# Criteria for

# Food Safety Management Systems

# Auditor/Lead Auditor Training Course

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## Glossary

Successful completion of a Food Safety Management System Auditor/Lead Auditor training course will satisfy the training requirements for SAATCA certification to all grades of Food Safety Management Systems (FSMS) auditor.

## Authorization

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|---|---|
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## BACKGROUND TO THIS COURSE

The purpose of this training course is to provide food safety professionals with the skills and knowledge necessary to audit management systems within a food safety context.

Although there is a clear, identifiable trend toward adopting a systematic approach to the regulation of food safety, at present there is little commonality internationally amongst current practices, with a great many different standards and guidance documents in use, including rating systems, point systems and a variety of management systems and management system guidelines.

There are well-publicised problems with the currently available standards and the associated inspection and audit practices:

- The relationship between management system elements, hazard assessment tools and other food safety activities is often confused both by the organization and auditor.

- Generally across all the standards there is inadequate analysis of food safety issues and reliance on a checklist approach.

- Many organizations report inconsistency of ongoing inspections and audits and there are often large variations in the qualification, experience and competence of inspectors and auditors.

- The differences between the approaches to the implementation and assessment of each of these food safety systems based on the various standards may be large or small, but there is a real need for international agreement on equivalence of available standards or the adoption of a single standard.

This course is based on SABS 0330:1999 HACCP, SABS 049 Food Hygiene Management, ISO 9001, ISO 15161, ISO 19011 and the **National Legislation**, but until such time as ISO issues a Food Safety Management System Standard we have taken the position that current audit activity of a food safety management system will often require the auditor or audit team to recognize a wide variety of system components.

ISO 15161:2002 (*Guidelines for the implementation of ISO 9001:2000 for the food and drink industry*) provides an interim arrangement and this is possibly the best guide for the food safety management systems auditor at this point.

The food safety management system auditor's task is likely to be a complex one, at least until a common approach is accepted, with audit activity having to take into account many different systems, practices and procedures that support food safety, compliance to food safety legislation and other food safety requirements.

Whatever is actually in place within an organization, there is a need to recognize that food safety priorities must form the focus of the audit process. For many this will mean a transition from current, inspection-focused practice and require the development of new protocols for food safety management system audits, taking into consideration the new auditing standard (ISO 19011), which outlines a staged audit process.

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## 1. INTRODUCTION

1.1 We, the Southern African Auditor and Training Certification (SAATCA), have developed this document to help you, the Training Course Provider, achieve certification of a ***Food Safety Management Systems (FMS) Auditor/Lead Auditor*** training course.

1.2 Before designing a ***FMS Auditor/Lead Auditor training course*** to meet the requirements of this document you should consider the following:

1.2.1 ISO 15161:2002 and/or SABS 0330:1999 provides industry with a useful guide for managing and reducing the risks to health resulting from food-based operations.

1.2.2 The principal aim of this course is to help students with a food industry background to assess the adequacy of the design, implementation and improvement of a food industry organization's food safety and quality management system against ISO 9001:2000 and SABS 0330:1999 HACCP, using ISO 15161:2002 as a guide, in accordance with ISO 19011.

1.2.3 The focus of this course must be on evaluating the effectiveness of a FMS through interpretation of ISO 9001:2000 and SABS 0330:1999, using ISO 15161:2002 as a guide, in the context of the scope of an organization's management arrangements, its legislative framework and the significant hazards of its operational processes.

1.2.4 We understand that there are a variety of food safety management's system specifications in existence. If you wish to base your course on an alternative specification, this will need to be approved by SAATCA in advance of any presentations.

1.2.5 This course is not intended to be an implementer's course, or one that will create an expert in food safety legislation, or one that will train to an acceptable level a student with no prior knowledge of the standard or of the food industry.

1.2.6 Your training course must be designed and delivered in accordance with the criteria in this document, although you may exercise flexibility in the inclusion of additional learning objectives, additional material, and in the structure and selection of specific training methods used during the course.

1.3 We would be pleased to review your proposed approach and course outline before you begin detailed course development to help ensure that your final training product will meet the requirements in this document. The application fee must be paid before we will review any proposed course outlines.

## 2. PRIOR KNOWLEDGE REQUIREMENT

2.1     This course is designed for experienced food safety professionals seeking an understanding of the management systems approach to food safety and the skills required to audit effectively against food safety management systems standards.

2.2     Therefore, prior to attending this training course students must:

2.2.1     Have experience working in the food/drink industry, preferably with an understanding of implementing or operating a management system.

2.2.2     Have an understanding of relevant key food safety legislation (this may be specific to their food industry context and location).

2.2.3     Have an understanding of prerequisite programmes.

2.2.4     Have an understanding of Good Manufacturing Practices (GMPs).

2.2.5     Have an understanding of the principles of HACCP (SABS 0330:1999).

2.2.6     You must inform prospective students of the required pre-course knowledge and provide clear guidance for tutors, who find that they have students lacking this prior knowledge, to ensure that this does not adversely affect other students' learning on this course.

## 3. LEARNING OBJECTIVES

3.1    Learning Objectives describe in outline what students shall be able to do by the end of the course. Students will need to demonstrate acceptable performance in all of these areas in order to complete the course successfully, and you will need to demonstrate a factual and objective approach to the assessment of student performance against the following.

3.2    By the end of the course students will be able to:

### Knowledge:

3.1.1   Describe the fundamental purpose of a food safety management system as well as the principles, processes and techniques used for the assessment and management of food safety hazards, including the significance of these for FMS auditors.

3.1.2   Explain the purpose, content and interrelationship of the following: management system standards (the ISO 9000:2000 series); guidance documents (ISO 15161:2002); industry practice; standard operating procedures; and the legislative framework relevant to a FMS.

3.1.3   Explain the role of an auditor to plan, conduct, report and follow up and food safety management systems audit in accordance with 19011 (see 4.3).

### Skills:

3.1.4   Interpret the requirements of ISO 9001:2000 (with ISO 15161:2002 as a guide) in the context of an audit an organization's FMS (see 4.4), with particular reference to:

- The effectiveness of the organization's management of risk through its food safety risk assessment programme.

- The capability of an organization to maintain and exceed compliance with legislative requirements.

- The adequacy of the organization's emergency preparedness and response.

- The implementation of operational hazard control, monitoring and measurement.

- The continuous improvement of food safety management system performance.

3.1.5   Plan, conduct, report and follow up a food safety management system audit in accordance with ISO 19011.

## 4. ENABLING OBJECTIVES – KNOWLEDGE & SKILLS

In order for students to achieve the overall Learning Objectives, they will need to acquire and develop specific **knowledge** and **skills.**

These are specified below as Enabling Objectives and can be considered as steps to the achievement of Learning Objectives.

4.1     Describe the fundamental purpose of a food safety management system and explain the principles, processes and techniques used for the assessment and management of food safety hazards, including the significance of these for FMS auditors.

4.2     **Knowledge**

4.2.1   Describe the purpose and business benefits of a food safety management system, which includes managing and reducing hazards.

4.2.2   Describe background and general food safety issues, including:

   a.   The concept of food safety risk management as a strategic business driver.

   b.   The historical and social aspects of public health and food safety provision.

   c.   International frameworks and protocols for the safe provision of foods.

   d.   General food microbiology and hygienic food practices.

   e.   The typical hazards associated with the full range of food products from primary production to consumption.

   f.   The application of food safety management principles and relevant management tools and techniques.

4.3     Explain the purpose, content and interrelationship of the following:

   -   management system standards (the ISO 9001:2000 );

   -   guidance documents (ISO 15161:2002); industry practice;

   -   standard operating procedures; and the legislative framework relevant to a FMS.

### Knowledge

4.3.1   Explain the purpose and intent of the ISO 9001:2000 and how it interrelates with the other ISO 15161:2002 and/or SABS 0330, distinguishing between guidance and requirements.

4.3.2   With regard to ISO 9001:2000 and ISO 15161:2002:

a.   Explain the principles of HACCP SABS 0330:1999,

b.   the 8 principles of quality management, the process approach and the Plan, Do, Check, Act (PDCA) cycle.

c.   Explain the structure, intent and requirements of each clause of ISO 9001:2000 and/or ISO 15161:2002 and/or SABS 0330

d.   Explain the benefits of documenting a food safety management system and suggest approaches for doing so in a variety of situations.

e.   Explain the difference between legal compliance and conformance with ISO standards, including the significance of these terms when conducting audits.

4.3.3   Outline other applicable food safety management standards and guidance.

4.3.4   Outline the framework of relevant regional, national and local legislation, codes of practice etc., and the interaction between the food organization and the relevant authorities.

4.4   Explain the role of an auditor to plan, conduct, report and follow up an audit in accordance with ISO 19011.

### Knowledge

4.4.1   Describe the structure of the FMS certification industry, including:

a)   The differences and commonality in the purpose, scope and conduct of 1st, 2nd and 3rd party and regulatory audits.

b)   The International Accreditation Forum interpretations and guidelines for 3rd party Certification Bodies (Registrars).

c)   The system of accredited certification (registration), including the functions of the Accreditation Bodies and Certification Bodies (Registrars).

d)   The existence of private schemes and their differences in content and operation as prescribed by the scheme owners (e.g. BRC, EUREPGAP).

e)   The role of SAATCA in the approval of training courses and certification of auditors, including an outline of the SAATCA FMS auditor certification requirements as defined in, *Certification Requirements for Food Safety Management Systems Professionals.*

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4.4.2   Describe the role of the auditor, including:

 a)   The roles and responsibilities of the client, auditors, lead auditors, auditees and guides in accordance with ISO 19011, including the management responsibilities of the lead auditor in managing the audit and the audit team.

 b)   The need for effective communication with the auditee, for auditor confidentiality, and for auditors to be sensitive to local customs throughout the audit process.

 c)   The SAATCA code of conduct.

4.3.3 Describe the process of planning an audit:

 a)   Describe typical forms of pre -audit contact, their purpose and when they might be appropriate.

 b)   State the purpose of document review/stage one audits and describe a typical document review process and outputs.

 c)   Explain the purpose and significance of the audit scope, the importance of team competency and selection of team members particularly with regard to specific process knowledge and relevant food safety regulations and legislation.

 d)   Explain the use, benefits and potential limitations of a process-based checklist (or alternative), and considerations for planning an audit of an activity for which there are no documented procedures.

4.4.3   Describe the process of conducting an audit:

 a)   Describe the purpose of, typical content of, and attendees typically present at audit meetings, including opening and closing meetings, audit team meetings and auditee feedback/review meetings.

 b)   Explain the process of, and different methods for, gathering objective evidence during an audit, including the benefits and limitations of sampling.

 c)   Explain the typical role of top management in an audit and suggest approaches for auditing top management commitment.

4.4.4   Describe the process of reporting and following up an audit:

 a)   State the purpose and typical content of a non-conformity report, and describe typical systems for grading non-conformity reports, including the implications and further actions required for different grades of non-conformity.

 b)   Explain the terms correction, corrective action and preventive action and describe the roles and responsibilities for taking and verifying corrective action.

 c)   Identify types of objective evidence that may be required to demonstrate effective implementation of corrective and preventive action.

 d)   Explain the purpose of ongoing surveillance visits.

**Skills**

4.4.5 Determine the legislative and regulatory items appropriate to specific food and drink activities and the appropriate activities for an organization to maintain compliance with legislative and regulatory requirements.

4.4.6 Evaluate the appropriate attribution of risk to identified hazards and the effectiveness of the organization's management of risk through its food safety risk assessment programme.

4.4.7 Determine appropriate operational control(s) for specific food safety hazards and evaluate the implementation of operational risk control, monitoring and measurement.

4.4.8 Identify potential emergency situations for specific food and drink activities and evaluate the appropriate planning and capability of an organization to respond to emergency situations.

4.4.9 Evaluate the capability of an organization to maintain compliance with legislative requirements.

4.4.10 Identify appropriate monitors and measures for the operational control of specific food safety hazards and evaluate the organizations measures of performance for management system activity.

4.4.11 Evaluate the continuous improvement of food safety management system performance and evaluate performance improvement.

4.5 Plan, undertake and report an audit of a food safety management system in accordance with ISO 19011

**Lead Auditor Skills**

4.5.1 Undertake the role of an auditor and/or audit team leader to plan an audit:

   a) Identify the pre-audit information required to plan the duration and resources needed to conduct the on-site audit and write an audit scope.

   b) Prepare an on-site audit plan that is appropriate to the sequence and interaction of the organization's processes, their food safety hazards aspects, and produce a process-based audit checklist (or alternative).

   c) Perform a document review or stage one audit in order to assess whether documentation meets the requirements of ISO 9001:2000/ISO 15161:2002/SABS 0330 and to determine whether adequate arrangements are in place to justify proceeding with the implementation audit.

4.5.2 Undertake the role of an auditor to manage and conduct an audit to evaluate an organization's effective implementation of processes, procedures and methodologies for conformance with ISO 9001 in a food industry context, including those areas described in 4.4 above:

   a) Participate in and demonstrate ability to control opening and closing meetings.

   b) Make sense of the information gathered in the context of ISO9001:2000/ISO15161:2002/SABS 0330 and the audit organization by:

      - gaining an understanding of its processes, including their purpose, inputs, outputs, controls and related performance indicators

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- selecting sufficient and relevant samples
- reviewing appropriate documents
- differentiating between documentation and records
- exercising objectivity in the review of evidence collected.


c) Demonstrate effective interpersonal skills and interview techniques through ability to:
- build rapport with the auditee
- use appropriate types of questions and listen effectively
- make notes, use a checklist effectively and follow audit trails
- provide feedback to the auditee
- be sensitive to the needs and expectations of the auditee, including the local customs and culture.

4.5.3   Undertake the role of an auditor to report and follow up the audit:

a) Evaluate objective evidence gathered and correctly identify conformance and non-conformance with requirements.

b) Recognise and report positive audit findings and opportunities for improvements.

c) Write a meaningful and accurate summary report of the audit including graded non-conformity reports based on objective evidence obtained during the course of the audit.

d) Make recommendations for certification/supplier approval based on audit findings.

e) Present audit findings and recommendations to the client.

f) Evaluate proposals for corrective action and differentiate between correction, corrective and preventive action.

g) Establish what follow-up activities will be required after the audit.


## 5. TRAINING METHODS

5.1   Training must be highly participative to allow all students to practise new skills and apply new knowledge to enhance their learning.

5.2   Therefore the training methods you select should involve and engage students throughout the duration of the course:

5.1.1   Students must participate in skills -based practical activities for a minimum of 50% of the course duration.

5.1.2   All students must practise the skill-based elements of the course (defined in sections 3 and 4) through participation in appropriate practical activities.

5.1.3   Knowledge-based sessions may be tutor led, but your course must allow interaction with students, so that tutors can test learning and students can clarify their understanding, as required.

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5.1.4   Skill-based content must be covered through the participation of all students in appropriate practical activities.

5.1.5   Skills content may be supported by tutor input sessions to address the underpinning knowledge requirements, e.g. best practice techniques for running meetings, interview techniques, etc.

5.3   Your course must include methods for monitoring each student's achievement of the Learning Objectives, for providing timely feedback to students and for individual coaching (where necessary).

5.4   Any training aids that you use, such as videos that are directly relevant, may be used to supplement the training by the tutors. These may be commercial training videos or videos produced during the course to record and review the performance of students.

5.5   You may not devote more than three hours of the total course time to these non-interactive, passive training aids.

5.6   Timekeeping, planning and programme management are essential elements in the performance of an audit and, although we recognise that effective training is responsive to students' needs, deviations from the timetable must be managed so that all learning objectives are adequately covered and students are kept informed of significant changes.

5.7   Tutors must set a good example to students and maintain good discipline and timekeeping throughout the course.


## 6. COURSE CONTENT

6.1   At the beginning of the course you must provide the students with a description of the Learning Objectives, course structure, format and programme, student responsibilities and the assessment processes and assessment criteria.

6.2   The course must cover:

6.2.1   All aspects defined in Clause 3 Learning Objectives and amplified in Clause Enabling Objectives.

6.2.2   Local requirements, culture, practices or approaches to auditing and the application of ISO 9001 and ISO 15161 and SABS 0330, and food safety requirements/legislation appropriate for each country in which the course is presented.

6.2.3   You must demonstrate that your course meets this requirement for each national/regional context in which it is presented.

6.2.4   The course must cover the benefits of certification as an SAATCA FMS auditor, including brief details of the SAATCA *FMS Management Systems Professional* certification scheme, and provide students with details of how to contact SAATCA and apply for certification.


## 7 COURSE DURATION

7.1   The minimum course time is **40 hours**, over 5 consecutive days unless agreed in advance and in writing by SAATCA.

7.2 However, we recognise that it may be possible to cover the **Learning and Enabling Objectives** in a shorter time when there are fewer students and you may build this flexibility into your course programme.

7.3 Regardless of training methods and student numbers, it is unlikely that the requirements of these SAATCA criteria can be achieved where the overall duration is less than **36 hours**.

7.4 Although not mandatory, we recommend that this course be residential.

7.5 All students must be in attendance for the full duration of the course in order to successfully complete it.

## 8. TUTORS & STUDENTS

8.1 Student numbers:

    8.1.1 The maximum number of students per course is 20.

    8.1.2 The minimum number of students per course is 4.

    8.1.3 Where the number of students is 11 to 20 inclusive, the course must be run with two designated tutors, both of whom must be present for the full duration of the course. At least one tutor must satisfy the requirements for a Lead or Food Safety Management System Auditor.

    8.1.4 Additional resources or trainee tutors may be used for specific activities, however the two designated tutors remain responsible for the entire presentation,

    8.1.5 Where the number of students is 4 to 10 inclusive, the course may be run with one designated tutor, who must be present for the full duration of the course. That tutor must satisfy the requirements for a Lead Food Safety Management System Auditor

    8.1.6 Tutors must have knowledge of the specific local regulatory requirements in which the course is presented.

8.5 Tutors for this course must demonstrate competence in key attributes:

    8.5.1 Competence in Training; by satisfying the Lead Food Safety Management System Auditor requirements as appropriate.

    8.5.2 Competence in Auditing against ISO 9001 & HACCP SABS 0330:1999 in a food industry context; by demonstrating auditing competence as a currently certified Lead Food Safety Management System Auditor as meeting the requirements for such certification.

## 9. VARIATIONS

9.1 We will consider requests for variations to any of these criteria, or in respect of any special circumstances. In this situation you should submit a **written** request to us immediately the requirement for the variation becomes apparent.

9.2 We will consider the following when evaluating any request for variation:

    9.2.1 Reasons for the requested variation.

9.2.2    Proposed modifications to the training.

9.2.3    The impact on the learning and assessment processes and how this will be managed.

## 10. Student Assessment & Examination

We regard the assessment and examination of students to be a very important part of this course. SAATCA Food Safety Management System Auditor examination papers must be APPROVED by SAATCA

The benefits are many:

**Students** receive feedback on their performance during the course, helping them to identify their strengths and weaknesses and accelerate their learning.

-    **You** benefit from providing an added-value course.

-    **SAATCA** can be confident that it certifies potentially competent auditors, based on the student assessment that you perform.

-    **Industry** benefits from competent auditors.

10.1    In order to satisfactorily complete the course each student must:

10.1.1    **Complete all elements of the course:** covering all Learning and Enabling Objectives.

10.1.2    **Pass the Continuous Assessment:** Students must demonstrate acceptable levels of performance in the **Learning Objectives**

10.1.3    Some of these requirements will be tested in the examination, but you must incorporate the testing of skills –based Learning Objectives into formal continuous assessment processes.

10.1.4    **Pass the written Examination:** One of the SAATCA Approved set of FMS papers supplied by the Course Provider: Students must sit one of the current issues of SAATCA Approved FMS papers. The FMS examination paper must have three sections. (Multiple choice, Essay questions and scenarios.

10.1.5    All questions should be attempted, a maximum of 100 marks is available, and the pass mark is 70. The Course Provider should provide students with guidance on examination technique before the examination.

10.1.6    The Course Provider must develop 2 examination papers and model solutions together with a specimen paper with answers, and submit these for our approval before their use.

## 11. COURSE PUBLICITY & ADVERTISING

11.1    Your course advertising and promotional literature must not state or imply that this course satisfies more than the training requirements for certification as an SAATCA FMS auditor.

# APPENDIX

**Auditing Food Safety Risk and Controls**

We expect your course to test students' ability to audit an organization's risk assessment of product and process and determine the appropriate controls for the specific hazards.

Simple examples limited to physical/foreign object risks will not suffice and we expect to see some basic technical aspects such as chemical or microbiological hazards in the case studies and examples you select, even if this is at a simple level.

**Learning Objectives & Enabling Objectives in Session Plans & Continuous Assessment**

The steps below shows how the overall Learning Objectives of a course cascade down to facilitate the formal assessment of student performance, and the linkages between the Learning Objectives, Enabling Objectives, session plans and formal assessment of student knowledge and skills.

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**1. Overall Course Objectives**.

The overall Learning Objectives summarise the overall aim of the course. At the beginning of the course students must be informed that they need to achieve all of these Learning Objectives and must be informed of the way in which their achievement will be assessed, i.e. through an examination and continuous assessment of knowledge and skills.

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**2. Session Plans.**

The Learning Objective(s) for each session of the course should be stated in tutor notes. These Learning Objectives may be supported by knowledge and skills-based Enabling Objectives. A sample session plan is provided below.

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**3. Assessing Student Achievement of Learning Objectives.**

Formal assessment of student achievement of the Learning Objectives must be included at appropriate points in the course. Each student's achievement of these objectives must be assessed through written or practical work, validated objectively by the tutor(s) against set criteria (e.g. marking schemes). Students must achieve each of the Learning Objectives to pass the course.

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***Examples of formally assessed written work include:***

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Analyses of case study scenarios; production of audit plans/programmes; production of audit checklists; producing non-conformance reports.

Student output shall be measured against set criteria, e.g. model answers or marking schemes.

***Examples of formally assessed practical assignments include:***

Conducting audit interviews; conducting audit meetings; managing an audit team. The performance of students in these activities must be measured against set criteria. These criteria could be based on the Enabling Objectives.

**Note** that the knowledge-based objectives are formally tested in the examination but may also be included in the formal continuous assessment process to facilitate feedback to students and aid learning.

**Note** also that not every Learning Objective will be tested on a daily basis. It may be useful for course designers to write a conformance matrix to ensure that student achievement of the Learning Objectives have been included and formally assessed during the course.

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### 4. Recording Student Achievement.

Each student's performance in the Learning Objectives must be recorded on his/her continuous assessment form. Students must be informed if their performance in any Learning Objective is unacceptable and be provided with opportunities to improve.

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