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Audit report for the 2014 badger control project

Conducted and prepared by:

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1. Executive Summary

The 2014 badger control project study was audited by an independent principal auditor. The audit was commissioned and paid for by Defra and the work audited was undertaken by Natural England (NE) and the Animal and Plant Health Laboratories Agency (APHA).

The audit covered the controlled shooting aspect of the project i.e. it excluded cage trapping. It was performed by following the processes involved and by assessing the work against the Standard Operating Procedures (SOPs), their updates and other available documents. It should be noted that the auditor did not have access to the culling data held by contractors conducting the cull on behalf of the NFU. Therefore an assessment of the processes followed and data collected for this integral part of the project did not form part of the audit and its data quality was not assessed.

Specifically the audit covered: the data collected in the field by NE; the *Post Mortem* Examination (PME) of badger carcases by APHA; the provision of daily and weekly reports by APHA staff; the DNA analysis of badger ear tips by APHA staff and the data management activities in all areas.

A wide range of activities were followed as part of the audit. These included – interviewing the teams involved; a review of documentation; assessing the monitoring data recorded in the field and follow up activities; following the selection process for carcases to be necropsied; following the laboratory activities in the *Post Mortem* laboratory from carcase reception to necropsy (also referred to as Post Mortem Examination); assessing the recording of the PME data and following the DNA profile analysis of the carcase ear tips.

After completing the above activities the auditor's findings and recommendations can be summarised as follows:

- The teams: The various groups that worked on the project proved to be both adaptable and flexible and worked well. Due to the late appointment of the auditor, not all training activities could be attended, but the one *post-mortem* training event carried out by APHA that was observed, was of a high standard. Whilst the APHA *post mortem* training included a trainee assessment, some of the other training did not and the auditor's recommendation is that all future training should include such an assessment. She also makes the recommendation that end to end rehearsals should be carried out in all areas of the project. In terms of the overall co-ordination of the project and the teams – the appointment of a Principal Investigator (PI) i.e. a lead scientist who had an overview of all the work, as well as day-to-day control over all its aspects would have been beneficial. Whilst overall communication was good, communication regarding the final reconciliation of the data could have been improved.

- Data quality: Overall the data collected and processed are of good quality. For the APHA *PM* laboratory data a high quality database was in place. The observational field data was stored in spreadsheets and this was a potential risk to the project in terms of data quality. However, this risk was never realised and the data is also of a high standard, as is the APHA reporting and DNA data. The reliance on Excel spreadsheets did however mean that a disproportionate amount of time was spent on ensuring the quality of these data and the auditor again makes the recommendation that for future projects a database solution needs to be in place for all aspects of the work. A specific recommendation is that because of the complexity of the NE Follow-Up (FU) data it would benefit from a re-think of the way it is managed and stored.

- The documentation: As with the 2013 project an over-arching project protocol was not in place and the auditor again makes the recommendation that the project would benefit from an overall project protocol that clearly outlines the aims, objectives and definitions of the outcome measures. Not all areas of the project were covered by SOPs. In particular, the auditor recommends that data handling and management SOPs are created for all areas of the project and should cover the Quality Control (QC) measures that are in place. Not all the documentation that was in place was prospective (i.e. some was created after the project start). For future work all processes and associated documentation needs to be in place and finalised before the project start, thus ensuring that any changes made after the project start are kept to a minimum. Version control was lacking for some documentation. A specific recommendation regarding the field observational data is that the notebooks used by the lead observers is source data and as such should be kept.

- Post project activities: The auditor recommends that database lock is performed, along with the archiving of all source data.

As part of this report a series of audit recommendations are made. A summary of these can be found at section 14.

All teams have been very open and proactive and recommendations made by the auditor during the course of the audit have in the main been addressed immediately. Future audit activities need to be organized so that there is sufficient time for comments made by the auditor to be acted upon before the project commences.

The auditor operated independently and experienced no influence from Defra, APHA or NE.

In conclusion, the auditor is satisfied that the study has been run according to the SOPs and other available documents that were in place and that the data recorded is complete and accurate.

The auditor would like to thank all members of the project team for their help and co-operation over the past months.

2. Terms of reference

The scope of the audit, as agreed with Defra, was to audit the processes, documentation, training and data collection of the 2014 badger cull.

It should be noted that this did not apply to the activities of the contractors which were deemed out of scope of this audit. Also, in the main the audit followed the controlled free-shooting aspects of the cull and not cage trapping.

Specifically the audit covered:

- The data collected in the field by Natural England (NE) monitors (including the follow-up activities)
- The receipt, tracking and *post-mortem* selection and examination of badger carcases by APHA staff
- The provision of daily and weekly reports by APHA staff
- The handling from reception to laboratory DNA analysis of badger ear tips by APHA staff
- The data management activities related to all aspects of the project

Because of the late appointment of the auditor a number of relevant activities could not be performed or could only be performed retrospectively. For example the auditor was not able to attend any of the training sessions (with the exception of a rehearsal of the PME activities) because they had already taken place when she was appointed; meaning in the main training had to be reviewed retrospectively.

3. Statement of Limits

The absence of an observation in any particular area should not be perceived as an indication that there is no need to improve upon existing practices or procedures, or that non-compliance is not present. Such an absence shows that the audit did not detect any significant non-compliance during the sampling of data and document review.

4. Methods

A variety of methods were used throughout the audit:

- Interviews with members of the teams involved in the project in order to assess their knowledge, expertise and consistency of approach

- The application of the processes as described in the SOPs and working instructions
- The quality of the data recorded in terms of completeness and accuracy (the 1-1 correspondence between the paper records and the database) and the cross consistency of data sets were assessed
- The quality of the documentation available was assessed

Throughout the audit a number of corrective actions were suggested by the auditor to improve the processes in place.

5. Follow-up of 2013 audit report recommendations

The auditor divided her 2013 recommendations into 3 categories:

- Recommendations already addressed
- Recommendations needing to be addressed and specific to the 2013 project
- Recommendations for future work

The following is an assessment of whether those recommendations from the third category have been implemented for this study.

Recommendation 2 – Principle Investigator (PI)
Although there was overall coordination for the project as a whole, it would have benefited from a principal investigator i.e. a lead scientist who had an overview of all the work as well as day-to-day control over all its aspects.

A PI was not appointed for the 2014 project. The auditor's view is that the 2014 study would have benefited from a lead scientist who had an overview of all the constituent parts of the work. Whilst there was more "active" management of the 2014 project (compared with the 2013 work), communication could have been strengthened in some areas, particularly between NE and the APHA PM facility. However each unit reported progress and issues, which were subsequently resolved by the responsible team leaders. There was overall responsibility within each organization and these reported to the Chief of Staff or Deputy Chief of Staff in the Defra Operations Centre by telephone conference every weekday morning during the 6 week culls and there was an on-duty system for out of office hours to manage urgent exceptions.

Recommendation 3 – Audit scope
Future projects of such magnitude and complexity require auditing throughout to ensure that the analysis and its interpretation are based on accurate, complete and reliable data.

The 2014 project was subject to external audit. However (as in 2013), the audit was restricted to the data after it passed from the NFU to Defra and its organisations i.e. the audit did not cover the source data.

Recommendation 4 – Data management

Serious consideration should be given to the development of a database at the start of any new work. Excel sheets should be kept to a minimum.

There was no overall project database. A relational database existed for the PME work and this made a considerable contribution to the data quality in this area. Excel spreadsheets were used in other areas causing considerable extra resource in terms of the quality assurance of the data. However, the overall quality of the data was good. One of the contributing factors to what the auditor considers was an over-reliance on spreadsheets was the relatively short lead-in time to the project (see 10.11.2)

6. Background to the 2014 badger control project

The 2014 badger culling project was the second year of culling in the two pilot areas of Gloucester and Somerset. It is planned that culling will be carried out for four consecutive years.

Culling lasted for a period of 6 weeks and was performed by contractors working for culling companies.

The way in which the project was carried out in 2014 differed from that in 2013 in a number of ways. In particular:

- In 2013 an Independent Expert Panel (IEP) existed and issues related to humaneness were reported directly to the IEP. At the end of the cull the IEP produced a report for Defra. No Independent committee was appointed in 2014 and in the main, staff involved in the project reported directly to Defra.
- In 2013 the field observation work related to the dispatch of badgers was undertaken by staff from what was at the time AHVLA. In 2014 staff from Natural England (NE) undertook this work. The detail of what was recorded at these humaneness monitoring visits was simplified e.g. no systematic video recording took place.
- The Post Mortem Examination (PME) process was also simplified and in particular no radiography took place
- The selection of carcases for PME was simplified. The aim was to PME at least one carcase from every contractor.[1]

The auditor had also been involved in reporting on the 2013 culling. The audit report for that work (Audit report for the badger control humaneness study) included both a data audit and a statistical audit of the analysis (undertaken by an independent statistical auditor). The report was presented to Defra and the IEP.

Because no formal statistical analysis of the 2014 data was undertaken this report is restricted to a process and data audit.

[1] A definitive list of all contractors was not available to the auditor for security reasons.

7. Overview of the 2014 badger control project

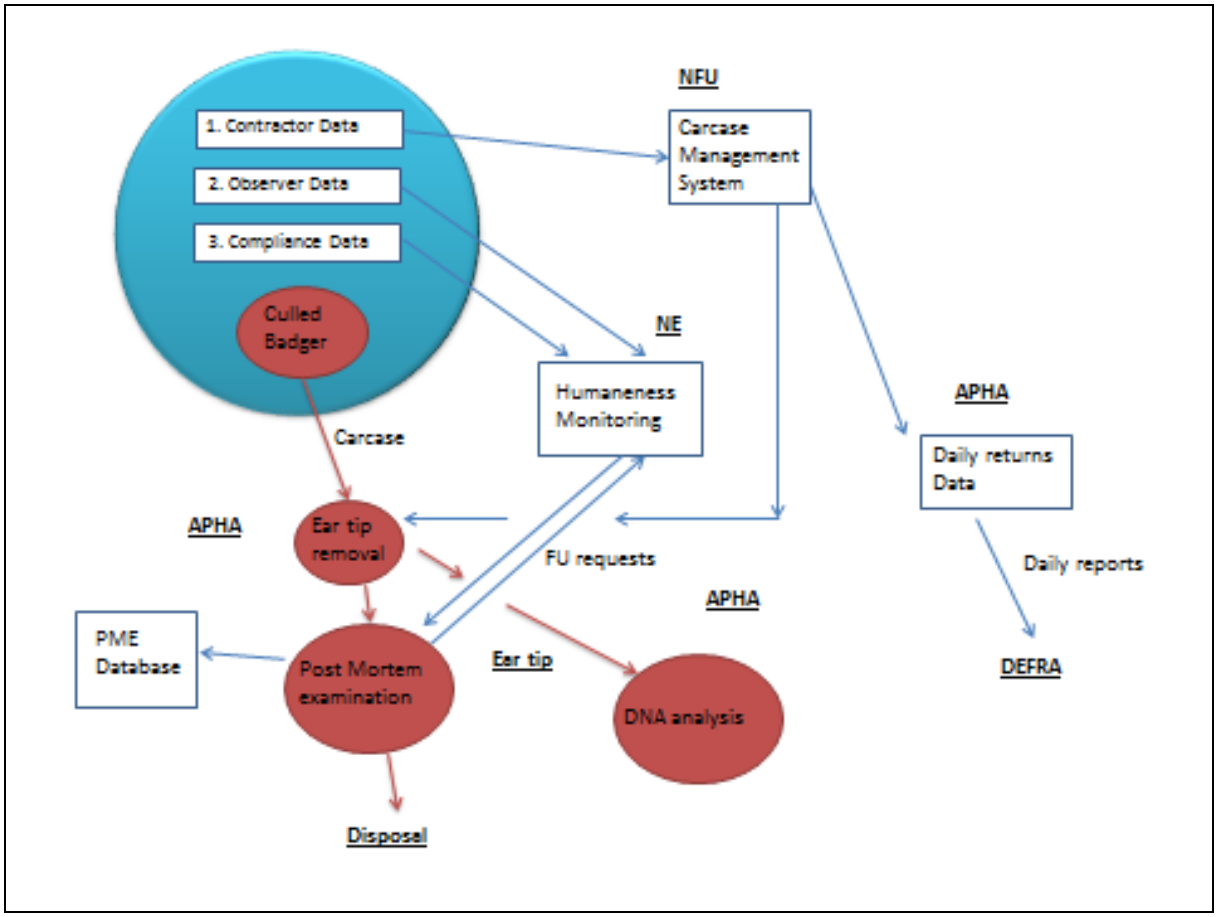

Figure 1 Simplified process and data flow diagram

Figure 1 shows a simplified overview of the sample, data flows and the organisations involved in the 2014 badger cull.

Contractors working in the field for the culling companies performed the cull between 08/09/14 and 20/10/14. They recorded their own "returns" in terms of the times when they operated, the numbers of badgers seen, the number of shots fired and badgers dispatched etc. This data was transferred daily to the NFU's carcase management system (CMS). As mentioned previously this data represented the "source data" and is not part of this audit.

A subset of the contractors in the field on any given night were subject to monitoring from NE. This took two different forms - humaneness monitoring and/or in-field assessment. This data was subsequently entered onto the spreadsheets NE used to capture these data. The aim was to observe 60 separate shooting events over the 6 week period. This was achieved.

Dispatched badgers were received each day at the *PM* facility, where carcases had their ear tips removed and sent for DNA analysis and a sample were selected for full post mortem examination (PME) and the results of the examination recorded in the PME database. The results of PMEs were shared with NE on a routine basis. Where appropriate, requests for specific PMEs were made by NE for compliance monitoring.

An extract of data from the NFU CMS was also sent to APHA and this data formed the basis for a series of daily and weekly data summaries.

8. The role of Natural England (NE)

8.1 Overview

NE is the licensing authority with regard to badger culling and as such they approved the licensing of the culling areas and ensured the compliance of individual contractors e.g. they ensured that only trained marksman were employed and that correct rifles and ammunition were used. Both of these two facets of NE's work were out of the scope of this audit, although part of the compliance work was an In-Field Assessment (IFA) and the data generated by that assessment is covered here.

The main audit activities were an assessment of the data quality of the humaneness monitoring (monitoring carried out in the field to assess whether badgers were humanely dispatched) and the Follow-Up (FU) activities (the follow-up of contractors where previous monitoring had potentially given cause for concern). It should be noted that these activities were restricted to the controlled shooting data.

8.2 Interviews

Interviews were carried out with five of the 13 monitors[2]. They were all very clear in the explanation of their tasks, as well as consistent in their approach, with the exception of the completion of note books in the field (See 8.4.1).

Having followed a contractor in the field, a humaneness monitoring form was completed with the help of any available field notes. Once completed these forms were emailed to the office; alternatively the data could be communicated over the phone. The forms had to be in by midday or if a PME was requested on a specific carcase by 8am, following monitoring.

The Follow-Up (FU) process was described to the auditor. The documentation associated with these activities had to be completed and returned within 3 working days.

8.3 Training

8.3.1 Overview

A four day training session "bovine Tuberculosis (bTB) monitor training" was held prior to the commencement of culling for all monitors. The course included presentations on: bTB as a disease, badger biology and behavior, policy

[2] There were 15 monitors in total, but 2 only observed cage trapping

background and licensing, best practice guidance, biosecurity, firearms awareness, sett surveying and cage trapping training and practical work on sett surveying and biosecurity.

A similar course had been held prior to the 2013 cull and if a monitor had attended that course it was not mandatory for them to attend the 2014 course. All newly appointed monitors attended the 2014 course.

Auditor's comment
Due to the delayed appointment of the auditor she was unable to attend or provide comments on the content prior to the training in the spring.

Auditor's recommendation 1 (General)
Future audit appointments need to give sufficient time for the auditor to be involved in the planning stage of the project, so that time exists for comments to be taken into account before documents go live or training commences.

Having studied the course programme retrospectively the auditor made the following comments and recommendations for future training:

- It is essential to show that the attendees have not only attended relevant training, but that they have benefitted from it and are fit to carry out their tasks. To show this, some form of assessment should be carried out at the end of the training. This could consist of questions related to the training course and the attendees should score some minimum percentage in order to be considered competent for the tasks they have to undertake.
- Sufficient time needs to be dedicated to reviewing SOPs and all forms that need to be completed. Examples of completed forms (possibly with errors in them) could be handed over as an exercise for people to familiarise themselves with them.
- The trainees should have the opportunity to complete a questionnaire at the end of the course, which assesses both the course and the trainers. They should also have the opportunity to suggest how the course could be improved.
- Training records need to show that staff have read and understood the SOPs issued (and their updates).

Auditor's recommendation 2 (Training)
Future training needs to include a trainee assessment.

A two day training session 'Firearms Awareness Training' was held for all monitors prior to the commencement of culling. The course aimed to provide monitors with the necessary knowledge and skills of best practice guidance compliant firearm/ammunition combinations, firearm handling and safe use and firearm application with regard to the cull, to enable them to assess contractor performance and safety in the field. Practical firearm demonstrations were conducted in the field,

with all monitors undertaking a marksmanship test. All monitors participated in simulated compliance/humaneness monitoring assessments at night to better prepare them for licensed activities.

A similar course had been held prior to the 2013 cull. All monitors who attended this course also attended the 2014 course.

Auditor's comment
In the main the subject matter covered in this course was out of the scope of this audit. However it was described in detail by the responsible person and the auditor was satisfied with the explanations.

It had been foreseen that a full end to end field rehearsal of all protocols by the combined teams would take place prior to the cull. This did not take place because of time constraints before the culls started. However, all the separate components of the monitoring were thoroughly tested.

Auditor's recommendation 3 (Training)
Full end to end field rehearsals or exercises should take place before any future work and cover all areas of the project. These would help assess the relevance of the processes in place, revise the procedures and familiarise the team with all the stages of the processes.

8.4 Documentation

8.4.1 Overview

At the start of the auditor's involvement a number of documents existed or were in the process of being developed. These included:

Best practice guides on:

- Controlled shooting of badgers in the field under license to prevent the spread of bovine TB in cattle
- Cage-trapping and dispatch of badgers under license to prevent the spread of bovine TB in cattle
- Firearms injuries

Guidance and other documents

- 3 step guide to submitting monitoring forms
- Timescales flow chart for monitors

SOPs:

- Humaneness Monitoring (HM) of badger control by controlled shooting
- In Field Assessment (IFA) of badger control by controlled shooting
- Post-Mortem (PM) request form (and other follow-ups).

In addition to the above documents notebooks were kept by the monitors for use during their observation of contractors. The use of such notebooks was inconsistent - with some monitors taking notes and others not and some monitors destroying their notes after use, because they held sensitive information about contractors names and contact details.

Auditor's comment
Consistency both within and between teams can only happen if all processes are written down and are in place at the start of the process.

Auditor's recommendation 4 (documentation)
The auditor's view is that the relevant information held in monitor's notebooks about observations and monitoring represents source data and as such should be kept.

8.4.2 SOPs

With regard to the scope of the SOPs in place - the auditor recommended that a data management SOP should be created. It is still the intention to put this in place retrospectively.

Auditor's comments
The auditor was provided with the humaneness monitoring SOP and made the following comments:

- It should be (as with all SOPs) numbered, dated and version controlled
- It should define all abbreviations
- It should state who has responsibility for it i.e. the author and approver. This could be done by describing their function, if the printing of actual names needs to be avoided
- It should cross reference any other relevant SOPs e.g. the IFA SOP
- It should include the forms on which the data is recorded as part of the SOP e.g. as an annex
- It should describe exactly how contractors are randomly selected for a humaneness visit

A new version of the HM SOP was subsequently created which took into account some of these comments.

Auditor's recommendation 5 (Documentation)
All project documents need to be numbered, dated and version controlled

8.4.3 Case Report Forms

1. Humaneness monitoring

The auditor reviewed the humaneness monitoring form prior to the start of culling and made the following recommendation and observation:

- The forms should be version controlled
- Pre-setting fields to 0 – She questioned whether there was not a danger that you will not know if a value of 0 is genuine or the pre-set value

Auditor's comments
The above recommendation was implemented

2. In-Field Assessment

The IFA form was in the main a "tick-box" form and recorded details on: Preliminary checks (ammunition used etc.), Site/target selection, shooting and selection, reporting, biosecurity and firearms.

3. Post-mortem (PM) request form and other follow-up

After initially reviewing the processes in place and noticing that the HM form referred to FU activities, the auditor recommended that the above form (in conjunction with an SOP) was put in place and this was done. However, the auditor noted that the final version date was incorrect.

Her recommendation is that the design of the *PM* request form needs to be re-visited (see recommendation 7), so that an audit trail of FU events can be more easily followed, this could be achieved by sequentially numbering the events for a given contractor. It also needs to be made clearer where a separate series of events finishes and a new one starts.

Auditor's recommendation 6 (Documentation)
All revised SOPs and forms need to be created and in place prior to next year's training exercise.

8.5 Communication

Every day from Monday to Friday at midday there was a teleconference between the managers and the monitors to catch up on - how the previous night had gone, who had been observed, the issues encountered and the plan for that night. The auditor attended one of these teleconferences and thought the lines of communication were clear and effective.

In addition, every week, the managers visited the team's temporary offices in Gloucester and Somerset.

8.6 In-Field Assessment (IFA)

IFAs were carried out for the purpose of assessing contractors' compliance with licence conditions and the best practice guidance. During IFAs, where shooting events were observed, the observation contributed to humaneness monitoring.

This role was suggested by the IEP "*Natural England, as the Licensing Authority, must have robust systems in place to monitor Contractor performance, identify inefficient individuals quickly and remove them from the cull*".

The IFA SOP sets out that a random selection of 20% of contractors will be selected for an IFA[3]. Contractors who have successfully completed a Field-Based simulation (FBS) will not be routinely selected for an IFA (unless it is through the FU process). A FBS consisted of a field craft element and a shooting test and the SOP set out that 30% of contractors should attend a FBS[4].

The following areas were checked during the IFA:

- An assessment of firearm and ammunition suitability, presence of a buddy, use of appropriate equipment and contractor knowledge of the area
- An assessment of bait point positioning, proximity of buddy to contractor, shot selection with regards to distances from setts and dense cover, use of field craft, and ability to locate and identify target species
- An assessment of shot placement, follow-up and humaneness of despatch, and checks for confirmation of death
- Carcase handling and bagging
- Records management
- Firearm safety includes an assessment of contractor handling, safety and efficiency with a firearm

[3] 28% of contractors were selected for IFA
[4] 54% of contractors attended a FBS in Gloucester and 41% in Somerset

- Biosecurity

Audit findings

21 IFA's were carried out in total, all these also had a HM form completed. All IFA forms were reviewed by the auditor for their completeness and to assess if there was a corresponding HM form and this was the case.

Only the dates, times and participants from the IFA form are entered onto the spreadsheet. All the data that did exist in the spreadsheet matched the data on the forms.

8.7 Humaneness monitoring (HM)

8.7.1 Overview

Humaneness monitoring takes into account the recommendations of the IEP and the Chief Veterinary Officer's (CVO) requirements. The IEP suggested that:

"Steps should be taken to reduce the number of badgers that may take more than 5 minutes to die after being shot at. This means improving the accuracy of shooting, so as to avoid non-lethal wounding and misses, and minimizing the number of badgers that are able to take refuse in cover or in a sett after being wounded".

It was decided that a similar number of field observations of shooting events should be monitored as in 2013 (60) and towards these ends NE planned over 180 field visits (across both areas) during the 6 week period. The IEP recommendation was at least 60 shootings should be observed in the field by independent monitors.

Audit findings

The recommendation of the IEP was met with regard to the number of shootings observed. 63 shootings events were observed in total (24 in Gloucester and 39 in Somerset).

Below is a detailed breakdown:

- 69 shots were recorded taken at 63 badgers
- Six badgers were not retrieved when a single shot was fired at them
- 52 badgers were dispatched with a single shot
- Four badgers were dispatched with two shots
- One badger was dispatched with three shots

8.7.2 The role of Monitors

HM was undertaken by NE appointed monitors. The auditor reviewed the data to ascertain their activity.

Monitor	Number of observations	Number of observations where a dispatch took place
M05	26	7
M14	21	4
M09	20	3
M15	16	3
M06	12	3
M11	5	0
M01	3	1
M02	1	0
Totals	**104**	**21**

Table 1 Number of observations performed by monitors in Gloucester[5]

Monitor	Number of observations	Number of observations where a dispatch took place
M10	26	18
M08	15	5
M07	14	2
M03	13	3
M13	8	1
M02	5	4
M01	5	3
Totals	**86**	**36**

Table 2 Number of observations performed by monitors in Somerset

As the above tables show the activity of monitors was skewed. In total there were 13 monitors, however 4 of them made 49% of the observations. One monitor never witnessed a dispatch.

Auditor's comment

Ideally the effort would have been apportioned better to avoid the potential bias of a few monitors contributing the majority of the data. Although the practicalities of achieving this may be difficult, the team should bear this in mind when planning for future years.

Tables 3 and 4 show the number of times individual contractors were observed. For example in Somerset one contractor was observed 8 times.

[5] For all tables where an IFA and a HM were conducted at the same visit (21) – they are treated as one observation

Number of times observed	No of contractors	No. of observations
7	1	7
6	1	6
5	1	5
4	4	16
3	15	45
2	7	14
1	11	11
Totals	**40**	**104**

Table 3 The number of times contractors were observed in Gloucester

Number of times observed	No of contractors	No. of observations
8	1	8
7	1	7
6	3	18
5	4	20
4	4	16
3	2	6
2	1	2
1	9	9
Total	**25**	**86**

Table 4 The number of times contractors were observed in Somerset

The large range in the number of times contractors were observed was to some extent a reflection of the activity of the contractor.

Audit findings

At an early stage of the cull, the auditor reviewed a random sample of 27 humaneness monitoring forms that had been completed and checked the data against that recorded in the spreadsheets. A small number of data discrepancies were found which were dealt with at once.

Having undertaken the above checks and reviewed the process by which the monitoring data was entered a number of quality control measures were recommended and discussed with the relevant staff.

- Prior to entering the data on the spreadsheet from the humaneness form, data should be cross referenced with the NFU data to ensure that there were no discrepancies. Any potential discrepancies should be queried prior to entering the data.
- A QC check should be implemented to ensure that the spreadsheet reflects what is captured on the humaneness form. The results of these QC measures should be documented. A column should be added to the spreadsheet which shows whether the QC check has been completed.
- All quality control measures in place should be described in writing.

The team put in place a process to implement the QC checks on all the data.

Audit findings
At completion of culling the auditor carried out a further 10% check for both of the culling areas, comparing the HM form with the spreadsheet data (in total 22 forms) and no errors were found.

In addition, at the completion of culling the auditor carried a series of checks with respect to the internal consistency of the monitoring data:

- Was the number of badgers dispatched always less than or equal to the number seen?
- Was the number of badgers dispatched always less than or equal to the shots fired?

No errors were found.

8.8 Contractor Follow-Up (FU)

The auditor identified the follow-up of events to be a vital process and as such recommended that all decisions made and the justification for a type of FU (even in informal talks when consulting management) should be documented throughout the process. In addition documentation should be created that explained how FU activities were initiated as well as their outcome.

8.8.1 The FU process

Figure 2 gives an overview of the FU process. A FU may be triggered in a number of ways:

Requests for FU to be undertaken by APHA *PM* facility

1. A request (by NE) for the PME of a particular carcase, following concerns raised by an observer.

   Note – All carcases retrieved from shooting events were subject to PME. If an IFA had occurred and no events were observed there would be a request for a PME on the next carcase dispatched by the contractor.

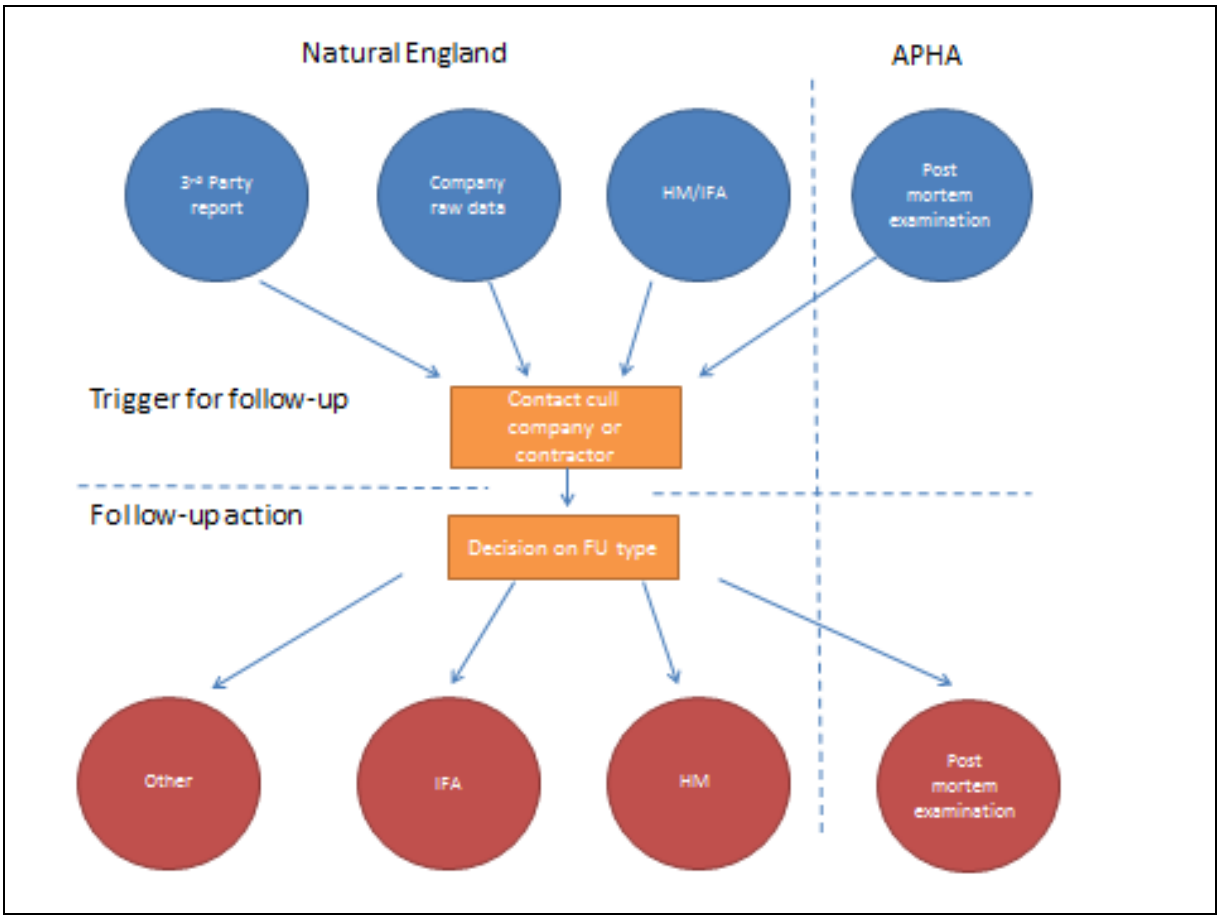

Figure 2 Overview of the follow-up process

Requests for FU to be undertaken by NE

2. A request (by NE) following concerns raised by an observer related to the dispatch of an animal during humaneness monitoring.
3. A request (by NE) following concerns raised by an observer during an IFA
4. A request (by APHA *PM* facility) for follow-up following concerns raised by the PME
5. A FU triggered by the company raw data. This is where a contractor records more than one shot (with no observer present)
6. A third party request[6]

As shown in figure 2, the initial FU took the form of a conversation with the contractor or cull company. If the monitor was content with the explanations given,

[6] An example of a third party request would be when a member of the public raised an issue. In fact no such FUs were received

no further action was taken. If further action was deemed to be required it resulted in: an IFA, a HM visit, a request for PM or "other"[7]. After the initial FU, further actions may result e.g. advice or warning letters to the company, further visits or the contractor's temporary or permanent suspension from the list of approved contractors.

Auditor's comment
The FU SOP gives a series of options for follow-up with accompanying codes. On the forms examined by the auditor these codes had not been used.

Audit findings
At various stages throughout the project, the auditor checked the FU process for all scenarios i.e. requests to APHA from NE and requests to NE (both internally and from APHA) and those triggered by company raw data. The check consisted of firstly checking that all requests for FU had been followed-up and appropriately actioned, secondly that the accompanying documentation was sufficiently clear and thirdly checking that all cases were satisfactory closed.

APHA PM Facility to NE
This was followed up twice during the study and once at the end. In total the APHA PM facility recommended to NE to follow-up 42 events. All requests had been or were actioned.

NE to APHA PM Facility (triggered by monitoring or other)
All NE requests for PM examination had been followed up where possible e.g. there may not have been a further carcase from the contractor to PM.

NE requests for non PM FU
The auditor checked that all occurrences of FU triggered by HM or IFA were actioned and this was the case.

FU triggered by company raw data
The auditor checked that all occurrences of a contractor using more than one shot to dispatch a badger had triggered a FU – this was the case.

At her interim visit, although all FUs had been actioned, four forms had not been returned and closed within the 3 working days set out in the document "time scales flowchart for monitors". In fact at the end of the culling it was not possible to ascertain how many FU forms were returned within 3 working days, because the date of return is not captured.

At the end of culling all FU forms were returned, closed and issues resolved.

[7] The most common form of "other" was – no further action required

Auditor's recommendation 7 (Data handling)
At present reconciling the FU data is a complicated and time consuming process. The process should be reviewed including the form design and the way the data is stored. Data management needs to be involved in this process from the start. The objective should be both to clarify the process and to store the data in such a way that an audit trail of events for a given contractor clearly exists and can easily be re-created. Specifically, the date the form is returned and who has entered and corrected data needs to be recorded.

The breakdown of FU activities is shown in tables 5 and 6.

Trigger for FU		Resultant FU taken	
Random PM	23[8]	Other	11
		IFA	2
		Request PM	3
		HM 7	7
Company raw data	8	Other	7
		HM	1
HM	3	Other	2
		Request PM	1
Totals	**34**		**34**

Table 5 Breakdown of FU activities - Gloucester

Trigger for FU		Resultant FU taken	
Random PM	9	Other	5
		HM 7	4
Company raw data	5	Other	4
		HM	1
HM	3	Other	1
		Request PM	1
		HM	1
Totals	**17**		**17**

Table 6 Breakdown of FU activities - Somerset

Auditor's comment
Whilst auditing the FU data a number of occurrences came to light where contractor teams used the wrong tag with a carcase. Often, listed contractors operated as a team, with one acting as a buddy rather than the marksman. In these circumstances, and allowing for the

[8] The total of FU triggered by Random PM from tables 5 and 6 is 32. In fact following *PM*, 42 requests were made. However, 10 of these had already been triggered by company raw data or HM prior to *PM*

fact that contractors worked in the dark and were keen to recover a carcase after a shot may have attracted the attention of protestors, the buddy's tag may occasionally have been placed in the bag with the carcase instead of the tag ID of the contractor who made the shot. This means that the dispatcher's ID was incorrectly recorded against the other contractor who acted as the buddy. Seven such occurrences came to light; these were all followed up and resolved at a later stage, with all organisations correcting their data accordingly.

This issue highlights how, in a multi-site study, data errors in one area, will impact on all other areas. It once again emphasizes the importance of good communication between all parties throughout the study to identify and resolve such issues in a timely way.

8.9 Data Management

8.9.1 Overview

All of NE's data was held in spreadsheets, rather than in a project database, with separate sheets recording the monitoring returns and FU events. Recording data in this manner meant that quality control was more difficult to achieve and took longer than if a database solution was in place. This was particularly true for the FU process (8.9.2)

As mentioned under 9.4.2 the auditor would recommend that a data management SOP is created. Amongst other things the SOP would describe the process of data entry and specify the QC checks that were carried out.

Without such an SOP in place it would be extremely difficult for anybody unfamiliar with the process to step-in if required.

8.9.2 Data Management of FU process

Because the data is held in a series of spreadsheets it is not easy to quickly gain an "overall view" of the entire sequence of events related to one contractor. For example ideally one would be able to select the event that triggered a FU and see all FU actions that resulted. A project database would allow this, but at present it can only be achieved by searching through a series of spreadsheets. Because the number of FU events is relatively small this is not a critical issue. However, as stated in recommendation 8 the creation of a database (rather than a series of spreadsheets) for data recording purposes needs to be considered for future work.

9. Daily and weekly reporting by APHA

9.1 Overview

The role of the team was to produce a series of daily and weekly reports for Defra using the contractor's daily returns data supplied by the NFU.

The daily reports gave information, for each of the two areas on: controlled shooting (the numbers of badgers dispatched, numbers of badgers seen etc.), cage trapping (the number of traps set and the number of badgers trapped and dispatched) and the surveillance effort (the total time spent and the numbers of badgers seen). The reports also included the cumulative totals up to that date.

The reports were run twice daily. The morning reports included the latest daily data (data that had not been quality assured by the NFU). The reports were subsequently run later in the day using quality assured data. The quality assurance (QA) process was undertaken by the NFU and as such is outside the scope of this report.

9.2 Interviews

On more than one occasion the auditor went through the document that described the procedure for producing the daily reports with the responsible person and followed the steps used to produce the daily summary which used the data sent by the NFU.

The back-up of the responsible person was also interviewed. The person was capable of producing the daily outputs, but should there have been a database issue he would not have had the necessary database skills and experience to address the problem. The auditor asked for a solution to be put in place and it was arranged that if a database problem arose APHA's data management group would be contacted.

Auditor's comment
Whilst there was an informal agreement for expert database management cover from the start this wasn't formalised until a fairly late stage. Had a problem arisen early in the process and only the back-up member of staff been available, it may not have been possible to produce the daily reports on time. Any back-up capability needs be able to cover the full range of tasks at short notice.

9.3 Documentation

With regard to the procedure in place the following summarises the recommendations she made:

- The document describing the process needed to be version controlled and to give details of the author, the date of the version and a list of roles and responsibilities
- The procedure to be followed if the data did not appeared in the mailbox at the given time needed to be added to the document.
- The document referred to “Deleting raw data”. This was unfortunate terminology (in so much it gave the impression that the source data was deleted) and in fact is not what happened (the raw data was still available). It needed to be re-worded
- The document referred to running QC checks. More detail needed to be given as to what these checks where. In addition, the auditor recommended that one further QC measure would be for one of the back-up staff to reproduce blindly (at a later time) the reports for a given day.
- The result of running each QC process needed to be documented e.g. who ran the QC checks and any exceptions recorded

The auditor subsequently followed up the above recommendations to the procedure. All her recommendations were implemented, specifically for the next version of the procedure:

- The document was version controlled
- The reference to the wording “deleting raw data” had been modified.
- The queries were described in more detail
- One of the reserve database users reproduced the afternoon and morning procedures on a copy of the database made specifically for this purpose
- A QC check was carried out at least once a week on each database.

Audit finding
On one occasion the auditor reproduced (from the raw data provided by the NFU) a number of the outputs by hand. No errors were found.
On two occasions the auditor requested the daily reports to be re-run to double-check they produced the same outputs as had been produced previously – this was the case.

9.3.1 Reconciliation with NFU data

The auditor asked what happened in the case of there being a discrepancy between the QA and the non QA data provided by the NFU. It was explained that such discrepancies were checked with the NFU and that the ultimate decisions regarding the validity of the data lay with them.

In fact full reports were provided by the NFU at regular intervals and/or as requested by the responsible person and this provided a further QA check to ensure data was consistent with the data held by the NFU. In the event of any discrepancies, the NFU had the final decision on which data was correct.

9.3.2 Reconciliation with APHA PM data

Audit finding
At an interim review, the auditor cross referenced the total number of culled badgers from the daily report with the number held locally at the APHA PM facility. There was a discrepancy of four (two from Gloucester and two from Somerset) – all of which could all be explained and were subsequently resolved.

The correspondence between the data sets was good because there was a weekly reconciliation of data between APHA and the NFU – this was good practice and the auditor welcomed the fact this was undertaken on an ongoing basis rather than waiting for the end of the project.

9.4 Communication

The responsible person was in daily contact with all parties involved in the daily reporting cycle (both the NFU from whom the data was received and the Defra and APHA team to which the outputs were delivered). She was also in contact with NE and the APHA *PM* facility regarding the reconciliation of data. Any potential queries were actively followed-up.

9.5 Data Management

9.5.1 Overview

An Access database was created that contained all the data and queries required to produce the daily and weekly summaries. The Excel spreadsheets that the NFU provided every morning detailing the daily returns were read into the database and Access tables created. The process followed to import the NFU data was well documented in the procedure described in 9.3.

Because the data was in a database format a large number of quality and cross comparison checks could be carried out with relative ease (9.5.2).

9.5.2 QA checks

A number of quality and "sanity" checks were run on the raw data on a daily basis. Examples of these checks included running queries to check the following:

- Had more badgers been reported as culled than reported as seen
- That the number of Carcase IDs equalled the number culled
- A sanity check of the total number of traps set by each contractor

Any potential errors were discussed and resolved with the NFU who held the source data.

10. The role of APHA *post mortem* facility

10.1 Overview

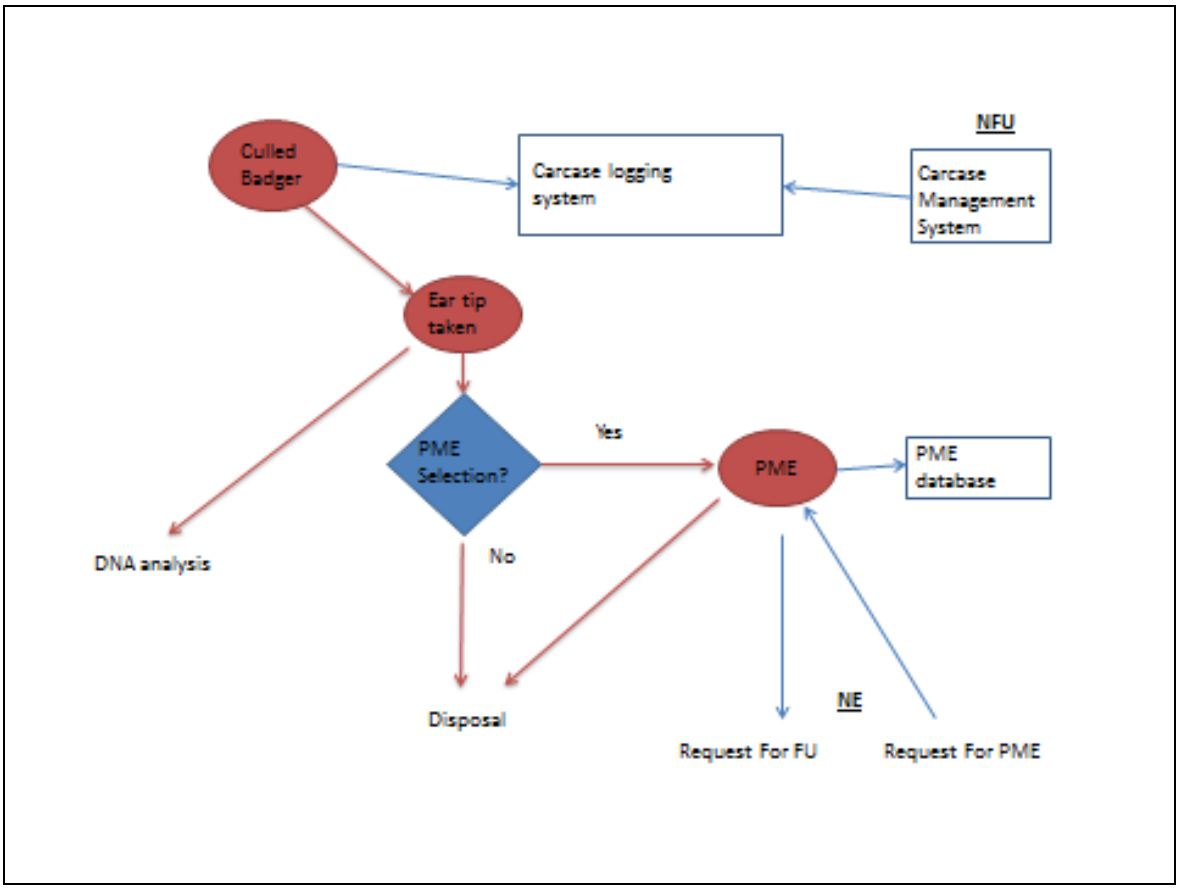

Figure 3 Overview of APHA PME process

Figure three details the flow of carcases and data into and out of the APHA *PM* facility.

Carcases arrived in bags with tags which could be scanned to give the contractor and carcase ID of the culled badger they contained. All arrivals were logged onto the local logging system (a spreadsheet system). Any discrepancies were actively followed-up with the NFU as well as any exceptions e.g. carcases without a tag.

When the carcase was moved to the *PM* facility an ear tip sample was taken and this was sent to the APHA laboratory for DNA analysis during the operation. If the carcase had not been selected for PME it went straight to the disposal area. PME

selection resulted from the local process of selection or from FU requests received from NE for a particular carcase to undergo PME. If the carcase had been selected it either went straight for examination or for chilling – depending on the current operational workload at the *PM* facility. The results of the PME were entered onto the PME database (a web-based system). After PME the carcase went for disposal. If the PME gave cause for concern e.g. shots had not hit the target area – a request for a FU was sent to NE.

The facility used and many of the staff involved were the same as in the previous year. However, the process followed was not the same. The major changes were:

- All carcases arrived at the facility (not just those destined for PME as had been the case in 2013).
- All carcases had ear tips removed for DNA analysis (this had previously been performed in the field)
- The facility was responsible for the selection of carcases for PM. In the previous year they had been informed of what to examine by the AHVLA wildlife group
- No radiography was performed
- There were major changes to the PME process, forms and database

10.2 Interviews

Interviews took place with the various persons involved in the team and the folders of a person in each role were reviewed e.g. one veterinary, one administrative and one technician post. All those interviewed showed a professional approach to their work, they were knowledgeable, knew exactly what their role was and where they fitted into the team.

For each person interviewed the auditor reviewed their training record, which contained amongst other things: a description of the role, a job description, a check list of requirements, competence assessments (their exam completion), the training records and the competency records.

10.3 Training

The auditor did not attend the induction training programme which took place in July and was run over 2 days. It covered amongst others things: the security risks, the results of the previous year's cull, the PME procedure, data capture and the process flow. It was arranged in two parts with veterinarians and technicians attending what was relevant to their role. The veterinarians had to complete a post training questionnaire and the technicians had to answer a number of questions. These were all filed in each person's individual folder, as mentioned above. The auditor

recommended that the questionnaires should be dated and signed by the attendee and their manager.

The auditor attended the process rehearsal and the data management training session. The scenarios reviewed were - carcase reception and sorting, data entry and quality control on data entry. The day went very well and resulted in a number of action points, which were documented and given an "owner" to follow up. The actions included – requests for extra kit e.g. an extra wand for scanning the carcase labels, modifications to the SOP and modifications to the data entry forms

10.4 Documentation

10.4.1 SOPs

SOP Number	SOP title
1	Badger Carcase Receipt, Tracking and Dispatch
2	Ear tip sampling from badger carcases as part of the study to monitor the efficacy of the badger cull
5	Monitoring controlled shooting of badgers - Necropsy procedure for badger carcases submitted during the second year of the culls
8	Data Flow
9	Post mortem Unit Entry and Exit Procedure
10	Database Data Entry

Table 7 List of PME SOPs

Table 7 lists the SOPs that were in place prior to the commencement of the cull. The auditor reviewed the SOPs which are centrally filed and available to those requiring access. The SOPs are clear and concise, whilst still being detailed enough.

The gaps in the numbering of the SOPs is due to certain procedures e.g. radiography having been carried out in 2013, but not in 2014 and hence the SOP not being relevant to the 2014 study.

A number of initial recommendations were made:

- To add to SOP 1 clear instructions about how and where the source data for the weight is recorded. In particular to ensure that it is clear regarding the instructions that are given in terms of entering the weight on the necropsy form.
- To add to SOP 8 a description of what is being done in a situation when a badger had been selected for necropsy, but was put on hold for various

reasons (other priorities, unforeseen issues etc.) and eventually was not processed.
- To add (when NE requested a PM), that the reasons for the request are not spelled out (thus ensuring blindness)
- To add that the veterinarians in the PM room were blinded as to which contractor's badger they were autopsying

With regard to the last bullet point, for practical reasons (because the PM veterinarian needed to cross-check the identity of the carcase) they were not truly blinded as to the identity of the contractor and this statement was not added to the SOP. All other recommendations were taken on-board and new versions of the SOPs issued.

10.5 Communication

The communication within the team was excellent. Every morning and afternoon prior to any activities being undertaken there was a meeting to decide what was going to be done and review recent activities. In addition APHA senior management took an active part in ensuring the project ran smoothly and were present on site throughout the project. The auditor attended two of these meetings.

10.6 Receipt tracking and dispatch of badger carcases

The receipt process was followed and the auditor was satisfied that it was done according to the corresponding SOP (Badger Carcase Receipt, Tracking and Dispatch). In total 615 carcases were received and logged onto the tracking system.

Carcases consignments were inspected to ensure there was no damage to them e.g. broken tags. In the sorting room the carcases were scanned and the details entered into the local carcase management system, labels were printed, the carcases were weighed and the weight recorded. Once all tasks were completed the administrative team was notified and carcase selection carried out. Prior to entry into the PM room a final scan was carried out to cross check the contractor ID and carcase Electronic ID (EID) displayed on the NFU software against the labels printed and allocated for each carcase.

10.7 Exceptions

Examples of "exceptions" included carcases arriving without a tag, the tag information not matching the NFU information, multiple tags in the bag and the cull type and/or cull date missing on the data supplied by the NFU.

For these exceptions the carcases were held until the discrepancy was clarified. All of the information was logged on a spreadsheet e.g. the issue, the action taken and by whom and the status of the exception.

On two occasions the auditor reviewed the entire list of exceptions. Following her first review she recommended that an adequate description should be made of the issue as well as how it had been resolved. For example the text for WS 00274 was "confirmation of ID by NFU" meaning one did not know how it was confirmed.

Audit finding
Her second review took place at the end of the cull and her recommendations had been implemented. Each of the 38 exception cases was reviewed from initial issue to its resolution. All exceptions were fully documented and had a resolved status. The auditor also checked in each badger ID folder whether the appropriate documentation (hard copies of emails etc.) was filed and this was the case for all exceptions.

10.8 Selection of carcases for Post Mortem Examination

The selection process was driven by the target of meeting the criteria of 60 *PM*s (for unique contractors) in each area, as well as meeting the NE requests for Follow-Up (FU) *PM*s.

As mentioned in 10.1 the APHA PM facility was responsible for the PM carcase selection process. This was a change over the previous year when they were sent a daily list of carcases requiring PME.

The site developed a local ranking spreadsheet which was used in conjunction with the local carcase management system to: select, record and ensure the appropriate carcases were necropsied.

In fact the selection process in 2014 changed during the cull – this followed a request from Defra. The auditor recommended that the change to the process be documented and this was done. The requested changes are set out below:

- 09/09/14 – APHA operational target was originally 60 rifle controlled shot carcases per area to be necropsied, at least one necropsy per contractor, also including carcases/contractors requested via NE pro-forma to be necropsied. Defra also requested APHA to select cage trapped carcases to be necropsied on an ad hoc basis.

- 11/09/14 –Defra agreed with the APHA PM team that there was scope to carry out more necropsied with the existing resource that had been scheduled, and that the opportunity should be taken to gather further data. From this point onwards all rifle controlled shot carcases submitted to Aston Down were to be necropsied.

- 19/09/14 – NE, with Defra agreement, requested that every rifle controlled shot carcase from a contractor with a follow up on a previous necropsy be selected for necropsy. This request was for compliance monitoring purposes.
- 07/10/14 – Because a large number of necropsies had been carried out by this stage in the cull, Defra requested that only rifle controlled shot carcases from new contractors or requested by NE pro-forma be selected for necropsy.
- 13/10/14 – On NE's instructions, all carcases (cage trapped and rifle controlled shot) from three selected contractors to be selected for necropsy, for compliance monitoring purposes.

Auditor's comment

In principle, any changes made to a project that affect the sample selection once the project has commenced are not ideal and should be avoided if possible. However in this case, the methodology for the necropsies and data capture was not changed. The number of necropsies was increased for the purposes of gathering more data. Other changes were for the separate purpose of compliance monitoring. All changes need to be clearly documented and describe the rationale and outcome of the changes.

10.9 Post Mortem Examination

10.9.1 Overview

As mentioned earlier no radiography was performed prior to the necropsy. The aim of the assessment this year was to estimate the number of entry wounds (acute ante-mortem fire-arm induced skin wounds) and whether there was evidence of "major" fire arm induced injury in the thorax region. The assessment of the severity of the damage was only undertaken for thorax wounds. Entry and exit wounds were assessed as well as damage to thorax region.

A second veterinary opinion by the lead veterinarian was always sought when there was more than one acute ante-mortem entry wound. It was also sought if the answer could not be classified or was "uncertain".

In total, necropsies were performed on 234 carcases (112 from areas in Somerset and 122 from Gloucester). One *PM* on a carcase from Somerset could not be interpreted due to advanced autolysis.

10.9.2 The PM process

The auditor followed the necropsies in their entirety for two badgers (WS00131 and WS00124), as well as the assessment for another badger (WS00025). The work

was carried out in a thoroughly professional manner and in accordance with the corresponding SOP (SOP 6).

Badgers were only disposed of following necropsy once the QC person gave their consent and the correct identity of the badger was checked throughout the process.

10.9.3 Quality control measures in place

At all stages of the process, QC measures were in place. Specifically they were implemented in the following areas:

- The PM room by the appointed QC person
- Following data entry onto the necropsy form, by the
    - Responsible officer
    - Lead Veterinarian
    - Administrative staff

10.10 Ear tip sample removal for analysis

The ear tip sampling was also followed and was undertaken according to the corresponding SOP (SOP 2). The fact the ear tip had been removed was logged in the local carcase management system (10.11.3).

10.11 Data Management

10.11.1 Overview

APHA have a dedicated data management group who had been involved in the 2013 activities developing the PME database. Because APHA in 2014 received all carcases (rather than just those sent for PME) a new system had to be put in place to deal with the receipt of all badgers - the tracking log (10.11.3).

10.11.2 Interviews

The group explained their role which involved the redevelopment of the 2013 PME database to take into account the changes made and the development of a new tracking system to handle the receipt of all carcases.

The group made two main points. Firstly, it would have been ideal if there had been one integrated system that dealt with all aspects of the project. For example it would have been ideal if the wand system had been able to initially populate the

APHA system. However, this was not possible because they had no access to the NFU IT system prior to the start of the cull. The second point was that there was insufficient lead-in time to the project which had meant that the tracking log solution had to be a spreadsheet based one; there was insufficient time to develop a database solution.

10.11.3 Development of tracking log

As mention in 10.1 all carcases came to the APHA PM facility, which was a change from the previous year. The carcase management system was a spreadsheet based tool developed to record – the fate of each carcase, to perform QC and to keep a log with dates of all events happening to a carcase. Specifically it recorded: the carcase ID, contractor, cull type, cull date, NE request for necropsy, receipt and fate of all carcases e.g. whether they went for immediate disposal or for PME. It also recorded the carcase weight and allowed labels to be printed that were used on various data capture sheets.

The auditor reviewed the system with the responsible person and made a number of initial recommendations with respect to the system:

- A column for “exception” should be added, so that at a quick glance one would know if the exception was being addressed.
- The admin staff should be able to record the questions they may have when entering the data, as well as the answers being given. This could then be used to ensure a consistency of approach over time and across members of the team, thus avoiding bias.

These comments were taken into account and the carcase management system was updated accordingly.

10.11.4 PME Database

The web-based PME database was re-developed to reflect the changes made since 2013. The auditor believes that the development of a proper database solution for the recording of the results of the PME has been one of the major factors contributing to the high quality of the PME data in both 2013 and 2014. In particular it allows initial validation and post data entry cross-comparisons to take place see (10.11.5).

Although the PME data has been simplified since the previous year, the final specification was not reached until several potential iterations had been run through. These iterations are version controlled, both as data capture forms and as database solutions.

10.11.5 Data quality

The auditor followed data entry and the update of the APHA CMS (the tracking of what happens for each badger) including the exception log.

Audit findings

The one to one correspondence between the PM forms and the database was checked, initially for a small sample and at the end of the cull for a 10 % sample for each of the two culling areas. Twenty two forms were checked for the correspondence between the form and database. No data entry errors were found and thus the sample size was not increased.

After data entry had been completed, the lead Veterinarian in conjunction with data management ran a series of "20 logical and veterinary sanity checks" on the data. An example of these checks was "No evidence of acute ante-mortem firearm injury in the lungs (Q 4a), but evidence of pulmonary emphysema due to acute ante-mortem firearm injury (Q4b)". No inconsistencies were identified.

In addition the auditor also identified and ran (in conjunction with data management) a number of cross consistency checks. These are detailed below:

1. The IDs of the 5 lowest and highest weights were extracted

   The database values were checked against the source paper records – no errors were found.

2. The IDs for All Animals with 0 or > 1 Entry Wounds (Q3)

   There were 12 animals. All of these animals should have generated a FU to NE and this was the case

3. All Animals where the field in "Evidence of acute ante-mortem firearm injury" (Q 4) is "yes", but there is no accompanying % given

   This generated no animals

4. The classification of the severity of the acute ante-mortem firearm induced tissue damage (Q5) was "Not Applicable"

   This generated 19 animals, which are a subset of those identified in 5. All these animals generated a FU to NE

5. All animals where Q5 was "not major"

   This generated 39 animals. All these animals had generated a FU to NE

Audit findings

In summary, no errors were found after running the cross consistency checks and all animals requiring FU had been actioned. The FU actions had been documented in both the APHA PM facility and NE.

Auditor's comment

The ease with which the above cross-consistency checks (both the internally and externally generated ones) could be run again emphasises the importance of (where possible) recording data in a relational database – rather than in a series of spreadsheets.
The minimal number of inconsistencies identified by these checks confirms the high quality of the PME data. The auditor re-iterates her 2013 recommendation

Auditor's Recommendation 8 (Data management)

Serious consideration should be given to the development of a database at the start of any new work. Excel sheets should be kept to a minimum.

11. The role of the sequencing laboratory, APHA

11.1 Overview

In 2013, the DNA analysis of badger hair taken before the cull and of ear tips taken after the cull were both performed by the AHVLA (former FERA) wildlife group. In 2014, DNA analysis was restricted to a post-cull ear tip analysis, which was undertaken by laboratory staff at APHA.

The fact that profiling was restricted to ear tip samples in 2014 meant that the standard of the DNA samples was substantially higher, resulting in very few samples needing to be retested.

At the time of the audit the analysis of the DNA data had neither commenced nor been specified and therefore does not form part of this audit.

11.2 Documentation

11.2.1 SOPs

SOP Number	SOP title
SOP AD 231	Receipt, storage, retention & disposal for CSU PrP genotyping and microsatellite Identification test
SOP MB.002	Quiagen DNeasy® Blood and Tissue Extraction Kit for the Extraction of DNA from Animal Material (Tissue and Blood)
SOP MB. 039	Badger Microsatellite Identification Test
SOP MB.028	CSU ABI Genetic Analyser, Operation, use and maintenance

Table 8 List of sequencing laboratory SOPs

The SOPs were handed over to the auditor as well as worksheets and risk assessments.

SOP MB 039 was written specifically for this project and is an amended version of the one created for the 2013 work. It details the Badger Microsatellite Identification (BMI) test, which is used to generate a genotype for badgers.

The majority of SOPs were not written specifically for badger samples, but where relevant, were adapted to include references to ear tip handling.

The auditor received the SOPs prior to the commencement of work and made the following comments with regard to SOP MB 039:

- It should include a clear description of the QC procedure for the 1% of samples that are being checked (retested) and in particular it should describe how the decision on what to retest was calculated.
- It should include a flow chart describing the test process.

Both these suggestions were taken into account and a new version of the SOP was issued with a separate flow chart.

11.3 Receipt of ear tip samples

The laboratory received: the sample ear tips, a sampling logbook which contained the dates of sampling and preprinted labels with the badger IDs.

Initially the receipt of ear tips from the PME facility had not been ideal because the only way of recording the carcase ID had been to transcribe it from the accompanying paper record. However, at a later date, the data management group were able to provide a download of the IDs of culled badger from the tracking log which could be used as part of the logging of samples in the laboratory.

A cross-checking process was carried out between the sending and receiving laboratory throughout the cull and any discrepancies were resolved on an ongoing basis.

Audit findings
At the time of the last audit of the data, only one discrepancy had been found. This was where a sample was received in a bottle with no accompanying label. All other expected ear tips had been received.

11.4 Microsatellite Identification test

In the lab the auditor followed all the stages of the process. The sample preparation for the genetic analysis was followed from the time of cutting the ear tip, to the DNA extraction, PCR set up, performing the PCR and preparing the PCR products for loading on the capillary DNA sequencer.

One comment was made and that was that data on printed worksheets should remain legible at all times e.g. If a correction needed to be made, a horizontal line should be put through the data to be corrected and the correction should be initialled and dated.

Auditor's comments
The auditor was very satisfied with the whole process. Each step followed the procedures, was quality controlled and appropriately documented.

At her initial visit, the worksheet describing the plate position for extraction and all the equipment and material used for the extraction, had only one box for the initials of the person checking the sample order and tube labeling. As these are two processes and could be carried out by two different people, the auditor recommended that the box was split into two - one for the check of the sample order and the other for the check of the sample tube labelling. The form was subsequently amended to reflect this.

11.4.1 Retest procedure

Whilst reviewing the retested samples, the procedure was described to the auditor. Retesting was used where profile values were lower than had been seen with other samples. For these occurrences the PCR was repeated. Where the values were too high this was overcome by diluting the DNA samples.

Audit finding
All retest outcomes were consistent with the original profiles. In instances where the DNA was re-extracted and the PCR re-performed again the same profile was found.

11.5 Data Management

As mentioned in 11.3 the data management group provided a download of the IDs of culled badger from the tracking log, meaning that sample IDs could be entered onto the local system via a drop down menu, rather than transcribed from the sample label. This undoubtedly led to the very good correspondence between samples sent and received.

At present everyone who uses the Central Sequencing Unit (CSU) system uses the same login and password. This means that although the system keeps an audit trail of changes, it is not possible to identify who actually modified data.

Auditor's recommendation 9 (Data management)
Access privileges need to be documented for the CSU. These should record who has and grants access. In addition unique user logins should be used to ensure a full audit trail is created

11.6 Review of Data quality

Audit finding
Together with the responsible person the auditor reviewed the results of the allele summary for October 31, 2104. Every result for each badger is either ticked (indicating it is of sufficient quality) or commented upon e.g. DT1 or DT 2 to be repeated. In addition the auditor checked together with the responsible person the results for the internal QC checks for 11 ear tip samples. She was satisfied that the internal QC did not raise any issues and that the retested data matched the original data and hence there was no need to trigger a repeat testing of the original batch or to increase the internal QC sample size.

11.6.1 Review of final data

A final review of the DNA data was carried out when all laboratory work had been completed. All 29 re-tested samples were reviewed and had been performed to the method that had been explained to the auditor in section (11.4.1). There were no outstanding actions and every sample received (615) had been processed and had generated a DNA profile.

All hard copies of the DNA microsatellite profiles had been QC'ed, signed and checked against the electronic data by the responsible person.

Auditor's recommendation 10 (General)
The CSU should keep a visitor log

12. Overall co-ordination

The overall day-to-day co-ordination of the project is an area where the auditor feels the project could be strengthened. As figure 1 shows there is considerable interaction both within and between NE and APHA and this needs careful and proactive management.

Auditor's comment

The project suffered from "compartmentalisation", with too many of the activities being treated in isolation. In some areas communication and co-ordination was good e.g. between the NFU and APHA, but in other areas e.g. between NE and the APHA PM facility it needed strengthening. An example of this was the liaison to produce the final figures for FU activities.

Auditor's recommendation 11 (Communication and co-ordination)

For future years the interaction between all parties needs to be strengthened from the planning stage to the completion of the project.

The auditor's 2013 recommendation regarding the appointment of an overall PI had not been implemented. The auditor notes that all units in APHA, NE, and NFU involved in the monitoring and data capture (apart from the DNA sequencing team) reported to the Chief of Staff or Deputy Chief of Staff in the Defra Operations Centre by telephone conference every weekday morning during the 6 week culls and there was an on-duty system for out of office hours to manage urgent exceptions. Each unit reported progress and issues, which were subsequently resolved by the responsible team leaders. The changes to the carcase selection process for necropsy were agreed through this established process. The auditor is satisfied that there was sufficient oversight by Defra during the 2014 cull, but remains of the view that it is best practice to appoint a PI whose role is to oversee every detail of the design and implementation of the monitoring SOPs, protocols and data capture systems in the lead-up to and during the culls. The auditor realises that the practical implementation of such a person for an inter-agency project is not easy, but would again re-iterate her 2013 recommendation.

Auditor's recommendation 12 (Communication and co-ordination)

Although there was overall coordination for the project as a whole, it would have benefited from a Principal Investigator i.e. a lead scientist who had an overview of all the work as well as day-to-day control over all its aspects.

The project would also have benefited from an overall project protocol that referred to the work of both organisations and its co-ordination. In particular the document should clearly set out the aims and objectives of the project and the outcome measures. Such objectives did exist e.g. to monitor as many contractors as

possible, to observe 60 shooting events and to carry out PMEs on at least 60 carcases per cull area.

Auditor's recommendation 13 (Documentation)
For future work an overall project protocol needs to be in place

13. Post Project Activities

13.1 Database lock

At the time of the audit report, neither database lock nor the archiving of the source data had yet been implemented.

Auditor's recommendation 14 (Data archiving)
Once all QC checks and reconciliation has been performed, all data needs to be locked to prevent future changes and the data archived on a secure server.

13.2 Archiving of source Data

Auditor's recommendation 15 (Data archiving)
Source data (paper records) need to be catalogued and securely archived.

14. Summary of Recommendations

14.1.1 General

Auditor's recommendation 1
Future audit appointments need to give sufficient time for the auditor to be involved in the planning stage of the project, so that time exists for comments to be taken into account before documents go live or training commences.

Auditor's recommendation 10
The CSU should keep a visitor log.

14.1.2 Training

Auditor's recommendation 2
Future training needs to include a trainee assessment.

Auditor's recommendation 3
Full end to end field rehearsals or exercises should take place before any future work and cover all areas of the project. These would help assess the relevance of the processes in place, revise the procedures and familiarise the team with all the stages of the processes.

14.1.3 Documentation

Auditor's recommendation 4
The auditor's view is that the relevant information held in monitor's notebooks about observations and monitoring represents source data and as such should be kept.

Auditor's recommendation 5
All project documents need to be numbered, dated and version controlled.

Auditor's recommendation 6
All revised SOPs and forms need to be created and in place prior to next year's training exercise.

Auditor's recommendation 13
For future work an overall project protocol needs to be in place.

14.1.4 Data handling

Auditor's recommendation 7

At present reconciling the FU data is a complicated and time consuming process. The process should be reviewed including the form design and the way the data is stored. Data management needs to be involved in this process from the start. The objective should be both to clarify the process and to store the data in such a way that an audit trail of events for a given contractor clearly exists and can easily be re-created. Specifically, the date the form is returned and who has entered and corrected data needs to be recorded.

14.1.5 Data management

Auditor's recommendation 8
Serious consideration should be given to the development of a database at the start of any new work. Excel sheets should be kept to a minimum.

Auditor's recommendation 9
Access privileges need to be documented for the CSU. These should record who has and grants access. In addition unique user logins should be used to ensure a full audit trail is created.

14.1.6 Communication and co-ordination

Auditor's recommendation 11
For future years the interaction between all parties needs to be strengthened from the planning stage to the completion of the project.

Auditor's recommendation 12
Although there was overall coordination for the project as a whole, it would have benefited from a Principal Investigator i.e. a lead scientist who had an overview of all the work as well as day-to-day control over all its aspects.

14.1.7 Data archiving

Auditor's recommendation 14
Once all QC checks and reconciliation has been performed, all data needs to be locked to prevent future changes and the data archived on a secure server.

Auditor's recommendation 15
Source data (paper records) need to be catalogued and securely archived.

15. Acknowledgments

The auditor would like to thank all the members of the project teams in Defra, APHA and NE for their help, co-operation and assistance during the course of the audit.