS in the event of a <u>negative test result.</u>		
8.11	Carcass and offal released as fit for human consumption		
8.12	MHS staff retain copy of lab test report for 12 months		

9. Health marking	Carcases and offals not health marked until negative result received?		
9.1	Where plant staff apply health marks (after MHS staff have applied at least 1 health mark); is this done under direct MHS supervision?		
9.2	Where applied by plant staff when there are difficulties in application, e.g. in chillers with difficult access to upper carcase areas, is this done under direct MHS supervision?		
9.3	Carcasses from cattle under 30 months identified by blue-striped label (VC not SRM)		
10. Dispatch	OTM animals slaughtered for HC, VC removed in approved cutting plant? MHS informed of dispatch of OTM for VC removal (48 hrs, or shorter if agreed)?		
10.1	Plant operator provides MHS with: Name. Licence No. and Location of cutting plant Number of carcases Anticipated date & time of dispatch		
10.2	After Loading, the operator: Seals the vehicle Completes the commercial document Ensure paperwork with the consignment details accompanies the load in transit		

10.3	MHS staff at the slaughterhouse: Notify the cutting premises that a load of carcases have been dispatched to them Random spot checks on 15% of carcases to verify that labelling and identification is correct MHS 42 (Note: will be renumbered) Complete section A Take a copy and retain it on site Send original with consignment Complete day book		

Attachment 1 - Checklist for RMOPs

Requirements as per TSE Regs 2005	✓× Comments
Details about partnership or limited company fully completed?	
How will OTM / UTM be identified?	
How will OTM / UTM be marked?	
How will OTM / UTM be segregated?	
What if pre August 1996 arrive?	
How will eartags be correlated with passports ante-mortem?	
Who is responsible for carrying out this work?	
How will the order of kill be identified ante mortem?	
Where will the order of kill be checked?	
How will OTM carcases be identifiable from UTM carcases post mortem	
Which carcases are to be sampled? Specify dates	
During sampling, what will be done to minimise cross contamination?	
What H&S considerations are applicable (including waste disposal)?	
Who is responsible for the sampling co-ordination?	
Who is responsible for the packaging and despatch of samples?	
Are the samples correlated with the number notified to LGC?	
Where are the training records to show which staff have been trained in sampling?	
How have staff been trained (does it state where records are kept)?	
Who is responsible for this work?	
How do the samples correlate to the carcase?	
How are the hides correlated?	
How are the (red & green) offals correlated?	
Is blood going to be correlated?	
Is individual or batch correlation to be used?	
Who is responsible for maintaining the correlation system?	

Where will carcases be retained whilst awaiting test results? Where will offals be retained whilst awaiting test results?	
Where will hides be retained whilst awaiting test results?	
How will security of the retained bodies & parts be achieved?	
Will offals / hides / blood etc be batched or individually identified?	
What will happen to carcases and associated body parts detained / rejected for pathology?	
Who is responsible for this carrying out this work?	
Who will seal chillers?	
If any body part(s) are not retained, how and where will they be disposed of?	
How will gut content be disposed of?	
Plant Operator to keep records for 12 Months?	
Who is responsible for this activity?	
How will the plant receive the test results from LGC?	
Who will communicate these results to MHS and how?	
How will carcases/body parts/hides be handled in the event of a positive or no-test result?	
How will carcases/body parts/hides be handled in the event of a negative result?	
Who will carry out this work?	
How will carcases/body parts/hides be handled in the event of a negative test result?	
How will carcases be presented to MHS for health marking?	
Who will healthmark negative result carcases?	
What procedures are in place for carcase transfer?	
Who is responsible for this work?	
How are results to be received from LGC	

CUTTING PLANT CHECKLIST

PROCESS	PURPOSE	Comments/ Objective evidence	Conforms Y / No
1. SRM controls at cutting plants	**Checks to verify that**: Relevant carcasses are identified and appropriately dealt with. Document and physical checks to ensure:		
1.1	Effective arrangements in place for carcasses from all OTM cattle testing negative to be sent to licensed cutting plants and that vertebral column is removed as SRM.		
1.2	Adequate OVS checks on MHS 42 form (SRM 35 in NI)		
1.3	Satisfactory MHS/VS-VPHU enforcement of identity checks on carcasses		
1.4	MHS daybook entries satisfactory (not applicable in NI).		

Attachment 2 - Checklist for CUTTING PLANT RMOPs

Requirements as per TSE Regs 2005	✓✖ Comments
Details about plant name & operator details?	
How will MHS staff at CP be notified of impending arrival?	
What notice will be given to MHS staff at CP of impending arrival?	
How will MHS staff at CP be notified consignment (s) are on site?	
Where will unsealing of vehicles take place (stand alone)?	
What arrangements made for MHS staff to unseal chillers/rails (co-located)?	
Will MHS staff be present at unloading/transfer?	
What will happen if segregation is not clear (OTM/UTM)?	
Where will MHS checks on incoming beef take place?	
If carcases are not to be deboned on the day of arrival/transfer, where will they be stored under official control?	
How will MHS staff at CP be notified when boning will take place?	
How have staff been trained (does it state where records are kept)?	
What measures are in place to reduce the risk of cross contamination during boning?	
Are sufficient Cat 1 transfer/storage bins available?	
Is stain (Patent Blue V) available?	
Where will staining of Cat 1 material take place?	
Is SRM and non SRM going to be mixed?	
Where will SRM be despatched?	
How/where will ABP records be maintained?	
What are the procedures for cleandown after OTM VC removal of tools & surfaces?	
How will SRM/non SRM tools be segregated/identified?	
What controls are in place for storage of health marked bags and labels?	

ANNEX D

Official Response to the Final Report to the Food Standards Agency by DNV Consulting

Main Report

Audit finding	**Response**
3.2.4 – Feedback had been given verbally to plant and OVS after each audit but no further reports sent and there had been no formal follow-up of audit recommendations	DARD now have a system in place to issue formal reports immediately following each audit. Major non-conformities would be followed up immediately. To date there has been no major non-conformities identified. Minor non-conformities are followed up at the next audit. MHS Internal Audit and Verification have a similar feed back and follow up system in place.
3.3 – one plant recommended to review hygiene practices between brain stem sampling to avoid contaminating outer packaging containing the sampling spoons	The Food Business Operator has taken corrective action to ensure that sampling equipment is not contaminated.
3.3 – at another plant - • sampling operative not wearing visor provided in accordance with RMOP • disposal system for sampling equipment breached Environment Agency rules regarding clinical waste • Shortcomings in MHS record keeping	Guidance on the use of BSE sampling equipment, protective clothing and the disposal of clinical or hazardous clinical waste from cattle brain stem sampling, will be re-issued by Defra to all approved OTM abattoirs (and to any wishing to be approved in the future). General advice to abattoirs on controlling the risk of exposure to BSE issued by the Advisory Committee on Dangerous Pathogens (ACDP), is included in the MHS OTM application pack. AOV will monitor requirement to maintain full and accurate records. MHS Internal Audit and Verification process includes record keeping checks.
3.3 – audit did not cover controls at hides premises	The Meat and Livestock Commission (MLC) enforce these controls at hide premises in GB on behalf of Defra. Defra has asked the Rural Payments Agency (RPA) to undertake an audit of these enforcement arrangements. Controls on hide premises will also fall within the scope of the FSA audit of the testing system.
3.3 – some training certificates of authorised brainstem sampling personnel were not dated on the certificates issued by VLA	There are two boxes on the VLA confirmation form (certificate) for when formal training was provided. This date, rather than the date of issue of the certificate itself, is the crucial date. Defra have reminded VLA trainers on the importance of ensuring that this information is provided in all cases.

Audit finding	Response
3.3 (1.) – questioned whether there is a formal process and definition of responsibility/ authority relating to concessions on operational matters; e.g. acceptance of an unlabelled sample as negative on the basis of additional information/evidence provided by the plant to MHS HQ and resulting consultations that took place	The RMOP approval process takes into account concessions that are applicable to the particular premises and these are also discussed/agreed with the MHS OTM Veterinary Advisor. The effect of any such concessions is further monitored through regular AOV assessment visits. All exceptions must be reported to the AOV who in turn agrees action with the MHS OTM Veterinary advisor. On the specific issue of acceptance of samples, there are a number of procedures which underpin the controls relating to samples with incomplete or incorrect labels and/or accompanying documentation/data files. Which procedure is followed depends upon the severity of the problem. It should be noted that because of the multiple layers of controls, one item of missing information (such as an eartag number) does not necessarily jeopardise traceability of the brainstem sample to the tested carcase because other information (such as kill number and kill date) is available to confirm adequate traceability.
3.3 (3.) – suggested that: • effective date of implementation of any agreed RMOP amendments be identified • version number of RMOP be included in internal document control system	Guidance was sent to AOVs on 10 January 2006. MHS Internal Audit & Verification will monitor the effective use of this guidance

Appendix – additional points from audit summaries

(c) • records of cleaning around sampling area could be improved, in particular for sample table • current practice of DARD staff crossing off carcases identified as acceptable on RN2 due to non TSE reasons, but with no reason detailed on the record, is misleading to a third party auditor and should be changed	Corrective action now taken by Food Business Operator. Carcases no longer crossed off RN2 for non TSE reasons.
(e) • delay in response from Defra on confirmation of samplers on Defra register	This is not a routine part of Defra's procedures: Defra are considering the continued value of maintaining a centrally held register.
(g) • Security of the system in preventing data loss in the event of a power cut or similar events should be evaluated	The recommendation was passed to the Food Business Operator to investigate the potential consequences should data not be restored. The RMOP already contains contingency arrangements for manual identification.

Audit finding	Response
(i) • Suggested it would be good practice to have a fridge in/near brain stem sampling area to store samples	Defra accept that refridgeration of samples awaiting despatch is best practice, although refridgeration is not critical for the performance of the rapid test. If the sample stays hot for long enough it will turn to liquid and if the obex was not identifiable would be deemed a "No Test". LGC have confirmed that no autolysed (liquid) samples have been received since testing of OTM cattle began in November 2005.
(k) • Suggested that software should be adapted so that "spare" third labels should not be produced as they could result in mislabelling	MHS has passed on this recommendation to the Food Business Operator.
(l) • RMOP did not state how plant handled schedule 19 animals • dentition check records for checks carried out by both plant and MHS on odd occasions show discrepancies • tweezers in LGC sample box kits of poor quality	The Food Business Operator has stated schedule 19 cattle will not be accepted for slaughter. AOV will monitor requirement to maintain full and accurate records. LGC has ordered new forceps which should be rolled out to abattoirs in the next few weeks.
(m) • OV recommended to avoid use of correction fluid when making corrections in records • operator recommended to make a record of each collection by clinical waste company	OV instructed not to use correction fluid. MHS has passed on this recommendation to the Food Business Operator.
(n) • Not clear in the operator's manual how to handle a 6 tooth UTM carcase	Policy on how to handle the testing of 6 tooth UTM animals has been clarified since the audit visit and is now reflected in the MHS Manual for Official controls
(p) • Suggest that MHS record in day book Trading Standards Officer's decision on 6 tooth cattle and action taken • Plant could make it clearer in RMOP that tongues are labelled to ensure correlation to sample/kill number	MHS Manual for Official Controls covers the requirement to record this information. A note will be issued in MHS news to clarify that recording of trading standards decisions should be included in the day book. Plant RMOP will be reviewed.
(w) • amendment to transfer permit document to include a box for insertion of a date within the section for completion by despatching-abattoir MHS staff	The form has a box at the top for despatching-abattoir stamp and date. MHS will clarify instructions and remind staff to ensure the form is so stamped.