

Requirements for Recognition of Hygiene Rating Audit Agency

Hygiene Rating Scheme

(For Food Establishments)



QUALITY COUNCIL OF INDIA

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**PADD: HRAA: PR: 02: Requirements for Recognition of HRAA
70345/2023/REGULATORY-FSSAI**

1. Scope

This document elaborates on the requirements to be fulfilled as pre-requisite for the recognition of the Hygiene Rating Audit Agency (HRAA) operating the Hygiene Rating Scheme, hereinafter referred to as Scheme.

2. Objectives

The criteria described in this document shall form the requirements and shall be complied by the Hygiene Rating Audit Agency, in addition to the Roles and Responsibilities of Audit Agencies and Auditors prescribed in Chapter 3 of the FSSAI – Hygiene Rating Scheme document.

3. General requirements

3.1 Legal responsibility

3.1.1 The Hygiene Rating Audit Agency shall be a legal entity, or a defined part of a legal entity that can be held legally responsible for its audit activities.

3.1.2 Hygiene Rating Audit Agency which is a part of government, or government department, shall be deemed to be legal entities on the basis of their governmental status. The status and structure of such bodies shall be formally documented and the bodies shall comply with all the requirements of this document.

3.1.3 The recognition shall be granted to a legal entity, who can be legally held responsible for its work irrespective of whether the entire organization or a part of it performs the audit activities.

3.2 Impartiality and independence

3.2.1 Audit activities shall be undertaken impartially. The top management's commitment to impartiality shall be demonstrated by documenting the HRAA's policy on safeguarding impartiality and ensuring that it is understood at all levels of the organization and making available its policy on impartiality, to the public through its website.

3.2.2 The Hygiene Rating Audit Agency shall be responsible for the impartiality of its audit activities and shall not allow commercial, financial or other pressures to compromise impartiality. The HRAA shall not have any direct relationship with the Food Establishments (FEs) other than audit activities as a third-party conformity assessment body.

3.2.3 The Hygiene Rating Audit Agency shall identify the risks to its impartiality on an ongoing basis. This shall include the risks that arise from its audit activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a Hygiene Rating Audit Agency with a risk to impartiality.

PADD: HRAA: PR: 02: Requirements for Recognition of HRAA
70345/2023/REGULATORY-FSSAI

- 3.2.4 A relationship that threatens the impartiality of the Hygiene Rating Audit Agency can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.
- 3.2.5 If a risk to impartiality is identified, the Hygiene Rating Audit Agency shall enable to demonstrate how it eliminates or minimizes such risk.
- 3.2.6 The Hygiene Rating Audit Agency shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions, it shall meet the minimum requirements as given below:
- a. The Hygiene Rating Audit Agency, and its personnel shall not engage in any activities that may conflict with their independence of judgment and integrity in relation to their audit activities. In particular, they shall not be engaged in the design and establishment of a FE, supply, purchase, installation, maintenance of equipment or services used in a FE and prohibited from any kind of consultation or offering training.
 - b. A Hygiene Rating Audit Agency shall not be related to an entity that is engaged in the design and establishment of a FE, supply, purchase, installation, maintenance of equipment or Services used in an FE including any kind of consultation or training.

Note

- i.HRAA and its related bodied are not allowed to impart any kind of in-house training programs to any FE.
- ii.HRAA and its related bodies may conduct open house programs subject to the condition that those trainings are not imparted to FEs.

3.3 Confidentiality

- 3.3.1 The HRAA shall have a documented policy and mechanism to safeguard the confidentiality of information obtained or created during the course of audit activities. It shall also be part of the audit agreement.
- 3.3.2 Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the HRAA's behalf, shall keep confidential on all information obtained or created during the performance of the HRAA's activities. There shall be a mechanism such as obtaining signed confidentiality agreements, etc, for ensuring the same.

PADD: HRAA: PR: 02: Requirements for Recognition of HRAA

70345/2023/REGULATORY-FSSAI

4. Administrative Requirement.

4.1 Audit agreement

4.1.1 The HRAA shall have a legally enforceable agreement for the provision of audit activities to the Food Establishments (FEs). Audit agreements shall consist of the responsibilities of the HRAA and its clients (FEs).

4.1.2 The HRAA shall ensure that its audit agreement specifies the requirements to be complied by the FEs as mentioned in the following:

- a. Fulfilling the scheme requirements as specified in the “Hygiene Rating Scheme”, and the changes notified by the HRAA, time to time;
- b. Make all necessary arrangements to conduct audits, including provision for examining documentation and the access to all processes and areas, records, and personnel for the purposes of initial audit, surveillance, renewal audit and resolution of complaints.
- c. Make provisions, where applicable, to accommodate the presence of observers (e.g. QCI assessors or trainee auditors)
- d. When the HR scheme introduces new or revised requirements both in audit criteria and audit process requirements that affect the applicants and the rated FEs, the FEs shall implement the changes in its systems, necessitated by these changes.
- e. The FEs shall inform to the HRAA during the contracted period, without delay in the event of any of the following:
 - i. Changes and / or modifications of premises.
 - ii. Major changes in the internal control measures.
 - iii. Major changes in the system which could have bearing on implementing the pre – requisites such as Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP) as per the Schedule IV of FSS (Licensing & Registration) Regulations, 2011 and amendments thereto of FSSAI.

4.1.3 The HRAA shall document procedures for providing the information about audit status to the FEs. It shall also identify the aspects that would be considered as misleading and unauthorized as relevant to the relevant Hygiene Rating Scheme. The audit agreement shall make appropriate cross reference to the scheme requirement to make it legally binding.

4.1.4 Audit Fees

- i. The fee shall be charged to the FEs in a non-discriminatory manner.
- ii. The HRAA’s fee structure shall be publicly accessible and also be provided on request of the FEs.
- iii. HRAA shall notify and obtain consent to its fee structure from its client / FEs prior to grant of audit. As and when the fee undergoes a change, the same shall be communicated to its clients including applicants and the FEs already rated for hygiene rating scheme for their acceptance.

PADD: HRAA: PR: 02: Requirements for Recognition of HRAA
70345/2023/REGULATORY-FSSAI

- 4.1.5 Liability Provisions- Hygiene Rating Audit Agency shall also be able to provide sufficient evidence to demonstrate its stability. The Hygiene Rating Audit Agency shall have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations.

5. Structural Requirements

5.1 Organization and management

- 5.1.1 The Hygiene Rating Audit Agency shall be structured and managed to safeguard impartiality, where the Hygiene Rating Audit Agency forms a part of a legal entity performing other activities, the relationship between audit activities and other activities shall be defined in the organization chart or organisation structure. The Hygiene Rating Audit Agency shall have documented roles and responsibilities of the employee with their qualification and experience involved in the audit activities including the employee involved in hygiene rating scheme.

- 5.1.2 The Hygiene Rating Audit Agency shall organize and manage its capability to perform its audit activities.

- 5.1.3 The Hygiene Rating Audit Agency shall have available one or more person(s) as Subject Matter Expert (SME) or technical manager(s) who have overall responsibility to ensure that the audit activities are carried out in accordance with the scheme requirements. This person shall have a postgraduate in Food Science and/or Microbiology with 2 years of experience in the field of food safety.

- 5.1.4 The SME / Technical Manager in a HRAA to be technically competent and experienced in the operations of a HRAA and fulfils the responsibilities as mentioned in the clause

6. Resource requirements

6.1 Personnel

- 6.1.1 The required competence of Subject Matter Expert / Technical Manager and auditors shall be fulfilled according to the HR scheme requirement document. The Hygiene Rating Audit Agency shall have the documented competence requirements for the role SME / TE and the auditor. However, for ease of reference the same is mentioned below:

The following minimum requirements shall be met by the Hygiene Rating auditor, namely:

- a. Bachelor's degree in Food or Dairy or Fisheries or Oil Technology or Biotechnology or Agricultural or Veterinary Sciences or Bio-chemistry or Microbiology or Chemistry or Catering Technology or Hotel Management from a recognized university;
- b. Knowledge of the Food Safety and Standards Act 2006 and the rules and regulations made there under; sector specific knowledge of hygienic and sanitary practices,

**PADD: HRAA: PR: 02: Requirements for Recognition of HRAA
70345/2023/REGULATORY-FSSAI**

- c. processing techniques, hazards identification, analysis and control and knowledge of contaminants, allergens, etc.;
 - d. Any other additional requirement or mandatory training as maybe specified by the FSSAI.
- 6.1.2 The HRAA shall have at least three auditors with the mentioned qualification (refer 6.1.1).
- 6.1.3 The auditor must have at least 30 man-days audit experience in Schedule IV of FSS (Licensing & Registration of Food Business), Regulations, 2011
- 6.1.4 Auditor shall undergo and qualify mandatory auditor's training for Hygiene Rating Scheme conducted by FSSAI/QCI as a part of the recognition, on successful completion of the training, QCI shall grant the final recognition to HRAA.
- 6.1.5 The Hygiene Rating Audit Agency shall employ, or have contracts with, a sufficient number of persons with the required competencies, including, where needed, the ability to make professional judgements, to perform the type, range and volume of its audit activities.
- 6.1.6 The personnel responsible for audit shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the audits to be carried out. They shall also have relevant knowledge of the following:
- a. Operation of processes and the delivery of services.
 - b. End use of the product, processes involved and the services delivered;
 - c. Critical parameters on the use of the end products, any failures in the operation of the process and any deficiencies in the delivery of services.
 - d. They shall understand the significance of deviations occurred in the operation of the processes and the delivery of services
- 6.1.7 The Hygiene Rating Audit Agency shall make clear to each person their duties, responsibilities and authorities.
- 6.1.8 The Hygiene Rating Audit Agency shall have documented procedures for selecting, training, formally authorizing, and monitoring auditors and other personnel involved in audit activities.
- 6.1.9 The documented procedures for training (refer 6.1.8) shall address the following stages:
- a. an induction period.
 - b. a mentored working period with experienced auditors.
 - c. continuing training to keep pace with developing technology and audit methods.

Note: The period of training and being mentored for FSMS audits, QMS audits of Hotels/ restaurants, catering establishments and schedule IV of FSS (licensing and

PADD: HRAA: PR: 02: Requirements for Recognition of HRAA

70345/2023/REGULATORY-FSSAI

registration of food business) Regulations, 2011, audit will be reckoned for meeting the above requirement.

6.1.10 SME / Technical Manager shall monitor all the auditors and other personnel involved in audit activities for ensuring the satisfactory performance. Results of monitoring shall be used as a means of identifying training needs of the auditors.

6.1.11 Each auditor shall be observed onsite by the SME / TM, unless there is sufficient supporting evidence that the auditor is continuing to perform competently the hygiene rating audits independently.

Note: It is expected that on-site observations are performed in a way that minimizes the disturbance of the audits, especially from the FEs viewpoint.

6.1.12 The Hygiene Rating Audit Agency shall maintain records of monitoring, education, training, technical knowledge, skills, experience and authorization of each member of its personnel involved in audit activities.

6.1.13 The personnel involved in audit activities shall not be remunerated in a way that influences the results of audits.

6.1.14 The HRAA is permitted to empanel qualified external personnel meeting the competence criteria for carrying out audits; however, it is not permitted to sub-contract its activities to any organization.

6.1.15 The empanelled auditor shall not be linked with other HRAAs for audit activities as specified in the scheme, undertaking shall be submitted by the auditor at the time of empanelment.

6.2 Facilities and Equipment

6.2.1 The Hygiene Rating Audit Agency shall have available, suitable and adequate equipment to perform audit activities in a competent and safe manner. Auditor shall have the following equipment's for conducting an effective audit includes:

- i. A probe type thermometer with range from -25 degree C to +125 Degree C with marking of 1 degree centigrade.
- ii. A natural colour flashlight with minimum 800 lumen.
- iii. A magnifying glass with 10 X magnification.
- iv. A stopwatch to measure time where measurements are critical
- v. A camera with minimum 12-megapixel resolution or smart phone with minimum 10-megapixel camera with zoom function for capturing evidences for citing in the report.

Note: The Hygiene Rating Audit Agency need not be the owner of the facilities (except the smart phone) or equipment that it uses. Equipment can be borrowed, rented, hired, leased or provided by another party (e.g. the manufacturer or installer of the equipment). However, the responsibility for the suitability and the calibration status of the equipment used in audit, whether owned by the Hygiene Rating Audit Agency or not, lies solely with the Hygiene Rating Audit Agency.

PADD: HRAA: PR: 02: Requirements for Recognition of HRAA

70345/2023/REGULATORY-FSSAI

- 6.2.2 The Hygiene Rating Audit Agency shall have rules for the access to, and the use of, specified equipment used to perform audits.
- 6.2.3 The Hygiene Rating Audit Agency shall ensure the continued suitability of the equipment mentioned in 6.2.1 for their intended use.
- 6.2.4 All equipment having a significant influence on the results of the audit shall be defined and where appropriate, uniquely identified. All equipment shall be maintained in accordance with documented procedures and instructions.
- 6.2.5 Where appropriate, equipment's measurement having a significant influence on the results of the audit shall be calibrated before use, and thereafter calibrated according to an established programme. The overall programme of calibration of equipment shall be designed and operated to ensure that, wherever applicable, measurements made by the Hygiene Rating Audit Agency are traceable to national or international standards of measurement, where available.
- 6.2.6 Reference standards of measurement held by the Hygiene Rating Audit Agency shall be used for calibration only and for no other purpose. Reference standards of measurement shall be calibrated providing traceability to a national or international standard of measurement.

7. Auditing

7.1 Audit Methods and Procedures

- 7.1.1 The Hygiene Rating Audit Agency shall adopt audit requirements as defined in Chapter 3 of the FSSAI - Hygiene Rating Scheme document. These are reproduced below.

Note: The requirements against which the audit is performed are those specified in Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011; requirements of Schedule 4.).

7.1.2 Audit Evidence

- i. Audit examination shall cover collection of objective evidence and documenting audit observations. Evidence can be collected through interviews, examination of documentation and observation of activities.
- a. Photographic evidence of documents must be captured in the software application.
- b. Each observation must be recorded in a software application.
- c. Interview notes with auditor comments must be captured

**PADD: HRAA: PR: 02: Requirements for Recognition of HRAA
70345/2023/REGULATORY-FSSAI**

- ii. Where the deficiencies or non-conformances are detected, they shall be documented clearly and concisely and shall define the regulatory requirements that are being contravened.
 - a. Each non-conformance must be recorded, and gap must be highlighted which can be viewed by both FEs and FSSAI.
 - iii. The Hygiene Rating Audit Agency shall examine the relevant documents related to test reports maintained by the FEs as part of compliance with various regulations made under the FSS Act.
 - a. The documents must be preferably photographed in the software application.
 - iv. The auditor must load the findings to the centralized repository maintained on behalf of FSSAI.
 - v. The non-conformities of the audit shall be classified into two categories, namely:
 - a. Major non-conformity- When there is a serious failure in the food safety management system of the FEs, which may result in adverse health consequence possibly even fatal, the auditor shall report such findings to FSSAI within 24 hours. FSSAI after ascertaining the seriousness of the situation shall take necessary action against the concerned FEs. The software application triggers an automated e-mail with audit finding to FSSAI as soon as the auditor submits the report online and the data syncs with the server.
 - b. Minor non-conformity- When there is a shortcoming in the food safety management system or regulatory contravention of the FEs, which may not cause any adverse health consequence, the auditor shall set up an appropriate timeframe for its rectification and follow up, so that the non-conformance shall be rectified.
- The software application has a built-in capability to define appropriate rectification timeframe. In-case, if the FEs fails to rectify the minor non-conformity within the specified timeframe it shall be referred to FSSAI.
- vi. The FEs shall respond with corrective actions for the non-conformances to the HRAA and FSSAI within 24 hours of conducting the audits in case of major NCs.
 - vii. The audits shall be conducted onsite. Online audits maybe carried out in exceptional cases to be considered individually.
 - viii. Audits shall be carried out with the appropriate checklist available on Hygiene Rating Portal under Hygiene Rating Scheme. The audit checklist/report shall be acknowledged by the FEs after the conduct of the audit done by the auditors.
 - ix. The Auditor shall upload the audit checklist in the portal with the registered login credentials and hygiene rating certificate shall be generated on successful submission of audit data.

PADD: HRAA: PR: 02: Requirements for Recognition of HRAA

70345/2023/REGULATORY-FSSAI

- x. The Hygiene Rating Audit Agency and the auditor shall register on the FSSAI – Hygiene Rating Portal for obtaining their login credential for the activity as mentioned in the above clause (viii).

7.1.3 The Hygiene Rating Audit Agency shall have documented procedure for planning of audits and the techniques involved in the audits to perform audit in safe manner.

7.1.4 All instructions, standards or written procedures, worksheets and reference data relevant to the work of the Hygiene Rating Audit Agency shall be maintained up-to- date and be readily available to the personnel.

7.1.5 When the Hygiene Rating Audit Agency uses information supplied by any other party as part of the audit process, it shall verify the integrity of such information.

7.1.6 Observations or data obtained in the course of audits shall be recorded in a timely manner so as to prevent loss of relevant information.

7.2 Audit records

The Hygiene Rating Audit Agency shall maintain a record system to demonstrate the effective fulfilment of the audit procedures and to enable an evaluation of the audit.

7.3 Audit Reports and Audit Certificates

7.3.1 After the verification process is completed, the HRAA can download the ‘ Verified Hygiene Rating Certificate’ and the handover the certificate to the FEs to display in the premise. Also, the Hygiene Rating Certificate will be send to the FBO’s registered email ID.

7.3.2 The Hygiene Rating Certificate generated from the FSSAI – Hygiene Rating Portal contains the following details:

- a. Identification of the issuing body (FSSAI)
- b. Unique identification and date of issue
- c. Date of audit
- b. Date of Certificate generated
- c. Name of HRAA
- d. Name of Auditor
- e. Validity of the certificate
- f. Identification of the areas/processes inspected
- g. Hygiene rating
- h. Signature or other indication of approval, by authorized personnel.
- i. QR Code

PADD: HRAA: PR: 02: Requirements for Recognition of HRAA
70345/2023/REGULATORY-FSSAI

8. Complaints and Appeals

8.1 Complaints

8.1.1 The HRAA shall have a documented process to receive, evaluate and make decisions on complaints.

8.1.2 A documented process for handling complaints shall be available to any interested party upon request.

8.1.3 Upon receipt of a complaint, the HRAA shall confirm whether the complaint relates to audit activities for which it is responsible and, if so, shall deal with it.

8.1.4 The HRAA shall be responsible for all decisions at all levels of handling complaints.

8.2 Appeals

8.2.1 Appeals against the decision of the HRAA to be first forwarded to the concern HRAA if unresolved to QCI and if not satisfied then the applicant may appeal to FSSAI. The timeline for the resolution of the appeals will be as under:

- a. HRAA- 15 days after appeal is made
- b. QCI- 15 Days after appeal is made
- c. FSSAI- 15 days after appeal is made

8.2.2 Investigation and decision on appeals shall not result in any discriminatory actions.



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PADD: HRAA: PR: 02: Requirements for Recognition of HRAA

Amendment Record

S No.	Date	Authorised by	Description of amendments
1.	24 Sep 2024	Joint Director	<ul style="list-style-type: none">i. Restructuring of documentation and editorial changes.ii. Updation of text in clause 3.2 for better understanding