Manual for Official Controls: Amendment 105 Chapter 4.1 Audit

Sections

1. Introduction	2
2. Legislation	11
3. FBO Responsibility	13
4. FSA Role	16
5. Risk Assessment	45
6. Annexes	56

1. Introduction

- 1.1 Definitions
- 1.2 Purpose of audits
- 1.3 Relationship between audit visits and OV attendance
- 1.4 Commencement of FBO audits following approval or periods of closure

1.1 Definitions

The following definitions apply for the purpose of this chapter.

1.1.1 OV presence

OVs are present in slaughterhouses and at the Smithfield Market to carry out inspection tasks every operational day.

Daily OV presence is not required for co-located cutting establishments and other establishments such as for standalone cutting plants and game handling establishments (GHE). However, co-located establishments operating at times coinciding with the slaughterhouse operational hours are under the supervision of the resident OV. Issues identified during the visits to the co-located cutting plant should be entered in the Chronos system and enforced under the standard enforcement principles. Deficiencies identified during these visits will be taken into account during the overall site audit.

Co-located establishments operating at times different from the slaughterhouse operational hours should be subjected to unannounced inspections (UAIs) same as stand-alone cutting plants. These establishments have already been included in the K2 system at the request of the FVC and a UAI visit request is automatically generated as if these were stand-alone cutting plants. If considered necessary, the inspector carrying out a UAI can also request the production of a UAI report for any co-located establishment to the K2 manager through the FVC.

1.1.2 Official visit

Official visits to any establishment (regardless of OV presence in slaughterhouses for carrying out inspection tasks), may be conducted for the purpose of carrying out a full audit, partial audit and/or a UAI.

1.1.3 Full audit

A full audit is an assessment of the FBO Food Safety Management Systems (FSMS). All listed approved FBO activities must be audited (within one day, or several days depending of complexity of the establishments considering several processes and operations).

1.1.4 Partial audit

Following a full audit, a partial audit will focus on specific themes identified as being non-compliant during the full audit.

Partial audits may be carried out on-site or remotely. See more details on remote audits in section 4.9.

1.1.5 Unannounced inspection

In addition to partial audits, and as part of the scheduled audit programme (see audit outcome and frequency of visits), UAI can take place to follow up specific issues identified during the audits or to verify continued compliance between audits.

1.2 Purpose of audits

1.2.1 Relevant premises

These audit arrangements apply to all meat establishments approved in England and Wales and under veterinary control.

These are:

- red meat / farmed game slaughterhouses
- poultry meat slaughterhouses
- cutting plants
- game establishments

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- minced meat, meat preparations and mechanically separated meat establishments co-located with slaughterhouses or cutting plants
- meat product plants and 'ready to eat' establishments co-located with slaughterhouses and cutting plants
- co-located cold stores

1.2.2 Risk assessment scheme

The audit risk assessment scheme applies the requirement of retained EU laws (REUL) 2019/627 Article 4 to determine the frequency of audit using the risk criteria set out in that Regulation:

- public health risks
- animal health risks (where appropriate)
- animal welfare risks (where appropriate)
- type of process carried out
- throughput
- FBOs past record of compliance with food law

Note: Risks associated with the throughput and type of process are not specifically listed in the AUD 9-3 but have been incorporated in the body of the audit report document.

1.2.3 Aim of audits

The aim of the FBO audit is to verify compliance with the legal requirements and to ensure adequate FBOs standards in relation to public health, animal health and welfare.

The audit sections in the audit report are based on the priorities set for the FSA that have been agreed between the FSA, Defra and industry stakeholders.

Audit findings should provide individual FBOs as well as the relevant competent authority (FSA and Local Authorities) with information on Non-Compliances (NCs) identified against regulatory requirements, and/or areas in need of correction or improvement. For the competent authority (CA), this may result in the review of the MOC or the development of new guidance, procedures and training.

1.2.4 'Effective' audit

An effective audit of FBOs obligations in respect of public health, animal health and welfare is defined as follows:

- complies with the requirements of REUL 2019/627 to determine the frequency of audit on the basis of risk
- applies appropriate standards in determining the level of assurance that can be given to the CA about the FBO management procedures and identification of risk
- accurately assesses the FBOs level of compliance with legal requirements and identifies necessary enforcement actions
- recognises the FBOs good practices and identifies opportunities for improvement
- communicates audit findings to the FBO and the CA
- is consistent in its approach

1.2.5 Compliance audit and systems based audit

An effective audit of FBO controls will require the use of both 'compliance audit' and 'systems based audit' techniques, which are described below:

Audit technique	Description	
	This is a review and examination of FBO records and activities to assess compliance with legislative requirements and the FBOs established policies and operational procedures.	
Compliance audit	Much of the audit work to support compliance assessment will take place in the operational environment. In establishments where there is frequent OV presence, this assessment work will be ongoing as part of the FSA team's normal duties between the production of audit reports.	
Systems based audit	The auditor should seek to establish that the FBOs controls are fit for purpose and that the FBO has effective systems and processes in place to implement them on a continuous basis. Weaknesses and strengths in the FBOs control system should be recorded. Much of the audit work to support the systems assessment is	
	likely to take place outside the operational environment.	

1.2.6 Publication of FBO's audit report

The Freedom of Information Act 2000 gave individuals a general right to information held by public authorities (subject to certain exemptions) and to have this information communicated to them. The Environmental Information Regulations 2004 also provides a right of public access to a range of environmental information held by public authorities.

Important note: <u>Audit reports</u> will be published for FSA approved meat establishments in England and Wales on the FSA website after the period for appeals has expired.

1.3 Relationship between audit visits and OV attendance

1.3.1 Overview

All audits of FSA approved establishments are to be carried out by Veterinary Auditors (VAs) or Audit Veterinary Leaders (AVLs), who are independent and separate from operations and routine inspection duties.

The audit frequency represents the **minimum** number of times in a period that a completed audit report will be produced by a VA / AVL. This approach applies to slaughterhouses with or without a co-located cutting plant, game handling establishments, standalone cutting plants and cold stores under FSA supervision (for example, Smithfield Market).

Note: for simplification, further references to VAs / AVLs will be referred to as auditors unless specifically stated as VA or AVL.

1.3.2 Premises with frequent OV presence

OVs who work in a slaughterhouse approved for co-located operations may enter the production areas of other operations regardless of the audit timetable. However, the OV should consider the reasons for entry and ensure that it is part of their official control role. Daily checks in co-located operations are not required and the frequency of inspections should be determined based on risk assessment and third country export requirements.

Reference: The Food Hygiene (Wales) Regulations 2006 (as amended), Regulation 14, 2 / The Food Safety and Hygiene (England) Regulations 2013 (as amended), Regulation 16, 2.

Co-located operations will be audited at the same time as the slaughterhouse, as part of the same process, with a single audit report being produced.

1.3.3 Premises with infrequent OV presence

Stand-alone cutting plants and any co-located operations will also be audited at the same time. In between audits or partial audits there may be UAIs.

1.4 Commencement of FBO audits following approval or periods of closure

1.4.1 Premises with specific requirements

The table below summarises the circumstances under which specific types of establishments operate under a different audit regime.

Establishment	Audit regime
All conditionally approved establishments (slaughterhouses, cutting plants and GHEs)	FBO audit by an auditor will not commence until full approval has been granted to the establishment following the FVL approval assessment(s). The OV / FVC may be requested to conduct monitoring and enforcement visits during the period of conditional approval; this will be at the specific request of the FVL.
	Where full approval has been granted, the first audit will take place in 3 months, from the date of full approval. The first UAI will take place during the first 3 months, from the date of full approval.
Existing premises: on change of FBO	A change of FBO marks the end of an existing establishment's approval. The new FBO is required to make an application for a new approval.
	FBO audit by auditors will not commence until full approval has been granted following the FVL approval assessment(s). If during an audit it is identified that the legal entity has changed and a new approval is required, the audit must be stopped and the approvals team informed. The OV / FVC may be requested to conduct monitoring and enforcement visits during the period of conditional approval; this will be at the specific request of the FVC / FVL respectively.

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Establishment	Audit regime	
	Where full approval has been granted, the first audit will take place in 3 months, from the date of full approval.	
Existing premises with full approval- on application to extend or vary activities	In these circumstances, the FBO audit should continue as already scheduled for the fully approved activity. The additional activity will only need to be audited once full approval for that activity has been granted and following the FVL's approval assessment. Any revision to the audit frequency, made necessary by the additional activity, will be established at the next regular scheduled audit after full approval is granted. For example: • where a fully approved slaughterhouse has applied for	
	additional approval as a cutting plant, audit of the slaughterhouse should continue as scheduled. The audit will include the cutting operations once full approval for that additional activity has been achieved.	
	 where a fully approved cutting plant has applied for additional approval to add minced meat operations, audit of the cutting plant should continue as scheduled, but the minced meat operations should not be included in the audit until full approval for that activity has been granted. Once the next scheduled audit takes place after full approval of the minced meat operation, all approved activities will be audited, and the future audit frequency will be set based on the risks posed by all approved activities. 	
Seasonal closure* and temporary or long-term closures	Following a period of closure, the FBO is required to notify FSA at least 2 weeks prior to re-commencing operations. The FBO must not re-commence operations until a pre-opening FSA visit has been conducted.	
	Note : Periods of closure are defined at paragraph 112 in the 'Operational policy for the approval of meat establishments undertaken by the FSA'.	
*Seasonal closures are pre- notified routine breaks in operation, to a seasonal pattern	Where the outcome of the pre-opening visit confirms that the establishment meets all legislative requirements, the next FBO audit should be completed no later than 2 months from operations re-commencing.	

Establishment	Audit regime
Premises under recommendation to suspend/withdraw approval	Audit activity is to be discontinued after a recommendation has been submitted by the FVL. Once the outcome has been decided, the audit cycle will be reinitiated with a full audit after 3 months. This audit will still take into account any minor non- compliance that remained open in the last audit, and that has not been part of the formal approval review.
	Note: The auditor would need to check with the FVL / AVL / Approvals team the relevant information from the review process as part of the audit preparation.

1.4.2 Pre-opening assessments

Following a period of closure (seasonal, temporary or longer term) the FBO must not start operations until the relevant FSA Head of Operational Delivery (HOD) has been notified in writing and a pre-opening assessment visit undertaken by the FVL / FVC. This visit is to assess that the establishment meets all structural and equipment requirements and other relevant requirements of food law, including the existence of a food safety management system based on HACCP principles.

The FBO's food safety management system must be available at the visit but as the establishment will not be operational, it will not be possible to assess how effectively this works in practice. The effectiveness of the FBO's food safety management system will therefore be assessed at the first scheduled audit visit undertaken by the auditor.

Reference: An aide-memoire (Annex 1) is available. This is intended to act as a reminder of the areas to address when assessing whether the establishment meets all relevant legislative requirements.

1.4.3 Action following pre-opening assessment

Following the pre-opening assessment visit, if FSA is content that the establishment meets all of the relevant requirements of food law, the FVC must notify the FBO in writing that operations may re-commence.

In the event that FSA is not content for operations to re-commence, the FBO will be notified of the deficiencies and appropriate enforcement action will be taken. Operations may not re-commence until the deficiencies are resolved on a permanent basis.

If serious deficiencies exist, the FVL / FVC must refer the establishment to the relevant HOD, who should arrange for a formal review of approval request to be submitted to the Operations Head Veterinarian.

Reference: 'Operational policy for the approval of meat establishments undertaken by the FSA' available on food.gov.

1.4.4 Unauthorised resumption of operations

Where FSA becomes aware of an establishment that has re-commenced operations without prior notification and a pre-opening assessment visit has not been undertaken, the following measures must be taken:

- The FVL / FVC will take appropriate enforcement action to prevent the FBO operating the establishment until a formal assessment of compliance has been undertaken, or where deficiencies are identified, such deficiencies have been rectified.
- If food has been placed on the market prior to a formal assessment, the FSA's action regarding withdrawal / recall of food will be risk-based and proportionate. However, food not yet placed on the market may be detained until the FBO has been notified by the FVL / FVC that operations may re-commence.

2. Legislation

2.1 Requirement for audit

2.1 Requirement for audit

2.1.1 General requirements for official controls

It is a principle of REUL 2017/625 and 2019/627 that official controls will verify the FBOs compliance with REUL 852/2004, 853/2004 and other REUL and national regulations that apply to approved meat establishments.

Part of that verification process is the audit of good hygiene practices and HACCP-based procedures as required by REUL 852/2004 Article 5 and REUL 853/2004 Annex II, Section II, the FBOs food safety management system.

In addition to the audit of good hygiene practice, the auditor must verify the FBOs continuous compliance with their own procedures for, amongst others, all aspects of animal by-product (ABP) handling (including SRM control), animal identification and animal health and welfare.

In addition to the audit of HACCP-based procedures the auditor must check that the operator's procedures guarantee, to the extent possible, that meat is free from patho-physiological abnormalities, faecal or other contamination and SRM (subject to Community rules).

Reference: REUL 2017/625, Article 18 and REUL 2019/627, Article 3

2.1.2 Food fraud

The recommendation of the Food Fraud Task Report 2007 is that auditors and other officials visiting food premises should bear in mind the possibility of fraudulent activities.

2.1.3 GHP audit

Audits of good hygiene practices shall verify that FBOs apply procedures continuously and properly. A detailed list of pre-requisites to consider can be found in sub topic 3.2.2 on 'HACCP and pre-requisites' in Part 1.

Reference: REUL 2019/627, Article 3,1

2.1.4 HACCP audit

Audits of HACCP-based procedures are to verify that FBOs are applying procedures continuously and properly. The auditor must determine whether the procedures guarantee, to the extent possible, that products of animal origin:

- comply with microbiological criteria laid down under EU legislation
- comply with Retained EU legislation on residues, contaminants and prohibited substances
- do not contain physical hazards, such as foreign bodies

Reference: REUL 2019/627, Article 3, 2 and 3

Where a food business operator takes additional measures to guarantee food safety by implementing integrated systems, private control systems or independent third-party certification, or by other means, and where these measures are documented and animals covered by such schemes are clearly identifiable, the competent authorities may take such measures into account when carrying out audits to review good hygiene practices and the HACCP-based procedures.

Reference: REUL 2019/627, Article 4,2.

3. FBO Responsibility

- 3.1 Compliance with the legislation
- 3.2 HACCP based systems

3.1 Compliance with the legislation

3.1.1 FBO standards

The FBO is required to comply with the requirements of REUL 852/2004, 853/2004 other REUL and national regulations that apply to approved meat establishments. These are the standards against which the auditor will assess the FBO performance at audit.

Food safety management systems must be implemented and must be sufficient to achieve the objectives of the Regulations.

3.1.2 Access, records and assistance

The FBO is required to offer all assistance needed to ensure that official controls carried out by the Competent Authority can be performed effectively, and in particular to:

- give access to all buildings, premises, installations or other infrastructures
- make available any documentation and records required under the Regulations or considered necessary for judging the situation.

Reference: Retained (EU) legislation 2017/625, Article 15, The Food Hygiene (Wales) Regulations 2006 (as amended) / The Food Safety and Hygiene (England) Regulations 2013 (as amended).

3.2 HACCP based systems

3.2.1 Obligation to implement

The FBO, considering the nature and size of the business, has a duty to implement a permanent procedure based on the 7 HACCP principles of:

- 1. identifying any hazards that must be prevented, eliminated or reduced to acceptable levels
- 2. identifying the critical control points (CCPs) / control points required by regulations at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels
- 3. establishing critical limits / legal limits at CCPs / control points required by regulations which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards
- 4. establishing and implementing effective monitoring procedures at CCPs / control points required by regulations
- 5. establishing corrective actions when monitoring indicates that a CCP / control point required by regulation is not under control
- 6. establishing procedures, which shall be carried out regularly, to verify that the measures outlined above are working effectively
- 7. establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined above

When any modification is made in the product, process, or any step, FBOs shall review the procedure and make the necessary changes to it.

The FBO must also provide the CA with evidence of their compliance and ensure that any documents describing the procedures are up-to-date at all times.

Reference: Retained (EC) legislation 852/2004, Article 5

Reference: See MOC Volume 2, 14f on EU guidance document on the implementation of procedures based on HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses;

3.2.2 HACCP and pre-requisites

HACCP systems are not a replacement for other food hygiene requirements, but a part of a package of food hygiene measures that must ensure safe food. It must

be borne in mind that 'prerequisite' food hygiene requirements must be in place

prior to establishing HACCP procedures, including in particular:

- checks on food chain information (FCI)
- the design, layout and maintenance of premises and equipment
- pre-operational, operational and post-operational hygiene
- personal hygiene
- training in hygiene and in work procedures
- pest control
- water quality
- temperature control
- controls on food entering and leaving the establishment, any accompanying documentation

These requirements are designed to control hazards in a general way and they are clearly prescribed in Community law. They may be supplemented with guides to good practices established by the different food sectors.

Reference: <u>EU guidance document on the implementation of procedures based</u> <u>on HACCP principles</u>, and on the facilitation of the implementation of the HACCP principles in certain food businesses.

Note: Other requirements of Community law, such as traceability, the withdrawal of food and the duty of informing the CAs should, although not covered under the food hygiene rules, also be considered as prerequisite requirements.

Reference: Retained (EC) legislation 178/2002, Articles 18 and 19.

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4. FSA Role

- 4.1 Responsibilities
- 4.2 Audit schedule
- 4.3 Audit protocol
- 4.4 Completing the audit report
- 4.5 Audit assessment
- 4.6 Actions following audit
- 4.7 Unannounced inspection (UAI)
- 4.8 Enforcement
- 4.9 Remote Auditing

4.1 Responsibilities

4.1.1 Who conducts the audit?

Specially trained and experienced veterinary auditors will conduct audits at all approved meat establishments under FSA responsibility.

Note: OVs and novice OVs (NOV) do not undertake audit work but will provide supporting evidence for the audit. All relevant evidence gathered by them during the audit period must be available for the auditor (including the up to date 'Enforcement Programme' available in Chronos).

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4.1.2 Audit tasks

The following table identifies the different tasks and responsibility for completion.

Task	Timescale	Responsibility
Arrange audit visit date with FBO or their representative	Based on risk rate frequency for the month the audit is due; best practice is a minimum of 2 weeks before audit is due	Auditor
Confirm audit visit date in writing/ e- mail	Via K2, shortly after arranging visit	Auditor
Audit preparation gathering information on FBOs food safety management systems	-	Auditor
Gather information on food safety management systems	-	MHI / OV / NOV
 Carry out audit visit: Opening meeting Inspection of the establishment and collection of evidence Documentary audit and collection of evidence creating audit notes Closing meeting Discussion of audit findings and final outcome (SH and GHE) Discussion of audit findings, final outcome and possible corrective actions, with the FBO or their representative (Stand Alone Cutting Plants (SACPs)) 	Depending on the complexity of the establishment, the auditor should consider allocating one or more audit days.	Auditor
Compile audit report and submit in K2	Within 5 working days after the visit	Auditor
Audit report authorisation in K2	Within 10 days of the audit visit	-
Distribute completed audit report to FBO, with copies provided to relevant FSA officials as required	-	Auditor or AVL Generated automatically by K2

4.1.3 Auditor's code of ethics

The following four principles are the standards of conduct that are expected from auditor carrying out FBO audits:

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1. Integrity

Auditors shall demonstrate integrity in all aspects of their work. The relationship with OVs, MHIs and with FBOs should be one of honesty and fairness. This establishes an environment of trust which provides the basis for all activities carried out by the auditor.

2. Objectivity

Auditors shall display professional objectivity when providing their opinions, assessments and recommendations. The auditor should not be unduly influenced by the views of others or by personal interest.

3. Competency

The auditor shall not carry out audits if they feel they do not have the base auditor competency or if they lack technical competency in the area being assessed. All auditors are to hold Food Safety Lead Auditor and Intermediate level HACCP qualifications.

4. Confidentiality

Auditors shall safeguard the information they obtain while carrying out their duties. There should not be any unauthorised disclosure of information unless there is a legal or professional requirement to do so.

4.1.4 Auditor duties

The auditor is responsible for:

- arranging the audit visit with the FBO
- completing the audit within the calendar month of the designated audit frequency
- auditing the FBOs FSMS and FBOs compliance with animal health and welfare Regulations
- completing the Audit report (AUD 9-3)
- determining an audit outcome and audit frequency
- advising the FBO on compliance with legal requirements in relation to the audit
- (in stand-alone establishments) agreeing any necessary remedial action and timescales with the FBO, ensuring deficiencies are effectively addressed liaising with the UAI team as required, and escalation of any necessary enforcement activity as a result of the visit.

4.1.5 Auditor exclusions

The auditor should not:

- assume accountability for FBO compliance
- take over tasks that are for the FBO to perform
- act as a quality assurance manager
- act as an advocate between industry and the FSA
- write company procedures or HACCP plans, although advice may be given
- provide the FBO with a copy of the un-checked audit report

4.1.6 Assurance measures: AVL duties

As an assurance measure, AVLs will carry out quality checks on a representative sample of issued audits within their areas (initially 10%). Those checks should include audits of poor performing plants (assessed as Improvement necessary and Urgent Improvement Necessary).

The AVL will also be responsible for profiling the audits in their area and ensuring targets are met.

4.1.7 Field staff duties

Field staff working regularly in an establishment must ensure that they are familiar with the procedures and systems put in place by the FBO, in particular for the processes for which they have an inspection role.

Note: The OV must ensure that MHIs working under their technical responsibility maintain a current understanding of the FBOs procedures and systems.

4.1.8 Automated system actions

The K2 system will:

- monitor the scheduling of the audit visits in accordance with the minimum audit frequency determined by the audit category
- monitor the timely production of audit reports

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- distribute the completed report to the FBO
- maintain audit records

4.2 Audit schedule

4.2.1 Arranging visits

The auditor will contact the FBO, where possible, one month in advance of the audit being due (two weeks' notice is acceptable but not best practice) to agree a date for the audit visit.

FBO audits should be arranged whilst the establishment is in operation and product being processed. If necessary, an audit may take place over a number of days of a week in order that as many processes as possible are audited. Where the establishment is not operational the audit may be delayed until the establishment is in operation with the agreement of the auditor.

The scheduling of the audit visits will be monitored in order to ensure that audit targets and frequencies are met.

The agreed date of the audit visit must be confirmed in writing to the FBO. This letter will provide the FBO with prior warning of an audit; outlining the scope of the audit and the access and information that will be required.

Notification of the audit will allow the FBO to make themselves, or the relevant members of their management team, available. In addition, it allows the FBO to have any necessary documentation available for audit.

Note: Where applicable (for example, seasonal operations), in order to confirm that the establishment is truly not operational, a regular programme of unannounced inspections should be set up until the audit takes place.

Reference: See sub-topic 4.7.6 on 'Unannounced inspection' in part 1 for additional information.

4.2.2 Target for subsequent audit completion

Subsequent audit visits will be within the month determined by the last audit category.

4.2.3 Alternative arrangements

Where an audit date has been scheduled with the FBO and the FBO needs to cancel / rearrange, the auditor shall reschedule the audit working collaboratively with the FBO to agree a mutually agreeable date and time, updating K2 accordingly with the current agreed date and the reason for the cancellation.

However, cancelling audits at short notice creates a considerable problem to the FSA in terms of wasted hours and a knock-on effect to the number of FSA audits and workload of FSA auditors accumulating into proceeding months. This situation can incur a cost to the agency due to auditors wasted time preparing and travelling to audits which are subsequently cancelled.

The VA should notify the AVL of the problems in arranging the audit. At the discretion of the AVL, a letter can be sent to make the FBO aware of the impact and the potential implication cancelations at short notice have on the audit system. The FBO audit cancellation letter template (Annex 5) can be tailored to the different scenarios that may occur.

4.3 Audit protocol

4.3.1 Collecting evidence as to the compliance of the FBO

In slaughterhouses: FSA staff are present every day the plant operates. As part of day to day business they should record objective evidence as to the level of compliance by the FBO with both his own procedures and with legislative requirements.

In cutting plants: FSA staff will normally only be present to conduct the audit, although the premises should have been the subject of UAIs in the period since the last audit. Prior to a scheduled audit taking place, the auditor should establish whether any UAIs have taken place and if so, what enforcement activity arose as a result.

Both the OV and MHI have an important role to play in identifying and recording NCs. Objective evidence of NC issues may be recorded:

- on the relevant operational form
- in the daybook
- in the enforcement programme (Chronos)

Note: 'Major' or 'critical' NCs should trigger an immediate action.

4.3.2 Assessment of operational records

Prior to the audit, the auditor must review enforcement records for the period since the last audit and use this information when assessing the effectiveness of the FBOs food safety management procedures and HACCP based system, taking account of corrective actions. For the purpose of the assessment, the auditor might request and review other records they find relevant, including hygiene, welfare, ABPs forms and UAI reports.

Auditors can obtain additional information about the level of FBO's compliance in an establishment through contact with the local FSA team (MHIs, OVs, FVC and FVLs).

Reference: See sub-topic 5.2.1 on 'FBO compliance history' in part 1 for additional information.

4.3.3 The opening meeting

Start each audit with an opening meeting with the FBO (or appropriate representative) and outline the:

- reason for and scope of the audit, anticipated length of the audit and the day programme
- information and access that will be required
- purpose of the subsequent closing meeting
- publication of audit categories

The opening meeting should also be used to:

- confirm that there are no changes to FBO, structures, equipment or activities since the last audit and that all necessary approvals are in place
- highlight that if during an audit it is identified that there has been a change of legal entity, the audit will be stopped, and the approvals team informed; a new approval is required
- review of the Non-compliance Report (NCR) from the last audit
- highlight any issue identified from the audit preparation review of operational forms.

4.3.4 When carrying out the audit

During the audit, the auditor will:

- collect and record objective evidence of the FBOs compliance with legislative requirements for food safety management systems based on HACCP principles, including ABP and where appropriate, SRM, animal health and welfare procedures
- inspect the establishment ('reality checks') to observe whether the FBO's procedures in practice reflect the policies and procedures as documented

Note: In slaughterhouses some of this information will be gathered on a daily basis by MHIs / OVs.

- score individual questions and sections as compliant or non-compliant (minor, major, critical)
- determine the overall audit outcome as Good, Generally Satisfactory, Improvement Necessary and Urgent Improvement Necessary

4.3.5 Serious issues identified during audit

If an issue of serious public health, animal health or welfare arises during an audit (for example, considered 'critical'), the auditor should:

- inform the FBO, the OV (where appropriate) immediately, and the FVL / FVC as soon as possible
- take / instruct the OV for any necessary enforcement action to be taken
- consider curtailing the current audit

4.3.6 Reference to previous audit reports

During subsequent audits, the auditor should refer to the previous Audit Report to direct priorities during audit in a risk based manner. The auditor should put special attention on areas where major or critical NCs were identified. Those will always have to be reassessed in the next audit.

4.3.7 Audit notes

It is important that audit notes are taken during the audit as they constitute an essential element to support the auditor audit findings and justify the audit assessments.

Auditors can use the audit checklist (Annex 3) to record evidence.

Each page should include:

- have the audit number which comprises the four-digit approval number, site type and audit date (month/year), that is xxxx-SH-mm/yy
- contain contemporaneous, detailed and legible notes which are crossreferenced to the aide memoire reference notes of the AUD 9/3 form
- date and signature of the auditor

Audit notes do not need to be submitted with the audit report but they should be retained and made readily available for next audit or as and when requested.

Audit notes must be retained for a minimum of 2 years (more than 2 years if there are ongoing outstanding enforcement actions).

4.3.8 FBO involvement in audit

The auditor should expect to be accompanied by the FBO (or a nominated representative) during the visit.

4.3.9 The closing meeting

The audit must be concluded with a closing meeting with the FBO (or appropriate representative) which will:

- summarise the audit findings (positive and negative)
- outline any NCs
- discuss the corrective action required, including any proposed timescales and possible enforcement action for Stand Alone Cutting Plants (SACPs)
- give an indication of the expected audit category
- give details of report procedure
- give details of publication of the audit categories
- outline subsequent action and right of appeal

The closing meeting provides an opportunity for the FBO to respond to audit findings, to discuss his proposed actions and to provide any further supporting evidence if he disagrees with any audit findings.

The resident OV in slaughterhouses, co-located cutting plants and GHE shall attend the closing meeting, whenever possible.

4.3.10 Further information provided by the FBO

The FBO may provide additional evidence following discussions at the closing meeting. Provided this evidence is received by the auditor within 5 working days of the audit, it may be taken into consideration.

4.3.11 Audit report

The Audit report (form AUD 9/3) must be compiled from the audit findings and should not be materially different from the findings presented verbally during the closing meeting.

The completed report should be submitted by the auditor within 5 working days of the audit visit.

Reference: See topic 4.4 on 'Completing the Audit Report' in part 1 for additional information.

4.3.12 Submission of Audit report (AUD 9/3)

The following table details the process which should be followed after completion of the audit report.

Step	Action
1	The auditor completes and submits audit report within 10 working days.
2	K2 automatically records the audit report
3	K2 distributes the completed audit report to the FBO, Service Delivery Partner (SDP) and to other parties if required for assurance checks.

4.3.13 Auditor's feedback to the FSA team

The SDP receives a copy of the completed audit report sent to FBO. The resident OV is responsible for making all members of the team aware of the audit results, including NCs, the corrective action and timescales.

Note: Any FSA performance issues identified during an audit must be reported using the K2 system.

4.4 Completing the Audit Report

4.4.1 Use of objective evidence

As the formal record of the audit findings, the audit report must contain objective evidence to support the overall findings of the audit and the results given to the FBO during the closing meeting of the audit visit.

Although it was agreed with industry stakeholders that the audit report will mostly contain exception reporting, good audit practice dictates that reports should include both positive and negative reporting. The trigger for the auditor to make narrative entries in the supporting evidence box will be based on the score in the assessment box. Assessment boxes which have not been marked as 'compliant', or changing scores from the previous baseline audit will require an entry in the supporting evidence box.

Note: The audit writing guidance document (Annex 2) has been developed to assist auditors with aspects of report writing. It includes tips on style, accuracy, consistency and objectivity.

4.4.2 Use of positive language

The auditor should use positive language during the closing meeting and in the audit report.

This will help to promote constructive communication of audit findings between the auditor and the FBO, better participation and resolution of NCs through joint identification of action and opportunities for improvement, which is the main aim of the audit.

4.5 Audit assessment

4.5.1 Recording compliance

Each question of the audit report requires the auditor to gather evidence regarding the level of compliance with the stated outcomes and record it as compliant, minor, major, or critical NC.

Note: Only one NC is to be recorded for each question; this is to be especially considered when using the link tool explained in 4.6.5.

4.6 Actions following the audit

Note: For the purposes of this section, the following definitions apply:

- deficiency an individual and very specific failure to comply with the legislative requirements (for example, in-rolling, dirty surface, uncut bird(s)) which are entered individually in the enforcement programme and are used as supporting evidence to justify audit NCs
- **NC** a failure to comply with legislative requirements against a question and which is supported by one or several related deficiencies
- **question** each sentence intended to elicit information in the audit report and which is assessed depending on the level of compliance
- **section** a group of questions in the audit report under the same general heading

4.6.1 Audit outcome

The approach following the audit will depend on the outcome of the audit and the number of identified minor, major and critical NCs.

In slaughterhouses, co-located cutting plants and wild game establishments, the resident OV owns and is responsible for the amendment, completion and update in Chronos. When the incumbent OV is not present at any stage of the audit, the auditor will ensure that the deficiencies are effectively communicated to the plant lead OV so that they can update the Chronos system and follow up on the enforcement.

For stand-alone cutting establishments, the responsibility is shared; this means the auditor will take any necessary enforcement action and record it in Chronos, but then the responsibility will be transferred to the field team.

4.6.2 Request to change the auditing frequency / early audit

Audit frequencies can be re-assessed at the request of FSA and/or the FBO.

On FBO formal request, the date of the audit may be brought forward under certain specific circumstances (for example, during busy periods, for commercial reasons or after a bad audit outcome).

However, an early audit should not be requested immediately after an unsatisfactory audit. In these circumstances scheduled audit frequency can be only changed if all major and critical NCs were signed off as complete and in the case of stand-alone cutting plants, an UAI has been completed as specified in the requirements. This should be assessed on a case by case basis.

The FSA may also decide to carry out a full audit of an establishment prior to its scheduled date if serious deficiencies are identified. This can be requested by either the field or assurance FSA teams.

Field teams request: if falling standards on a particular establishment leads to the last audit outcome not reflecting the actual situation of the site, despite the progression of the enforcement and the approach through the Intervention Protocol. For example, establishment on extended audit frequency with sudden continuous increase in the level of enforcement.

Assurance team request; if after a partial audit the number of major or critical NCs increases to the extent of these exceeding the permitted numbers in the previous audit outcome.

In order to keep the separation between the audit and enforcement functions, an audit cannot be brought forward from its frequency unless the Auditor is satisfied that all appropriate enforcement is in place, as it is a basic principle of auditing that an audit should not be another enforcement tool.

Each proposal will be discussed on a case by case basis with the AVL and the Approvals and Veterinary Audit Lead with a decision being made on the evidence available to ensure a consistent approach.

Audits may only be postponed in exceptional circumstances, for example, if the establishment is not operational when the audit is due or other unforeseeable circumstances.

4.6.3 Minor NCs

Minor NCs are followed up by the resident OV in the case of slaughterhouses, colocated cutting plants and GHE or during UAIs in the case of stand-alone cutting plants. FVC / OV / MHI involved in the UAIs can assess the corrective action taken by the FBO on the deficiencies identified during the visits.

The minor NCs will be reassessed in the following partial/full audit by the auditor, based on the information provided by the field teams, and then the auditor will decide to either close it or maintain it open.

4.6.4 Critical and major NCs

Auditors will carry out partial audits of any establishment with critical and/or major NCs to assess progress towards compliance. These visits will be chargeable to the FBO and will be treated separately to the UAI programme.

- Critical NCs can only be closed off by the auditor following an on-site partial audit where compliance could be verified.
- Major NCs can be assessed without the need of a visit if the VA considers that sufficient evidence of compliance can be obtained remotely (from the FSA local team or FBO) to close this off where:
 - The auditor is satisfied that a major NC identified at the full audit (from the Chronos report) has already been effectively rectified by the FBO during the audit period, that major NC can be closed off at the time of audit reporting. No visit or partial audit report will be required.
 - The audit outcome is 'generally satisfactory', the auditor has the option to accept evidence provided by the FBO and corroborated by the resident OV or the UAI to close off a major NC. A visit is not essential, but a partial audit report is required. The auditors have the discretion to visit plant if they consider it necessary.

4.6.5 NC closed count to vs do not count to outcome

When a NC is closed, either at a full or partial audit, the auditor should decide if the closed NC will count towards the outcome of the audit or not:

- If the NC raised at a full audit is closed at the next full or partial audit and the deficiencies have been resolved within the agreed timescale and without the need to escalate enforcement, the auditor should mark it as closed – do not count to outcome. The NC will not appear in the next full audit report.
- If the NC is closed at the next full or partial audit but the agreed timescales to resolve the deficiencies have not been met and/or enforcement has required escalation, the auditor should mark it as closed count to outcome. This will not appear automatically in the next full audit report and should be manually added in the following audit report. The auditor should decide the final assessment based on the evidence available during the audit period.

• If a NC raised at the full audit is closed at the full audit, it should always count to the outcome. This may be for matters that happened during the audited period (for example, raised by the OV on site or by the inspector during a UAI visit) but that had been correct at the time of the audit.

4.6.6 Use of the link tool

Linking of NCs should be done to prevent the same deficiency from being raised as different NCs in more than one question in the audit report.

If the auditor considers that there is a deficiency that constitutes a NC that applies to several questions, the auditor should use the link tool so that the same deficiency is recorded in all the applicable questions. This will count as a single NC for audit outcome purposes, and all linked questions will have the same NC with the same score recorded against them in the NC report.

Examples:

- NCs relating to contamination / cross-contamination (section 3) might be linked to the FBOs food safety management system failure so consideration should be given to linking these to the relevant question in the HACCP section (section 5).
- NCs relating to inadequate welfare practices might be linked to the FBOs welfare management system failure so consideration should be given to linking these to other questions in section 2.

4.6.7 Contribution of minor NCs to the severity of Major NCs.

If the use of the linking tool is not justified due to the same deficiency not affecting two different questions, the auditor can justify the increase in the severity of a question -scoring that question as a Major NC- based on the fact that deficiencies considered in other questions contribute to this assessment.

The other questions to which the Major NC relates will be individually assessed/scored, through the auditor's risk assessment, and the auditor can make a reference in the description of the relevant question, for example 'this deficiency contributes to the assessment of *Major* in the NC raised in question X' but without using the link facility. The contributing questions can have a different score from the one they are contributing to.

4.7 Unannounced inspection (UAI)

4.7.1 Background and Purpose

UAIs augment the audit process and support general field operations obligations by verifying FBO compliance in standalone cutting plants and establishments where there is not a regular FSA presence.

UAIs provide evidence of FBO compliance between full audits and the FBO's continued application of legal requirements, food safety management systems and HACCP based procedures. If deficiencies are found during a UAI enforcement action is taken, recorded online in the enforcement recording system and a UAI report is completed and sent to the FBO following the visit. The programme of unannounced inspections is a useful source management information that is used in the planning and application of official controls.

UAI tasks also include following up on deficiencies raised during previous audits and/or UAI visits. The deficiencies identified during UAIs are considered and form part of the overall picture of FBO performance/compliance between full audits which determines the final audit category assigned to the FBO.

Authorised officers (OVs, FVL, FVCs and C/MHIs) may undertake UAIs on cutting plants under the direction of the relevant FVC. EU regulations indicate official controls (which consist of audit or inspection tasks) should be carried out without prior warning (except audits).

4.7.2 Programme of inspections

The FVC, using results of previous audits, inspection and enforcement activity for a cutting plant, will choose the establishments and the frequency of inspections by the AOs. The relevant LUAI / ITL / SDP will be informed, so the inspections can be scheduled, taking account of the establishment and resources available. The visits will be requested, assigned and completed using the UAI scheduling system.

The programme of pre-planned UAI visits will be shared by the FVC with the relevant unannounced inspector, their ITL, the LUAI and SDP AVM where appropriate. The schedule will include the date by which the individual UAI's are to be undertaken.

Only MHIs who have completed the UAI training course and passed a practical assessment and OVs that are suitably trained/assessed will be permitted to undertake UAIs.

4.7.3 Frequency of UAI visits

The following table shows the frequency of UAI visits required.

Cutting Plant	Frequency
* Stand alone and co- located cutting plants	A minimum of one UAI is to be scheduled between full audit period.
Stand-alone cutting plants that are approved for ready to eat	A minimum of two UAI visits between full audits
Stand alone and co- located cutting plants where serious deficiencies have been identified during audit or UAI visits.	It is appropriate to schedule additional UAI visits. A UAI visit may also be scheduled prior to a partial audit to verify compliance on an unannounced basis.
Stand alone or co- located cutting plants where intelligence and/or food complaints are received relating to the approved premises.	It is appropriate to schedule a visit by a UAI inspector to investigate such occurrences. These visits would not normally be classed as a UAI visit, but should other new deficiencies be identified during the visit a UAI report should be completed and the visit classed as an unannounced inspection.

*Approved establishments receiving unannounced inspections can be subject to extended audit frequencies if two consecutive "good" outcomes are achieved, such premises will require additional UAI visits as described in 5.3.3 (Extended audit frequency)

Approved cutting premises that are co-located to and operating at the same time as approved slaughterhouses where there is a permanent OV presence will not be the subject of UAI visits. However, if the cutting premises operates only at different times to the slaughter operations when there is no OV presence, UAI visits will be scheduled appropriately. If the co-located cutting plant operates both on slaughter and non-slaughter days, it will not be subject to UAIs as far as all the approved activities can be observed on the days where the OV is in attendance. However, if there are specific issues or concerns, UAI visits can be scheduled by the FVC on non-slaughter days.

Where UAI visits identify serious deficiencies, FBO audits may be brought forward, a review of approval or the implementation of the intervention protocol may be triggered.

4.7.4 Roles & Responsibilities

Unannounced Inspectors are supported by local FVC's, one Lead Unannounced Inspector (LUAI) in each of the three FSA regions and their relevant Inspection Team Leaders.

FVC

Responsibility	Action
Schedule UAI visits	Using the UAI system.
Accuracy and	A representative sample of reports will be
consistency checks.	checked for consistency and accuracy across regions.
Advice to UAIs	Throughout the duration of the inspection carried
	out by the employed MHIs, the FVC should
	provide details of someone within the
	management chain available to take calls from
	the MHI should the need arise.
Approving letters	All draft letter to be sent to FBO's are to be
	approved by FVC before postage.
Checking of formal	Approve formal notices served by UAI Inspectors
notices	before postage, this is to be done without any delay.
Local Authority Liaison	Liaise with local authority officers and other
	bodies to facilitate the investigation of
	food/general complaints.
UAI performance	Liaise with LUAI to feedback on UAI performance
	and undertake one shadow visit per year with
	each UAI
Food Incidents	To liaise with and assist the food incidents team.
Schedule planning	Throughout the duration of the inspection carried
	out by the employed MHIs, the FVC should
	provide details of someone within the
	management chain available to take calls from
	the MHI should the need arise.

LUAI

Responsibility	Action
UAI performance	Liaise with FVC and ITLs to feedback on UAI
	performance and undertake at least one shadow

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Responsibility	Action
	visit per year with each UAI. Where appropriate
	LUAIs are to contribute to formal performance
	management meetings.
UAI Visits	Carry out some unannounced inspections in
	challenging premises
Liaison with FVCs	Work with FVCs to manage unannounced
	inspections across the region and explore
	improved ways of delivering them more
	effectively and efficiently
UAI Support	Support and develop the skill sets of UAIs in their
	area of control, assessing the capability of UAI
	resource in region including competence levels
	and identify any development needs
UAI Training	To develop training materials, arrange practical
	and theoretical training and assess the
	competency of new staff being deployed into the
	UAI role.
Coaching and	Act as a coach and mentor to UAI colleagues
mentoring	looking to continually improve the delivery of UAI
	across the agency.
Consistency checks	Consistency check a sample of UAI reports
	submitted in their regions, to identify training
	needs and ensure consistency in the delivery of
Liaison with other	official controls. LUAI's are responsible for liaison with OGDs,
	NFCU in conjunction with the memorandum of
public bodies	understanding and other external enforcement
	bodies.
Updating UAI Aide	To regularly review and where necessary update
Memoire	the enforcement aide memoire.
Complaint	To Liaise with FVC and other FSA staff to
investigation.	investigate food, other complaints and assist with
	food incidents.
Food Incidents	To liaise with and assist the food incidents team.

UAI

Responsibility	Action
Assigned visits	To liaise with ITL to ensure visits are completed on time in line with the request and are allocated into their work schedules. Sufficient time must be scheduled to include preparation, updating of enforcement and report writing time.
Liaising with FVCs	MHIs must liaise with their FVCs should they need to discuss technical issues prior to the

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Responsibility	Action
	inspection visit this includes where preparation of
	enforcement notices are /could be required.
Liaising with VAs	AOs conducting UAIs may need to liaise with the VA who conducted the last audit or OV responsible for the plant to discuss areas of operation to be reviewed following the last audit findings, the enforcement programme, local requirements and capture areas the auditing VA
	would like more focused attention.
Reporting systems	Use the UAI report system to access information required before the visit, write report and update record of enforcement.
The UAI visit	UAIs are to complete inspection visits in line with training and relevant guidance.
Report Submission	All reports are to be submitted, enforcement updated, photos added to share-point and draft letters are to be completed within 5 working days of the visit taking place.
Formal Notices	Wherever possible discuss the serving of a notice with the relevant FVC whilst at the premises. Notices must be scanned and sent to the FVC for approval on the same day they are served.

ITL

Responsibility	Action
Time allocation for UAI performance management	To Liaise with FVC and ITL ensuring sufficient time is allocated for the completion of all aspects of the UAI visit.
	Gather information regarding the MHIs UAI performance to assist with the MHIs performance management. Support with their training and development needs for the UAI role.

4.8 Enforcement

4.8.1 Slaughterhouses, game handling and co-located cutting plants

At Full Audit Auditor identifies NC (new & from the enforcement programme):

1. Urgent Improvement Necessary. Next full audit in 2 calendar months

Resident OV enforces/updates Enforcement Programme and feeds back to auditor on NCs (New and from Enforcement Programme)

Partial audit within 1 calendar month unless Full audit scheduled in that calendar month:

- If all Majors/Criticals are not closed another partial audit takes place within 1 calendar month.
- If all Majors/Criticals are closed, the auditor closes the non-compliances and no partial audits will take place until the next Full Audit.
- 2. Improvement Necessary. Next full audit in 3 calendar months

Resident OV enforces/updates Enforcement Programme and feeds back to auditor on NCs (New and from Enforcement Programme)

Partial audit within 1 calendar month unless Full audit scheduled in that calendar month

- If all Majors are not closed another partial audit takes place within 1 calendar month.
- If all Majors are closed, the auditor closes the non-compliances and no partial audits will take place until the next Full Audit.
- 3. Generally Satisfactory. Next full audit in 12 calendar months

Resident OV enforces/updates Enforcement Programme and feeds back to auditor on NCs (New and from Enforcement Programme)

Partial audit within 3 calendar months unless Full audit scheduled in that calendar month

- If all Majors are not closed another partial audit takes place within 3 calendar months.
- If all Majors are closed, the auditor closes the non-compliances and no partial audits will take place until the next Full Audit.

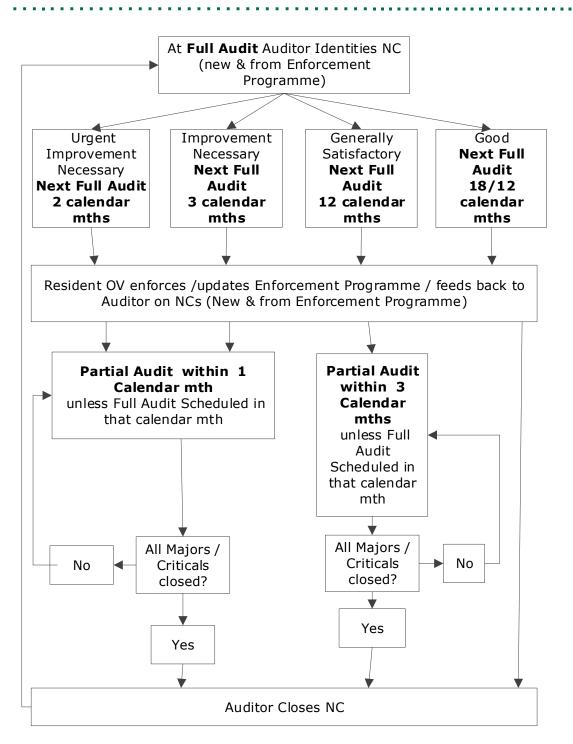
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4. Good. Next audit in 18/12 calendar months

Resident OV enforces/updates Enforcement Programme and feeds back to auditor on NCs (New and from Enforcement Programme)

No partial audit takes place until the next Full Audit.

These courses of actions are summarised in the chart below.



Note: This chart does not include the extended audit frequency for establishments with Good / Good outcomes in their last two audits.

4.8.2 Stand-alone cutting plants

At Full Audit Auditor identifies NC (new & from the enforcement programme):

1. Urgent Improvement Necessary. Next full audit in 2 calendar months

New minor Non-compliances. Auditor serves enforcement / updates ENF passes ownership to UAI process.

New Critical/Major non-compliances identified at Full Audit. Auditor serves enforcement / updates Enforcement Programme and follows the hierarchy of enforcement until closed.

Partial audit within 1 calendar month unless Full audit scheduled in that calendar month:

- If all Majors/Criticals are not closed another partial audit takes place within 1 calendar month.
- If all Majors/Criticals are closed, the auditor closes the non-compliances and no partial audits will take place until the next Full Audit.
 - 2. Improvement Necessary. Next full audit in 3 calendar months

New minor Non-compliances. Auditor serves enforcement / updates ENF passes ownership to UAI process.

New Major non-compliances identified at Full Audit. Auditor serves enforcement / updates Enforcement Programme and follows the hierarchy of enforcement until closed.

Partial audit within 1 calendar month unless Full audit scheduled in that calendar month

- If all Majors are not closed another partial audit takes place within 1 calendar month.
- If all Majors are closed, the auditor closes the non-compliances and no partial audits will take place until the next Full Audit.
 - 3. Generally Satisfactory. Next full audit in 12 calendar months

New minor Non-compliances. Auditor serves enforcement / updates ENF passes ownership to UAI process.

Partial audit within 3 calendar months unless Full audit scheduled in that calendar month

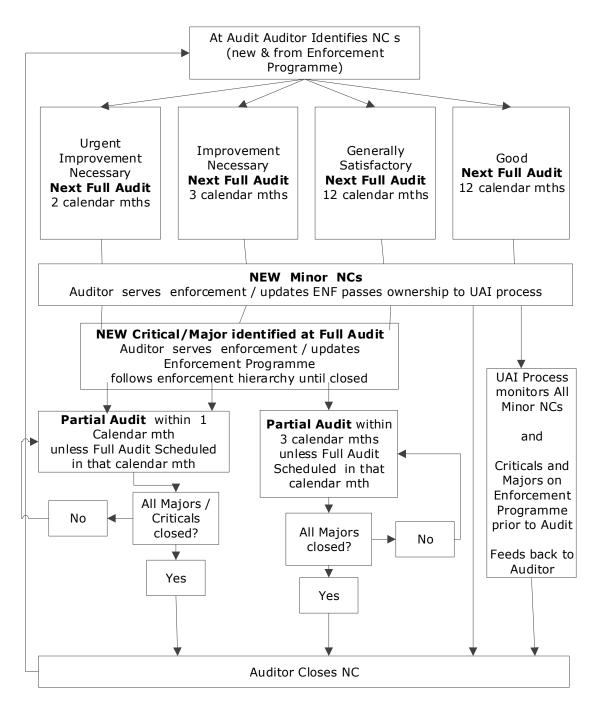
- If all Majors are not closed another partial audit takes place within 3 calendar months.
- If all Majors are closed, the auditor closes the non-compliances and no partial audits will take place until the next Full Audit.
 - 4. Good. Next audit in 12 calendar months

New minor Non-compliances. Auditor serves enforcement / updates ENF passes ownership to UAI process.

No partial audit takes place until the next Full Audit.

In all 4 Full Audit Categories the UAI Process monitors all Minor, Major and Critical Non-compliances and feeds back to the Auditor.

These courses of actions are summarised in the chart below.



Note: This chart does not include the extended audit frequency for establishments with Good / Good outcomes in their last two audits.

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4.9 Remote Auditing

4.9.1 Background and purpose

The FSA formalised the use of Remote Audits during the Covid pandemic, in line with other Auditing bodies worldwide. Remote auditing guaranteed the effective delivery of official controls at a time of crisis, whilst optimising resources.

Auditors utilise an approved software to conduct Remote Audits, which is in compliance with the FSA security policies available at <u>Privacy notice for audits of slaughterhouses and GHEs</u> and a specific document for the security of the software used for Remote Audits is available at <u>Librestream's Security and GDPR compliance statement</u>

4.9.2 Definitions

In accordance to how the audit is carried out, there are 3 main types of audits:

- **On-site audit**: An FSA audit involving on-site visit and auditing of documents/records at the premises.
- **Remote audit**: An FSA audit carried out by the auditor without visiting the site but supported by the FSA team (input from all Authorised Officers -AOs visiting the plant) and/or the evidence provided electronically by the Food Business Operator (FBO).
- **Semi-remote audit**: An FSA audit with a reduced on-site component in which part of the audit is carried out on-site (for example targeted physical checks) and part completed remotely (for example documentation/records, meetings).

4.9.3 When to use Remote Audits?

The Auditor will have to assess the suitability of this technology depending on the outcome of the previous Full Audit, the FBO's availability and the possibility to use it due to coverage in the establishment.

The decision tree below can help deciding when a Partial Audit is eligible for remote auditing using remote technology.

Full Audit:

Requires On-site visit.

Partial Audit:

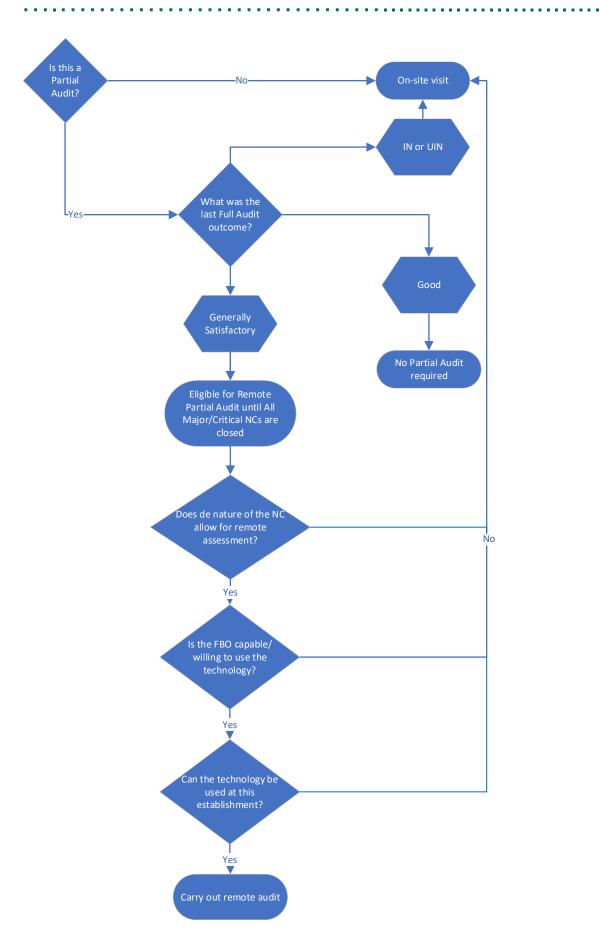
a. Previous outcome IN or UIN requires on-site visit. Onsite Visit

- b. Previous outcome Generally Satisfactory. Eligible for Remote Partial Audit until all Major Non-compliances are closed.
 - 1. The nature of the Non-compliance allow for remote assessment:
 - The FBO is capable / willing to use the technology.
 - The technology can be used in this establishment. Remote Audit.

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- The technology cannot be used in this establishment. On-site visit.
- The FBO is not capable /willing to use the technology. On-site visit.
- 2. The nature of the Non-compliance doesn't allow for remote assessment. On-site visit.
- c. Previous outcome Good. No partial audit required.

These courses of actions are summarised in the chart below.



5. Risk Assessment

- 5.1 Audit report
- 5.2 Audit compliance assessment
- 5.3 Audit outcome and frequency
- 5.4 Review and right of appeal

5.1 Audit report

5.1.1 Audit report form

The Audit report form (AUD 9/3) is available via the K2 system.

5.1.2 Summary of findings

The report contains an area to summarise the audit findings. The summary of findings should include positive findings (good practice), negative findings (NCs) and a brief description of any variations from the previous audit enabling the FBO and other interested parties to review the audit without needing to read the full detail contained within the report.

5.1.3 Non-Compliance Report (NCR)

At the end of the audit report there is a section containing the NCR.

The NCR summarises and provides a short description of the NCs identified.

Once the FBO receives the report with the NCR, the FBO is responsible for rectifying the NC identified during the audit.

5.1.4 Correction of NC

During the next audit, the auditor must verify whether the FBO has taken corrective actions and indicate those which have been completed.

5.2 Audit compliance assessment

5.2.1 FBO compliance history

The history of compliance relates to the deficiencies identified against legislative requirements or the FBOs own procedures and requiring OV intervention during the audit interval or the ongoing NCs from the previous full audit.

Note: FBO initiating corrective actions where the FBO has identified a breakdown in controls is a sign of a healthy food safety management system.

During the audit, the auditor will record evidence of the FBO compliance history, which will result in a risk score under each category based on the following criteria and type of NC:

Title	Description
Compliant	Compliance with a food safety programme, food regulatory requirements and animal health and welfare regulations (in the case of slaughterhouses) is achieved if the food business is operating in accordance with its food safety management systems, food safety standards and has met the requirements of the regulations.
Minor	A NC that is not likely to compromise public health (including food safety), animal health and welfare or lead to the handling of unsafe or unsuitable food. An isolated low-risk situation and does not compromise achieving control measures of the food safety program; that is, overall the food safety program is still effective in controlling the food safety hazards. When viewed collectively a number of related minor NCs may represent a major NC.
	Examples (not exhaustive):
	 a single monitoring lapse of a process that is shown to be otherwise under control
	minor structural defects
	 minor failure to follow good hygienic procedures specified in prerequisite programs
	 ineffective pest control in a limited area
	 slight variation from documented procedures
	inadequate cleaning in a limited area

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Title	Description
	• a few signatures missing on a record over a short time period intermittent or poor completion of records.
Major	A major NC is a one that is likely to compromise public health (including food safety), animal health and welfare or may lead to the production and handling of unsafe or unsuitable food if no remedial action is taken. When viewed collectively a number of related major NCs may represent critical NC.
	Examples (not exhaustive):
	• complete departure from procedures contained in the food safety, animal health and welfare program
	 incomplete action for washing and sanitising procedures
	 inadequate staff training leading to unhygienic practices
	recurrent monitoring lapses of a process
	numerous structural defects, with potential impact in food safety or animal welfare
	 failure to follow good hygienic procedures specified in prerequisite programs
Critical	A critical NC is one where the contravention poses an imminent and serious risk to public health (including food safety), animal health and welfare.
	Examples (not exhaustive):
	 systemic failure of critical aspects of the FBO practices and procedures for implementing food safety, animal health and welfare regulatory requirements
	a serious pest infestation
	intentional falsification of records
	• the same chopping board and knife being used for ready to eat food after being used for raw chicken without being cleaned and sanitised
	evidence of pest control chemicals such as rat bait in food
	 raw meat juices dripping onto uncovered ready to eat food
	 repetitive (more than once) major NC for the same practice or circumstance

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5.2.2 Audit categories

Using objective evidence, the type of NCs identified during an audit reflects the extent and effectiveness of compliance. The following grading system is outlined in the table below:

Compliance rating	Description	Tolerance for audit outcome
Good	No issues of significance for public health, animal health or animal welfare during the entire audit period.	No majors or critical on day of audit or during audit period
Generally Satisfactory	No immediate issues of significance for public health, animal health or animal welfare identified on the day of the audit. Any NCs identified during the audit period corrected promptly.	No more than 2 majors during audit or during audit period rectified promptly No critical during audit period
Improvement Necessary	Major NCs identified at audit and/or NCs during the audit period not always responded to and corrected promptly.	3-6 majors during audit or during audit period No critical during audit period
Urgent Improvement Necessary	Multiple major NCs or critical NC identified during audit visit or interim audit period. Official intervention required to ensure public health safeguards.	1 critical or >6 majors during audit or during audit period

5.3 Audit outcome and frequency of inspections

5.3.1 Determination of frequency

The frequency of audit reporting is determined on a risk basis; assessed, in part, on the outcome of previous audits as outlined in this chapter.

The scheme differentiates between slaughterhouses with or without co-located cutting plants, approved GHE and standalone cutting plants. Audit frequency for slaughterhouses / co-located cutting plants / approved GHE ranges from 2 to 18 months and for standalone cutting plants ranges from 2 to 12 months (due to an absence of routine official presence in standalone cutting plants 12 months remains the maximum frequency).

In addition to a scheduled full audit, a follow up partial audit is to be carried out in some establishments which is dependent on the full audit outcome.

5.3.2 Audit frequency

Please also see sub topic 5.3.3 Extended audit frequency.

The tables below list the minimum audit frequencies applicable to specific types of food establishment. They also include the number of necessary partial audits and UAIs that have to take place.

Audit frequencies for slaughterhouse / co-located cutting plants and approved game handling establishments

Audit outcome	Follow up partial audit	Full audit frequency
Good	0	18 months*
Generally satisfactory	Within 3 months**	12 months
Improvement necessary	Within 1 month	3 months
Urgent Improvement necessary	Within 1 month	2 months

* Except for establishments approved for export to third countries, which will have their audit frequency reduced to 12 months.

** Where there is sufficient evidence provided to the auditor by the FBO, and verified by the OV where possible, that the NC has been rectified, this can be closed off without the need for an establishment visit (it is at the discretion of auditor to decide if a visit is required). This is only possible if the audit outcome is 'generally satisfactory'.

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Audit frequencies for standalone cutting plants and cold stores (for example, Smithfield Market)

Audit outcome	Follow up partial audit	Minimum number of UAIs during interim audit period*	Full audit frequency
Good	0	1	12 months
Generally Satisfactory	Within 3 months	1	12 months
Improvement necessary	Within 1 month	1	3 months
Urgent Improvement necessary	Within 1 month	1	2 months

*RTE establishments will receive one additional unannounced inspection by a trained OV.

Additional visits based on the audit outcome

Audit Outcome	Revisits
Good	N/A
Generally Satisfactory	Follow up partial audits (where required) to be carried out by the auditor
or Improvement Necessary	Unannounced inspections to be carried out by a MHI or an OV (for example, in RTE establishments or co-located cutting plants)
	Major NCs in all instances shall be closed off by the auditor either following a site visit or upon acceptance of corroborated evidence of compliance
	Minor NCs can be signed off by the auditor upon information received by the field team

Audit Outcome	Revisits
Urgent Improvement Necessary	Follow up partial audits (where required) to be carried out by the auditor
	Unannounced inspections to be carried out by a MHI or an OV (for example, in RTE establishments or co-located cutting plants)
	Critical NCs can only be closed off by the auditor following an on-site partial audit where compliance could be verified
	Major NCs in all instances shall be closed off by the auditor either following a site visit or upon acceptance of corroborated evidence of compliance
	Minor NCs can be signed off by the auditor upon information received by the field team

5.3.3 Extended audit frequency

Extending audit frequency aims to provide recognition for FBOs who have sustained a high level of compliance over two consecutive audit outcomes with an aim to ultimately reducing footfall resulting from official control activities without increasing the risk to consumer protection or confidence.

The tables below list the minimum audit frequencies applicable to specific types of food establishment. They also include the number of necessary partial audits and UAIs that have to take place.

The FSA reserves the right to re-audit meat premises at any time and will act on intelligence and evidence in line with existing intervention protocols. Taking compliance history into consideration encourages businesses to maintain high standards at all times.

Extended audit frequencies for slaughterhouses / co-located cutting plants and approved game handling establishments

Audit outcome	Standard frequency	Follow up partial audit	Extended frequency
Good / Good	18 months	0	36 months

Extended audit frequencies for standalone cutting plants and cold stores

Audit outcome	Follow up partial audit	Minimum number of UAIs during interim audit period	Current full audit frequency	Extended frequency	Minimum number of UAIs during interim audit period
Good / Good	0	1	12 months	24 months	2

RTE establishments will receive one additional (3) UAIs during the interim audit period by a trained OV.

Any plant that qualified for extended audit frequencies and subsequent audit outcomes drop to Generally Satisfactory, Improvement Necessary or Urgent Improvement Necessary is automatically disqualified from the extended audit frequency system. They can requalify for extended audit frequencies by achieving two consecutive Good / Good outcomes, but, in the meantime, will revert back to standard audit frequencies.

However, if during a full audit a critical/major NC has occurred during the audit period, but remedial/preventive actions have been implemented promptly and no recurrence has been observed since, the NC can be "closed do not count to outcome".

In these cases, the Good outcome will remain, but there will be an impact in the Extended Audit Frequencies (EAF) status, as this will be removed until the next audit takes place. The status can be re-gained if a Good outcome, with no other Critical/Major NCs within the second audit cycle, is achieved.

5.4 Review and right of appeal

5.4.1 Regulators code

The appeals route for FBO audits follows the regulators code.

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5.4.2 FBO right to seek review

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If an FBO is dissatisfied with the outcome of discussions with the auditor after the closing meeting, or the audit report once received from the FSA Regulatory Delivery and Operational Transformation Team (RDOT), the FBO has the right of appeal in line with the following procedures:

Stage 1 Appeal	Action
Try to resolve informally	All efforts should be made to resolve any misunderstanding or dissatisfaction informally on a local basis between the auditor, AVL and FBO.
Direct FBO to RDOT Audit Coordinator to request an audit appeal form	If a FBO, or their representative, still wishes to appeal an audit report they should be directed to the Audit Coordinator to request the audit appeal form 'Request for a review of the audit of the FBOs food safety management system'.
Audit Coordinator receives request for audit appeal form	On receipt of the FBO's request for an <u>appeal request form</u> , the Audit Coordinator will send the form to the FBO, ensuring that the auditor is notified of the request, to ensure that all possible efforts have been made to resolve the matter informally.
FBO submits formal appeal, with supporting evidence	The FBO, or their representative, should complete their part of the form, stating which sections of the audit report the FBO is appealing against and giving objective evidence to support the claim that the auditor's assessment is incorrect.
	Any supporting evidence should be copied and sent with the form to the Audit Coordinator within 14 calendar days of receiving the initial audit report from RDOT.
	Appeals which are not supported with objective evidence may be rejected.
Investigating Officer (IO) appointed	On receipt of the completed appeal form, the Audit Coordinator will provide the Operations Head Veterinarian with a copy of the appeal, including any supporting evidence. The Operations Head Veterinarian will be responsible for appointing an AVL from a different area as the Investigating Officer (IO), and confirming the details.
	Note: RDOT Audit team will also advise FSA Finance that the audit is under appeal.

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Stage 1 Appeal	Action
IO reviews the supporting evidence supplied by the FBO	The IO will consider if the appeal has sufficient evidence to continue, if not the FBO will be notified that the appeal will not progress any further.
	IOs will focus on scores challenged and the submission of evidence to carry out the investigation.
	The IO is not obliged to examine other aspects of the audit to which the appeal is related; however, as findings are sometimes interrelated the IO will take these into account where it is appropriate to do so. The IO will not overlook other relevant information which may be used to inform any decision made.
IO conducts an investigation	The IO conducts an investigation and completes a report before the last date for completion (stated in part 1 of the appeal request form).
	The IO will determine which considerations should be made when making the assessment. Examples as follows:
	refer to audit notes
	 request documents from FSA / FBO
	 discuss with auditor and FBO
	 visit an establishment or not; telephone interviews may be sufficient to clarify doubts
	Note: IOs should always consider visits to premises where serious concerns are arising, such as critical or multiple major NCs.
Investigation outcome	On conclusion, the IO distributes their completed report to CSU York, who will take the necessary actions, depending upon the outcome of the IO's investigation.
	CSU York will email the IO's report to the FBO, (including any amended audit report if applicable) and copy the correspondence to the AVL and the Operations Head Veterinarian.
	The IO is responsible for discussing the investigation findings with the AVL, auditor and the FBO (or their representative) regardless of whether the investigation report resulted in an amendment or the score was upheld.

5.4.3 Stage 2 appeals

FBOs can request a Stage 2 appeal when they are not satisfied with the outcome of the stage 1 appeal.

A £250 fee is payable by the FBO for a stage 2 appeal process as a contribution to the FSA's costs. Stage 2 appeals will not commence until the fee has been paid. If the review/appeal rules in the FBO's favour and the audit frequency has been changed the £250 will be refunded. If the appeal changes the outcome of some sections, but this does not lead to a change in the overall audit outcome, the fee will not be refunded.

Stage 2 Appeal	Action		
FBO exercises their right to appeal at stage 2	FBO notifies RDOT Team Audit Coordinator in writing (for example, via email or post) within 7 calendar days of receiving the stage 1 outcome notification of his intention to appeal the stage 1 outcome. The required £250 payment should also be enclosed.		
RDOT receives FBO written confirmation and	On clearance of payment RDOT will contact an independent IO appointed by the FSA to carry out the investigation.		
payment	Stage 1 appeals pack is sent to Independent IO for review.		
Independent IO	The appeal will be determined within 14 calendar days by the independent person nominated by the FSA.		
	The nominated person:		
	 will give the business and the FSA an opportunity to make representations on the matter to be determined 		
	will determine the matter concerned		
	 will notify the FBO and the Operations Head Veterinarian of the final decision 		
	If the independent IO decides in favour of the FBO and provided the audit outcome has been changed the £250 fee for initiating the appeals process would be refunded to the business.		

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6. Annexes

N.B. These pages can only be accessed by FSA staff on FSA devices.

- Annex 1 <u>Audit aide memoire</u>
- Annex 2 Audit writing guidance
- Annex 3 Audit preparation Checklist
- Annex 4 Audit Checklist
- Annex 5 <u>Audit training notes</u>
- Annex 6 FBO audit cancellation letter template