PURPOSE: The internal auditing procedure has been designed to ensure that all the procedures laid down in the quality system documentation are being carried out, and that the quality system is adequate to implement the company's quality policies.

RESPONSIBILITY: It is the responsibility of the management to ensure that the following procedures are adhered to and understood by all relevant personnel and the personnel follow State or local health department requirements.

INSTRUCTIONS:

1. Whether conducted as a part of quality system accreditation, or in response to specific requirement by a major retailer, internal audit should be carried out to identify strength and weaknesses in the operating system and to clarify appropriate corrective actions.
2. Managers must not be allowed to audit their own department. If the internal audit of the factory is carried out by the qualified member of technical team, then a production or other designed manager must audit the technical department. By this method audit remains objective rather than subjective.
3. The audit and review of the production process to ensure the safe and legal production of products to an agreed specification must be part of ongoing, specific responsibility of all management.
4. The auditor must be appropriated trained.
5. Before starting an on-site audit, plan the audit. Review past audits, note indications of possible problem areas, and items, if any, that were identified for corrective action in a previous audit. If you are not already familiar with this facility, learn the type of product produced here and how it is organized by personnel and function. What does your "customer", i.e., your superior or senior facility management, expect to learn from this audit?
6. The checklist is to be used with a notebook into which detailed entries can be made during the audit.
7. While the checklist is to guide the auditor, is not intended to be a substitute for knowledge of the GMP regulations.

8. Although a single question may be included about any requirement, the answer will usually be a multi-part one since the auditor should determine the audit trail for several products that may use many different components. Enter details in your notebook and cross reference your comments with the questions.
9. At least three production batches should be selected for thorough analysis to include: (a) traceability of all components or materials used in the subject batches, (b) documentation of raw material or component, in-process, and finished goods testing for the subject product batches, (c) warehousing and distribution records as they would relate to a possible recall.
10. Internal audit reports shall identify and verify conformity as well as nonconformity.
11. Responses entered on the checklist should be consistent. "X" is recommended for "NO"; a checkmark for "YES"; "n/a" for not applicable to questions that do not apply. An asterisk and notebook page number should be entered on the checklist to identify where relevant comments or questions are recorded in your notebook.
12. The notebook used should be a laboratory-type notebook with bound pages. The notebook should be clearly labeled as to the audit type, date, and auditor(s). Many auditors prefer to use a notebook for a single audit so it may be filed with the checklist and the final report.
13. The references to sections in the GMP regulation are for your convenience should a question arise. In some instances, two or more sections within the GMP regulation may have bearing on a specific subject. The headings in the GMP regulation will usually offer some guidance on the areas covered in each section.
14. A general suggestion for a successful audit is to spend most of your time on major issues and a smaller portion of your time on small issues. There may be observations that you may wish to point out to supervisory personnel that deserve attention, but do not belong in an audit report because they are relatively insignificant. By the same token, *too many* small items suggest a trend of non-compliance and deserve attention as such. When citing these, be specific.
15. Audit checklist to include requirements accreditation bodies who the company work against.
16. Conformances and non-conformances must be recorded and distributed along with corrective actions and assigned responsibility for corrective action completion.
17. Each audit will be carried out accordingly to the schedule.

Audit schedule

	Quality Internal Audit	Traceability Audit	Food Safety Audit	Hygiene Audit
January	X		Daily	Daily
February		X	Daily	Daily
March			Daily	Daily
April	X		Daily	Daily
May		X	Daily	Daily
June			Daily	Daily
July	X		Daily	Daily
August		X	Daily	Daily
September			Daily	Daily
October	X		Daily	Daily
November		X	Daily	Daily
December			Daily	Daily

Quality Internal Audit Check list sample

Requirement	Conformity Y/N	Comments	Corrective action	Responsibility	Completion Date
Organization and Management Responsibilities					
Is there an appropriate quality control operation employed to ensure that food is suitable for human consumption and that food packaging material is safe and suitable?					
Is there a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated?					
Is there one or more competent individual(s) assigned responsibility for the supervision of the plant sanitation program?					

Is the responsibility for assuring compliance by all personnel with the requirements of the GMP regulation clearly assigned to competent supervisory personnel?					
Is there a formal, multidisciplinary plant food safety committee performing complete inspections of the entire facility at least monthly?					
Is a functional organizational chart maintained?					
Do all departments involved in implementing food product safety have adequate budgets established for the timely acquisition and maintenance of tools, materials, and equipment?					
Document Control					
Is there an adequate procedure for writing, approving, and distributing written procedures to the appropriate personnel?					
Is there a system for insuring the timely review of procedures and for the prompt removal of obsolete procedures from the system?					
Are there written procedures to delineate responsibilities of departments for implementing quality control/quality assurance?					
Are there written procedures to delineate responsibilities of departments for implementing the plant sanitation program?					
Are there specific procedures for the inspection of incoming raw materials?					
Are there written procedures for laboratory analysis and sampling, whether conducted in-house or by an outside laboratory?					
Are there written procedures or a written program for evaluating complaints of adulteration or misbranding?					
Are there written procedures to prevent adulteration of food or raw materials from pests or from the application of pesticides, rodenticides, insecticides, etc.?					
Are there written procedures, including schedules, for cleaning?					
Are there written procedures for handling regulatory inspections?					
Are all processing and production records reviewed and signed or initialed by a qualified					

representative of plant management no later than 1 day after the actual process and before shipment or release for distribution?					
Are records maintained of examinations of raw materials, packaging materials, finished product and supplier's guarantees for acidified foods?					
Are production and processing records showing adherence to scheduled processes maintained for acidified foods?					
Employee Orientation, Quality Assurance, and Job Training Program					
Do personnel responsible for identifying plant sanitation failures or food contamination have the combination of education and experience to produce clean, safe food?					
Do food handlers and supervisors have appropriate training in proper food handling techniques and food protection principles?					
Is there an orientation for new employees on food safety, employee safety and quality?					
Do temporary employees, contractors, and outside service personnel receive basic food safety training?					
Is there initial and periodic training for all who apply pesticides?					
Are employees instructed to report health conditions that might contaminate food, food product surfaces or food packaging materials to their supervisor?					
Are employees trained to protect against contamination of food by properly wearing suitable outer garments, hair nets, beard coverings, etc.?					
Are employees trained to wash hands thoroughly before work and after each absence from their work station?					
Are employees trained to remove unsecured jewelry and other objects that might fall into food?					
Are employees trained to confine eating, drinking, gum chewing, and use of tobacco to areas where food is not exposed or equipment and utensils are not washed?					

Plant Safety and Security					
Does the facility have a plant safety program?					
Are Material Safety Data Sheets readily available for all chemicals used in the facility?					
Are there written safety procedures?					
Is there adequate safety equipment in each area of the facility?					
Have employees and contractors received adequate safety training?					
Is access to the facility restricted?					
Is proprietary information identified and adequately secured?					
Are all computer systems regularly backed up and is the backup data stored in separate facility?					
Internal Quality System and Audit Program					
Does the facility have a Quality Policy?					
Is the Quality Policy distributed to all employees?					
Does the facility have a formal internal audit program?					
Is there a written procedure for internal audits that describes: who shall conduct the audits, the frequency of audits, how audits are documented, and the distribution of audit reports?					
Quality Plan					
Does the facility have a formal, periodic review of the quality plan?					
Does the facility have the capability through trained personnel, adequate accounting records and computer software to identify and capture quality plan?					
Is there a conscious effort to communicate quality cost savings to the workforce?					

MONITORING:

1. A designated employee will inspect that each employee is following this SOP.

CORRECTIVE ACTION:

1. Corrective actions assigned during the audits must be completed by the agreed, scheduled completion date.

VERIFICATION AND RECORD KEEPING:

1. Internal audit will be verified once the corrective actions are completed by the manager.
2. Internal audits will be reviewed during annual management review.

RECORDS APPLIED TO THIS PROCEDURE:

- Internal audit records.
- Refer to Internal Audit Checklist
  - Food Safety Audit Checklist
  - Hygiene Audit Checklist
- Refer to Internal Audit Record against
  - BRC Global standards
  - ISO 22000
  - ISO 9001
  - GlobalGAP

DOCUMENTATION RETENTION:

The records applied to this procedure are to be kept on file for a minimum of 3 years.