Managing Quality
of National Iodized Salt Supplies

Large and Medium-Scale Salt Industries

April 2012
Preface

With the ultimate aim to accelerate Universal Salt Iodization (USI) strategies in 10 selected countries, GAIN-UNICEF contracted ICCIDD, an international non-government organization solely dedicated to the elimination of iodine deficiency worldwide, and Intertek, a leading global provider of quality and safety solutions, to develop generic manuals with recommended protocols for ensured safety and quality of the iodized salt supplies for human consumption. This document presents these protocols and intends to assist salt producers and regulatory agencies, respectively, in their adoption and continuous development of Quality Management Systems (QMS) specific to the supply of quality iodized salt.

The document consists of three main parts:

- The first part is a generic Quality Manual for salt businesses
- The second part a generic Quality Manual for inspection (regulatory) bodies
- The third part, which immediately follows the manuals, consists of illustrative practical guidance to support the salt producers and regulatory agencies in their practical management of the quality of iodized food-grade salt intended for human consumption.

The global agreements and international standards have continuously expanded during the past few decades, along with the worldwide growth of industrial food manufacturing, increasing cross-border trade and rising expectations of product quality by consumers. Of the 192 United Nations (UN) member countries, more than 150 are full member of the World Trade Organization (WTO) and this list is continuously growing. In combination with the standard for food-grade salt in the FAO/WHO Codex Alimentarius, the current WTO and International Organization of Standards (ISO) agreements and standards offers an authoritative umbrella arrangement that can assist in effective improvement of national salt iodization strategies, while taking the interests of all stakeholders into account. Thus, ICCIDD used the WTO-ISO agreements as point of departure for describing what is required in salt industries who are interested to promote their manufacturing performance and in government agencies who are keen to develop effective systems to assure the safety and quality of the salt supply chain.

The salt production and supply situation in each country shows a wide variety in capacity and scale of salt businesses. Similarly, the set-up, capacity and outreach of food inspection agencies, the demands of the salt industry’s customers and the detailed quality requirements for the national iodized salt supply vary appreciably. Overall, the recommended systems and practices in this document are generic from each stakeholder’s perspective. In a next step, they need to become adjusted and tailored to the specific situation in each country.

ICCIDD and Intertek intend to continue their collaboration in the introduction of the guideline and manuals in the 10 countries of the GAIN-UNICEF Salt Iodization Project.

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# Table of Contents

I  INTRODUCTION ................................................................. 5

II  QUALITY MANUAL TEMPLATE FOR SALT BUSINESSES .............................. 11

III  QUALITY MANUAL TEMPLATE FOR INSPECTION BODIES ........................... 63

IV  MANAGEMENT OF THE QUALITY OF NATIONAL IODIZED SALT SUPPLIES ........ 121
   IV.A QUALITY ASSURANCE AND QUALITY CONTROL IN SALT FACTORIES ............ 121
   IV.B INSPECTION AND CONTROL OF NATIONAL IODIZED SALT SUPPLIES ........... 145

Appendices:

Appendix i  FAO/WHO Codex Alimentarius Standard for Food Grade Salt

Appendix ii  Determination of Total Iodine Titrimetric Method with Sodium Thiosulphate

Appendix iii  WYD Iodine Checker
I. INTRODUCTION

This document describes the generic management systems and recommended protocols for QA, QC and inspection of the production and national supplies of iodized salt for human consumption.

Salt, used as an ingredient in food, both for direct sale to the consumer and for food manufacture, has been defined as food-grade salt by the FAO/WHO Codex Alimentarius (Appendix i). Equivalent descriptions include edible salt, table salt, cooking salt and, less commonly, alimentary salt. For consistency throughout the text, this document refers to food-grade salt, as defined in the Codex Alimentarius or in a similar national standard. Food-grade salt consists predominantly of sodium chloride. It is obtained by dry or solution mining of underground rock salt deposits and by evaporation of sea water, salt lake water or natural brine.

Quality Assurance (QA)

Quality Assurance (QA) refers to the continuous, pro-active development and implementation of methods, procedures and coordinated actions in factories, aimed at quality of the end product according to standards or specifications. The objective of a Quality Management System (QMS) in the manufacturing industry is to always produce goods that satisfy the demands of customers and comply with the relevant legal standards. The major benefit of implementing a QMS is that the producer gets it right the first time, with no or minimum need for rework.

In this document, the QA description focuses on the set of specific activities in manufacturing iodized salt to ensure that the product prior to its release satisfies the expectations of the customers and meets the standards set by national regulators.

As a universal principle, each salt company is responsible for the design, introduction, development and systematic renewal of its QMS for iodized food-grade salt.

Quality Control (QC)

While QA applies to the totality of actions that concern quality salt manufacturing, Quality Control (QC) refers to making certain that the product does conform to the specifications desired by the industry's customers and in conformance with the national standards. In this document, QC consists of the set of activities to measure, verify and document that iodized food-grade salt satisfies these requirements. In regulating the national salt supply, the national food safety agencies use QC protocols as an integral element in inspecting the food-grade salt supply in salt factories, at the border, in food processing industries and in the market outlets where the population purchases their household salt.
In salt factories, QC is a subset of QA. Similar to QA, it is each salt company’s responsibility to conduct QC. The effective execution of a QA/QC system in salt factories permits the quick and timely correction of salt manufacturing when deviations from the set norms occur, while at the same time it produces evidence and enables reliable records of the results from QA/QC activities. Together, QA and QC lead to costs savings in the industry and improve the confidence of the industry’s customers in the uniform and proper quality of the product they desire.

**Inspection**

National regulations typically introduce the necessity to protect the public against the risk of purchasing impure, nutritionally inadequate, deceptively mislabeled or unsafe foods. Food control agencies in most countries have procedures for iodized food-grade salt inspections similar to the general food quality and safety inspections. When inspecting salt production facilities, the procedure includes assessments that the factory conducts an adequate QA/QC system, and that the iodine content in the iodized salt ready for release to customers conforms with the national standard. At the national border, the inspection of food-grade salt imports rests on similar principles to ascertain the trustworthiness of the supplier from a Certificate of Analysis (COA) and, as and when needed, an analysis of a salt sample to ascertain that the shipment conforms to its stated quality and the standard of the recipient country. Effective inspection systems help in preventing the supply, purchase and consumption of inferior iodized salt.

**Classification of the Salt Industry**

Several classification systems have been proposed in the course of time, most often based on the typical production capacity of salt factories relative to the size of the population using their products. Given the considerable variation in population size between countries and due to the increase in global salt trade, a classification of categories based on size or "capacity" only has proved less helpful than one that takes several management factors and market conditions into account. During the decade of the 1990s, MI and UNICEF developed the following description which has generally stood the test of time:

a. Small salt factories

- Production less than 1,000 metric tons (MT) a year: On average at most 3 MT a day throughout the year, or 10 MT a day if the business is seasonal. Amount of salt serves for ± 300,000 people. The factory is typically not officially registered. Manufacturing of salt is often complemented, or in lieu of, agricultural activities
- Uses artisanal methods, such as single-stage solar evaporation, harvesting of sedimentary lake salt or crushing of rock salt. Often "family" business without formal employees. The owners generally have a low level of education and literacy
The product consists often of large crystals and has a high level of impurities. The factory rarely has a sizable storage. Packaging mostly consists of jute bags, straw baskets or plastic sacks salvaged from other products.

Importantly, it should be noted that this document is not intended for improving the quality systems in small salt factories.

b. Medium salt factories

- Production between 1,000 and 5,000 MT a year: On average 3 to 15 MT a day, or up to 50 MT a day during the harvesting season. Serves from 300,000 to approx. 2 million people. The factory has been registered and provides income for the owner(s), who may employ up to 10 people on somewhat regular basis. Includes businesses that are run on cooperative basis by (very) small salt producers or artisanal salt farmers
- Uses manual or simple technologies, such as a pump (solar salt plants), grinder (lake or rock salt) or sometimes a roller or rotary drum. The factory typically has a small store for keeping finished product. There is simple book keeping to keep track of production and sales
- Packaging of a visibly "improved" (clean, white) product in various small-size plastic bags with a label and a brand name;

c. Large salt factories

- The factory has an annual production of more than 5,000 MT a year, or 15 MT a day. Although salt production may be seasonal (e.g. solar evaporation), product sales take place throughout the year. The factory is firmly established, registered, and provides employment for up to 30 people or more. Senior factory personnel is trained and their tasks are differentiated
- Mechanization is the norm; electrical or diesel mechanical equipment such as pumps, grinders, blenders, conveyers, up to fully automated spray iodization and packaging lines. Book keeping is professional. The company is registered, the food safety authority inspects regularly and profits are taxed
- The product is packaged in various large and small-size plastic bags with a label and a brand name. The quality is not necessarily superior to that of small- and medium-scale producers, however.

Standards and Measurements

QA, QC and inspections cannot be achieved reliably without proper measurements. A national standard typically includes the description of the required iodine content in iodized salt - for example “The level shall be X to Y parts of iodine per million parts of salt at its production and importation.” In this case, the X to Y range is “the standard” for iodine content in all the iodized salt that enters the national supplies, whether manufactured domestically or imported.

Measurements are needed for proper iodized salt manufacturing: Salt manufacturers should be able to determine the correct amounts of basic input salt and of fortificant, and the correct volume of water
needed for preparing a fortificant solution. These measurements are generally simple and for large and medium-size salt factories, the use of accurate measuring devices should present no obstacle. Also in small-size factories, such measurements can be performed inexpensively and with sufficient accuracy by using common containers such as plastic buckets and bottles with one or more marks for the amount (salt and fortificant) and/or the volume (water). In many instances, even small producers have been creative in making improvised devices for these measurements, which have proven to be sufficiently accurate for adequate quality iodized salt manufacturing.

Independent of size, salt factories should also be able to obtain measurements of the iodine content in the fortificant, in the salt during manufacturing, and in the final product stored in their warehouse. Because the standard is stated in quantity, these measurements must be sufficiently accurate and based on quantitative laboratory analyses.

The simplest, reliable and inexpensive analytical method for measuring the iodine content in salt is called iodometric titration. The procedure described in Appendix ii is directly applicable to this analysis. The same procedure can also be used for estimating the iodine content in the fortificant by mixing the fortificant with salt and correcting the analysis result for the dilution factor from mixing.

Large salt factories commonly have a side laboratory on site, for example for the analysis of humidity (water content), cleanliness (foreign particles such as dust and soil) and purity (contaminants) of their manufactured products. In such a case, the adoption of iodometric titration as an additional assay would be rather simple. In smaller factories, the WYD Checker can offer a dependable alternative. The description of the WYD Checker and the salt iodine measurement procedure with this instrument is included in Appendix iii.

In some factories, establishing a laboratory for salt titration or WYD Checker measurement may present an obstacle due to the needs for space and trained personnel. While training is obligatory in both cases, the WYD can be a better choice as the entire WYD equipment fits in one small zippered case. For reliable QC performance, the factory should at least invest in the WYD. Contracting or collaborating with an outside service laboratory for iodine measurements in salt and fortificant may seem an option but in reality it does not serve the purpose of swift decisions. QC results need to be instant in order to take immediate action while production is ongoing.

**Rapid Test Kits**

As the name indicates, rapid test kits (RTKs) offer a quick and simple way to test the salt for the presence or absence of iodine. Extensive studies, comparing RTK readings with titration measurements in a laboratory have confirmed that RTKs cannot provide reliable quantitative readings of the salt iodine content. Therefore, salt factories and laboratories should not use a RTK in their quality management systems. In rural remote areas with limited resources, the RTK may be selected for initial testing of iodized salt in shops or markets, but the test results will not stand up against a challenge of its reliability.
International Agreements and Standards

Global agreements on international trade are continuously expanding. These agreements, as regards to salt iodization strategies epitomized by the World Trade Organization (WTO), International Organization of Standards (ISO) and FAO/WHO Codex Alimentarius are devised to function in coordination. When a country becomes WTO member, it is duty-bound to promote the adoption of the quality management standards published by the ISO and the safety and purity standards adopted by the FAO/WHO Codex Alimentarius.

In country, the oversight of consistency with WTO rules and the promotion of ISO standards is typically vested in the Ministry of Industry and Trade or its equivalent, and official assessments of the proficiency of businesses against ISO standards typically include an audit of the quality management protocols during product manufacturing. Depending on the findings from such assessments, a company may receive official permission to sell its products, e.g. for a one or three-year period, or it may be given a temporary sales permit with binding recommendations for improvement. When a salt producer exports iodized salt across the border, the COA from the company authorized by a national standards agency on basis of the ISO certification can greatly facilitate entry into the recipient country.

The FAO/WHO Codex Alimentarius standard for food-grade salt, amongst other criteria, specifies that the sodium chloride content may not be not less than 97% on a dry matter basis, exclusive of additives. It is important to note that the Codex Alimentarius endorses salt iodization in the interest of protecting the health of citizens. The specific language for iodized food-grade salt states: “The production of iodized food-grade salt shall only be performed by reliable manufacturers having the knowledge and the equipment requisite for the adequate production of iodized food-grade salt, and specifically, for the correct dosage and even intermixing.” Harmonized national standards for food fortification, including salt iodization, are being prepared or have already been adopted by a number of countries as part of the continued expansion of regional cooperation agreements.

ISO Certification

The ISO 9000 family of standards have become the most widely known for "quality management" by their definition of what a business organization does to fulfill the customer's quality expectations, adhere to statutory and regulatory regulations, while continually improving its performance. The ISO 9001:2008(E) standard is applicable for determining a salt industry's ability to meet these requirements. Many large salt companies in the world are showing the ISO logo on their corporate website to demonstrate that their quality management system has been certified by an independent standards authority or an international company that provides quality certification services. The result of the certification against ISO standards is that the industry's customers can expect a greater choice of finished products, the consumers know they have access to more secure supplies, and that the producers and exporters are confident that foreign markets will remain open to them.
Importantly, ISO quality management standards and certification have been extended beyond the industry of manufactured products only. Together with the International Electrotechnical Commission (IEC), ISO has also drawn up a standard ISO/IEC 17020:2012(E) intended to promote the confidence in organizations that perform inspections. This international standard harmonizes the general criteria with which inspection bodies, including national regulatory agencies, are expected to comply so that their services are accepted both by their clients and by the supervisory Government authorities.

**Relevance to Salt Iodization Strategies**

As of 2012, the majority of countries around the world had passed a legislative act on salt iodization: A UNICEF progress report in 2008 already mentioned improved supplies and use of iodized salt in 120 nations. The analysis by UNICEF noted that the increase in consumption of iodized salt was significantly greater in countries where the salt iodization strategy had been made compulsory by official regulation, as compared to countries where the iodine content was defined in a standard, only applicable to salt when it is labeled as iodized salt.

As defined in WTO agreements, the food law in a given country sets broad principles for food control; a national regulation prescribes the required production and composition characteristics of foods, while the food standard describes the principles for guaranteeing the safety and quality of the product. For salt iodization strategies specifically, it is important to note that not all countries have enacted a regulation to require that food-grade salt must be iodized. Even though the standard for iodized salt in these countries does describe the characteristics and related production methods of properly iodized salt, it is not compulsory that the salt industries who supply salt in these countries must provide only iodized salt. In case that a country has defined a standard for iodized salt but not enacted a regulation, only the salt that is labeled as iodized salt must meet the standard.

Concluding, in countries without a regulation on salt iodization (for example, Ukraine), salt industries are permitted to supply either iodized or non-iodized salt for human consumption to their customers and traders. In these countries, it is not possible to make it required that salt factories only store iodized salt for sale to their customers, which makes the use of regulatory control with the aim to reach universal supplies of good quality iodized salt a much greater challenge.
II QUALITY MANUAL TEMPLATE FOR SALT BUSINESSES

Preface

This Quality Manual Template is designed for use by iodized salt producers as a guide in documenting their quality management systems. The template basically follows the ISO 9001:2008 outline, including the mention of relevant procedures and documents. However, for the purpose of the project (achieving universal salt iodization through the production of adequately iodized salt), only those procedures will be inserted and discussed that are directly related to the steps and activities of the processes that may affect the quality of the iodized salt product. Salt producers are encouraged to follow the template and adapt it to their specific operations.

Please keep the following points in mind when making use of this template:

- The template contains a cover page, table of contents and complete documentation for the quality management system. Where the words *The Salt Company* are mentioned, the name of the salt company who intends using this manual should be inserted.

- While working through the template, each individual salt producer can tailor each section to the specific requirements of their own company. They may wish to add, eliminate, or modify the procedures and other elements of the manual to fit their particular quality management system.
Draft

Quality Assurance Manual

for

The Salt Company

Date: ______
Revision 1.0

Prepared by: Quality Assurance Manager

Approved and authorized by: Chief Executive Officer, Managing Director
Table of Contents

Purpose of the Manual

0. References, definitions and abbreviations
1. Company description: The Salt Company
2. The Salt Company QMS
   2.1 Introduction
   2.2 Scope of The Salt Company QMS
3. Documentation.
   3.1 General
      3.1.1 Control of documents
      3.1.2 Control of records
   3.2 Documentation authority
   3.3 Controlled copies
4. Quality control policy and objectives

Management Processes

5. Management responsibility
   5.1 Organization and management
   5.2 Authority and responsibility
      5.2.1 Authority
      5.2.2 Responsibilities of management
   5.3 Management review
      5.3.1 General
      5.3.2 Review input
      5.3.3 Review output
   5.4 Audits
      5.4.1 Internal audits
5.4.2 External audits.

6. Resource management
   6.1 General
   6.2 Human resources
   6.3 Infrastructure and equipment

Key Business Processes
7. Product realization
   7.1 Planning for product realization
   7.2 Customer-related processes and order processing
      7.2.1 Determination of the requirements related to the product
      7.2.2 Review of the requirements related to the product
      7.2.3 Customer communication
   7.3 Purchasing
      7.3.1 The purchasing process
      7.3.2 Purchasing information
      7.3.3 Verification of purchased products
   7.4 Production and storage of iodized salt
      7.4.1 Control of production and packaging processes and of storage
      7.4.2 Validation of production and packaging processes
   7.5 Quality control of monitoring and measuring equipment

Support Processes
8. Measurement, analysis and improvement
   8.1 General
   8.2 Monitoring and measurement
      8.2.1 Customer satisfaction
      8.2.2 Product and process monitoring and measurement
8.3 Quality control of non-conforming products

8.4 Analysis of data

8.5 Improvement

8.5.1 Ongoing improvement

8.5.2 Corrective action

8.5.3 Preventive action

Informative Appendices

List of Procedures

List of Records

Procedures
Purpose of the Manual

The purpose of this manual is to serve as a road map to the quality management system (QMS) of *The Salt Company* and to house the procedures *The Salt Company* follows in implementing and maintaining this QMS.

The company has adopted the process approach by defining and managing process inputs, controls and outputs to ensure that the desired results are achieved and by managing the interfaces between interrelated processes to ensure that the system is effective.

The company’s quality system can be described in terms of the following processes and relevant procedures:

- *management processes* to help meet the specific needs of management and to meet, if applicable, the requirements of ISO 9001:2008 and other external standards and regulatory requirements
- *key business processes* that are customer oriented and that are in place to meet the specific needs of *The Salt Company’s* external customers
- *support processes* to help implement the key business processes in the most effective and efficient manner possible.

This manual and subsequent revisions are distributed by the quality manager (QM) to senior management and are available to all employees of *The Salt Company*, especially those involved in performing work related to the QMS.

The manual also serves as the basis for internal and external assessments of the QMS.
0. References, definitions and abbreviations

Normative references (if applicable)


Other references

The following documents have been relevant in the preparation of the QMS:

- relevant national food laws and regulations on edible iodized salt

Definitions

Calibration: comparison of a measurement standard or instrument with another standard or instrument to detect, correlate, report, or eliminate, by adjustment, any inaccuracy in the compared item

Corrective action: an action taken to eliminate the causes of an existing deficiency or other undesirable situation to prevent recurrence

External assessment or audit: appraisal of a company by an outside body using specified criteria and checklists to evaluate compliance for certification

Good manufacturing practices: practices and the systems that should be adopted in food manufacturing to govern the manufacture and quality testing of food products; good manufacturing practices represent guidance that outlines the aspects of production and testing that can impact the quality of a product

Internal assessment or audit: the process of self-appraisal in a company using specified criteria and checklists to evaluate compliance for certification or with regulations; the process may be used as part of a quality management review as well

On-site assessment: a formal examination or official inspection of a company producing iodized salt to evaluate the compliance with regulatory standards

Preventive action: an action taken to eliminate the causes of a potential deficiency or other undesirable situation and to prevent recurrence

Quality assurance: a proactive approach ensuring that processes and systems are developed and adhered to so that the products and services produced and delivered are of good quality according to standards or specifications
Quality audit: a systematic and independent examination to determine whether quality control activities and related results comply with planned arrangements, whether these arrangements are implemented effectively and are suitable to achieve objectives, and whether the quality control system is operating within acceptable limits.

Quality control: a process to check whether deliverables satisfy quality requirements, the specifications of customers and government standards.

Quality management system: the organizational structure, procedures, processes and resources needed to implement quality management in an organization.

Standard operating procedure: a procedure adopted for repetitive use in performing a specific processing operation; in the context of this manual, the procedure is described in a written document or instruction detailing all the steps and activities that are involved in a manufacturing process and that could affect the quality of the product.

Validation: the documented act of demonstrating that a procedure, process, or activity will consistently lead to the expected results.

Verification: confirmation by examination and by provision of evidence that specified requirements have been met.

Abbreviations

FAT: factory acceptance test

ISO: International Organization for Standardization

QA: quality assurance

QM: quality manager

QMS: quality management system

SAT: site acceptance test

SOP: standard operating procedure
1. Company description: The Salt Company

*The Salt Company* is a medium to large business dedicated to the manufacture and supply of salt products, including iodized salt for human and animal consumption.

*The Salt Company* owns and operates plants located in _______, was founded in _______, and has built and maintained a reputation as a responsive supplier of quality salt products.

2. The Salt Company QMS

2.1 Introduction

*The Salt Company* has developed and implemented a quality management system (QMS) to document the company’s best business practices, meet the expectations and requirements of its customers, ensure that its products comply with government standards and improve the overall management of the company.

This manual describes the QMS and delineates the authorities, relationships and responsibilities of the personnel responsible for performing within the system. The manual also describes procedures or provides references for activities comprising the QMS to ensure compliance with the requirements of customers and the relevant governmental standards.

The manual is used internally to guide the company’s employees through the requirements and standards that must be met and maintained to ensure customer satisfaction and ongoing improvement.

The manual is used externally to introduce *The Salt Company* QMS to customers and governmental bodies, familiarize them with the controls that have been implemented and assure them that the integrity of the QMS is maintained and focuses on customer satisfaction, regular improvement and compliance with standards.

2.2 Scope of The Salt Company QMS

*The Salt Company* QMS covers the _______ plant. More specifically, the QMS covers all operations occurring on-site at the plant, from the point of entry of raw materials and energy to the point of exit of finished manufactured products related to the production and supply of iodized salt.

The QMS incorporates the following:

- quality control of purchased equipment, raw materials and other supplies for processing and packaging
• validation and systematic quality control of iodization and packaging processes
• control of product quality during production and packaging
• quality control of packed products stored for distribution.

The QMS excludes the quality aspects of products to the extent that The Salt Company does not have influence over the design or disposition of the products.

3. Documentation

3.1 General

The QMS documentation includes the following:
• documented statements of the quality control policy and objectives (see paragraph 4)
• this quality assurance manual
• information on controlled documented procedures
• controlled records.

3.1.1 Control of documents

The documents required for the implementation of The Salt Company QMS are controlled. All documents are uniquely identified and reviewed for adequacy before approval. Controlled copies of the applicable QMS documents are made available at the sites of The Salt Company where they are used.

A detailed list of controlled documented procedures, with revision dates, retention periods and locations, is maintained by the quality manager (QM) to remain accessible and readily identifiable (see the appendix, List of Procedures).

All obsolete documents are withdrawn prior to the issuance of revised versions of the documents (see standard operating procedure [SOP] 3.1.1).

3.1.2 Control of records

Records are established and maintained to provide evidence of conformity to requirements. They remain accessible, readily identifiable and retrievable (see SOP 3.1.2).
The list of controlled records maintained by the QM, the location of the records and the retention times are located in the appendix (see the appendix, *List of Records*).

### 3.2 Documentation authority

The QM has the designated authority to modify or update the quality assurance manual. The quality assurance manual is reviewed annually and updated as needed by the month of ______ so that it has been reviewed prior to the management review. The managing director is responsible for the final approval of all changes made to the quality assurance manual, and the revised document takes effect when it has been signed and dated by the managing director.

### 3.3 Controlled copies

Controlled copies of this quality assurance manual are issued to the managing director and made available to all other staff members. All controlled copies are numbered and updated by the QM whenever changes are made. Recipients of controlled copies are issued the revised quality assurance manual with a cover sheet identifying the updates and other changes in the manual. It is the responsibility of the QM to ensure that the most current quality assurance manual is issued and followed by all staff. A list of the names, control numbers and locations of all controlled copies is maintained in *The Salt Company* files.

### 4. Quality control policy and objectives

*The Salt Company’s* quality control policy is aimed at achieving sustained, profitable growth by producing and supplying iodized salt products that consistently satisfy the needs and expectations of its customers and the criteria defined in the relevant food regulations.

This level of quality is reached through the adoption of a system of processes and procedures that reflects the competence of *The Salt Company* to its customers and regulatory auditing authorities.

The realization of this policy involves all staff, who are individually responsible for the quality of their work, resulting in a continually improving working environment for all.
Management Processes

5. Management responsibility

5.1 Organization and management

[Insert here an organizational chart of The Salt Company]

5.2 Authority and responsibility

5.2.1 Authority

All staff members share the authority and responsibility of identifying cases of non-compliance or possible improvements and recording these instances so that corrective action can be taken to rectify the immediate situation and to prevent recurrence. All staff members are assigned the authority to perform their assigned responsibilities.

The following provides a summary of the principal responsibilities of each job role; these are clarified in greater detail in the List of Procedures in the appendix.

5.2.2 Responsibilities of management

Managing director

The managing director is responsible for the overall compliance of the company with this quality assurance manual and is the direct supervisor of the production manager, the financial manager, the technical manager, the commercial manager, the QM and the warehouse manager.

Production manager

The production manager is responsible for the control of finance and accounts.

Financial manager

The financial manager is responsible for the control of finance and accounts.

Technical manager
The technical manager is the staff member responsible for the planning and performance associated with installations and equipment; technical assistance such as repairs, testing and maintenance activities; and the quality control of equipment and allocated materials.

Commercial manager

The commercial manager is the staff member responsible for the management and coordination of purchase, sales and support functions.

Warehouse manager

The warehouse manager is responsible for the proper storage and handling of (purchased) raw materials and other supplies for salt processing, iodization and packaging, as well as the final product.

Quality manager

The QM is the management representative responsible for the control and maintenance of the QMS, including this quality assurance manual, the measurement and documentation of salt iodine content, the analysis and maintenance of data and the coordination of internal and external quality assessments.

Note: Many salt producers have limited staff. In such cases, the responsibilities of various staff positions may be consolidated and fall to fewer individuals, for example, the production and technical manager or the managing director, financial manager and commercial manager. Special care must be taken to ensure that the quality system and quality operations are not adversely affected because of the limited staff.

5.3 Management review

5.3.1 General

A management review meeting to ensure the continuing suitability, adequacy and effectiveness of the QMS should take place at planned intervals, but at least twice per year.

The managing director has overall responsibility for conducting the meeting. During the meeting, tasks and responsibilities are assigned and recorded in the minutes to track the development of The Salt Company management system.

5.3.2 Review input

The input for the management review should include the following information:

- the findings of internal and external assessments and audits
- customer feedback, i.e., any complaints received
• process performance and product conformity
• status of preventive and corrective actions
• follow-up actions on previous management reviews
• recommendations for improvements.

5.3.3 Review output

The output of the management review includes any decisions and actions related to the following:

• improvement in the effectiveness of the QMS and associated processes
• improvements in products according to customer or regulatory requirements
• resource needs.

Records of management reviews are maintained and controlled (see the appendix, List of Records).

5.4 Audits

5.4.1 Internal audits

The results of internal audit represent critical inputs in assessing the effectiveness of The Salt Company QMS, in identifying opportunities for improvement and in promoting awareness of customer requirements and the effectiveness of the QMS among employees.

The Salt Company conducts internal audits to determine the effectiveness of its QMS and, if applicable, conformity with ISO 9001:2000–8. The internal audits are conducted in accordance with a published schedule that identifies the scope and frequency of the audits.

Each of the company’s key processes is reviewed at least once each year to determine effectiveness. The QMS process under review is considered effective if it is achieving the desired results or the established objectives. In addition, employee involvement in identifying process effectiveness or efficiency improvements is actively sought during internal audits.

The QM has overall responsibility for managing the internal audit process in accordance with the Internal Audit Procedure (SOP 5.4.1).

Internal audits are carried out by qualified personnel who do not have direct responsibility for the activity being audited. Auditors record audit results and submit findings to the management staff responsible for the process audited.

The management personnel responsible for the area audited implement, without undue delay, corrective actions to eliminate detected non-conformities and their causes. Follow-ups are conducted to verify the timely and effective implementation of the proposed actions.
The QM maintains all internal audit records, including the results of internal audits and related follow-ups. The QM periodically reviews the results of internal audits and provides related recommendations for review by top management during the management review meetings (see 5.3).

5.4.2 External audits

External audits (on-site assessments) are performed by the relevant governmental regulatory body at non-periodic intervals to verify that the products comply with government standards.

All external and internal audit review findings and any corrective actions that arise from them are promptly settled within the agreed time, documented by the QM, and maintained in The Salt Company files (see the appendix, List of Records).

6. Resource management

6.1 General

The managing director regularly reviews The Salt Company’s resources to ensure that adequate staff, equipment and materials are available to meet customer requirements.

6.2 Human resources

Top management ensures that personnel have the appropriate competence through education, training, skills and experience to perform any work that affects product quality.

The Salt Company maintains appropriate records of the competence of personnel (see the appendix, List of Records).

6.3 Infrastructure and equipment

The Salt Company determines, provides for and maintains the infrastructure necessary to achieve conformity with product requirements, including buildings, workspace, utilities and processing equipment (both hardware and software).
Key Business Processes

7. Product realization

Product realization involves the quality control of processes and procedures directly related to the request for and production and delivery of the product, including the following:

- customer requests for products
- the purchase of equipment, raw materials and other supplies for processing and packaging
- iodized salt production and packaging processes
- product quality monitoring and measurement.

7.1 Planning for product realization

In the case of requests for products or significant changes in products, quality control planning is required before (new) products are produced and supplied. Management or assigned personnel identify the following during this quality control planning:

- product quality requirements
- required processes, documentation and resources
- verification, validation, monitoring, inspection and test requirements
- criteria for product acceptance.

The output of this quality control planning includes documented quality control plans describing the processes and procedures required.

7.2. Customer-related processes and order processing

This subsection explains in more detail how customer and product requirements are determined and reviewed.

7.2.1 Determination of the requirements related to the product

The Salt Company sales personnel determines the following:
• the requirements specified by the customer, including availability and delivery schedules

• requirements not stated by the customer, but necessary for the intended or specified use, where known

• statutory and regulatory requirements related to the products.

7.2.2 Review of the requirements related to the product

The Salt Company sales personnel review the customer requirements identified during the determination process. This review is conducted prior to the commitment to supply products to the customer and ensures the following:

• Product requirements are defined

• The requirements do not conflict with governmental standards related to the products

• The Salt Company has the capability and capacity to meet these requirements.

Before the acceptance of a non-routine customer requirement, the request is reviewed by The Salt Company to ensure the following:

• Requirements are adequately defined and documented

• Differences between the standard requirements and those in the request are resolved

• The company has the capability and capacity to meet the non-routine requirements.

Records on the results and actions arising from the review are maintained (Order Change Map).

7.2.3 Customer communication

The Salt Company’s customer communications are established through a variety of channels:

• product information directly provided to customers by sales personnel

• inquiries, contracts, or order handling addressed by sales personnel

• customer feedback, including customer complaints handled by the relevant personnel (customer service) (Customer Complaints Map).

7.3 Purchasing

7.3.1 The purchasing process
Equipment purchased for iodized salt processing and packaging must show sufficiently high quality to perform consistently and adequately in the challenging environment of salt production and processing. *The Salt Company* ensures that this objective can be met by evaluating and selecting suppliers based on their ability to provide products, including equipment, and by ensuring that purchased equipment conforms to specified purchase requirements.

Equipment performance should be tested through factory acceptance tests (FATs) or site acceptance tests (SATs). The FAT variant is usually performed at the supplier’s site (e.g., the supplier’s factory) and involves a successful demonstration that the system works under generic conditions.

The SAT variant is usually performed at the operational site following installation. *The Salt Company* may require the successful completion of a SAT before permitting the system to become operational. Emphasis is usually on demonstrating that the system and application operate successfully within variations on the site-specific conditions.

*Note:* Because the application and scope of equipment performance tests such as FATs or SATs are results of agreements between equipment suppliers and individual salt producers, the relevant procedures are not within the scope of this manual.

These supplies must be inspected at purchase to ensure that they conform with the appropriate specifications adopted for raw materials, iodine sources and packaging materials. The salt and the iodate must be food grade and either tested in house or supplied by a certified supplier. The case of purchased packaging material is similar.

The type and extent of control applied to the supplier and purchased products are dependent on the type of product, on the effect of the product on subsequent product realization processes and on the final product (see SOP 7.3.1).

### 7.3.2 Purchasing information

*The Salt Company* personnel responsible for purchasing ensures the adequacy of the specified purchase requirements prior to communication to the supplier. The purchasing information communicated to suppliers contains the appropriate data needed to describe clearly and fully the requirements for purchased materials and the requirements for the approval and qualification of the equipment and products.

### 7.3.3 Verification of purchased products

Incoming products are not used until they have been inspected or otherwise verified against the specified requirements. The *Procedure for the Purchase and Receipt of Incoming Goods* (SOP 7.3.3)
describes the purchase process and the process to verify that the products purchased meet the specified purchase requirements.

7.4 Production and storage of iodized salt

7.4.1 Control of production and packaging processes and of storage

The Salt Company plans and carries out the production, packaging and storage of iodized salt under controlled conditions.

The processing steps that lead from raw material to adequately iodized salt – the refinement of the raw materials (if applicable), iodization and packaging – are described in more detail in Chapter 4 “Guideline to managing the quality of national iodized salt supplies”.

The Salt Company production manager ensures that production tasks are planned, scheduled and carried out in accordance with a production planning and quality control document. The production manager also ensures that the production process is carried out under controlled conditions and that each stage of the process is monitored.

The critical control points in production, i.e., the points at which problems are more likely to occur that may adversely affect product quality, are the raw salt after refinement (if applicable), the product after iodization, the operation of the equipment, and the product after packaging.

The control measures during the processing steps are described in Procedure for the Control of Production Processes (SOP 7.4.1.a).

The production manager, through his staff (department managers, team leaders, shift supervisors), ensures that all appropriate information, including the characteristics of the raw materials and the final product specifications, are provided to production personnel throughout processing. To ensure the quality of each output during production, work instructions are issued to employees to make them aware of the specifications to be maintained.

All critical operations are performed by adequately trained personnel. Their work is controlled by regular independent checks, as defined in the Quality Control Plan (see 7.1).

The authority to release semi-finished products for the next production step is properly defined at each stage of the process: the selected raw salt, the raw salt after refinement (if applicable), the iodized salt before packaging and the packaged iodized salt before storage.

To ensure the proper utilization of equipment and materials, the control of the production process is based on set targets at each stage.

The Salt Company technical manager is responsible for ongoing processing capability. All equipment and machinery required for processing activities are to be maintained in proper working condition by
carrying out planned preventive maintenance programmes and schedules (see SOP 7.4.1.b Procedure for Preventive Maintenance).

The packaging of products either manually or through packaging equipment, as well as weight controls on packaged products, is performed according to the company’s relevant packaging procedure (see the Informative appendix 3, Control of the Packaging Process).

Iodized salt is labeled in accordance with government regulations. Labels are printed on the packaging material in the official language of the country in which The Salt Company is located. They are clear and legible and printed in such a way that they do not wear away under normal conditions.

The Codex guidelines on nutrition labelling require the following information to be included in the labelling:

- product name
- commercial brand
- list of ingredients (type of salt, iodine source, anti caking and free-flowing agent, in descending order of percentage weight composition)
- net quantity in the package (in the designated weight system of the country)
- name and address of The Salt Company
- country of origin
- lot number
- date of manufacture
- expiration date (the date by which the iodized salt should be consumed).

*The Salt Company* warehouse manager ensures the prevention of any contamination or deterioration in the quality of the iodized product because of exposure to excessive humidity or direct sunlight. This is accomplished by storing the products of *The Salt Company* in covered rooms or in godowns (warehouses) that have adequate ventilation.

Bags of iodized salt both for retail and bulk sale are properly stacked, free standing and separated from any non-iodized salt, and are stored so that the batch number and other markings may be identified properly for implementation of the principle of first in–first out. A stock register with batch numbers and dates of receipt and dispatch is also maintained.

*Note:* Before the final product is released for shipment, the customer may require that the product be controlled through the sampling of lots or batches, preferably according to the principles of lot quality
assurance sampling (LQAS). This system is used to determine whether a batch or a lot of the product meets defined QA standards.

If required, The Salt Company will analyse a certain number of salt samples for each batch of salt. Of this number, no more than a generally low number can have values indicating either that the batch does not meet the standard or that the batch needs to be reiodized. The appropriate sample size and a threshold value – i.e., the amount of product in a single sample that fails to meet the standard – need to be determined, generally in consultation with the relevant authorities.

Note: For these verification measurements, The Salt Company will not use the rapid test kit (RTK).

7.4.2 Validation of production and packaging processes

The output of the production and packaging processes of The Salt Company are verified through subsequent quality controls and measurements to prevent the delivery of products with deficiencies (see section 8).

Note: In addition to the controls and measurements carried out during operations, The Salt Company may decide to require an acceptance test of critical purchased equipment to ensure that this equipment conforms to specified purchase requirements (see 7.3.1 and the informative appendix 1 for additional information).

7.5 Quality control of monitoring and measuring equipment

The Salt Company QM is responsible for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measuring devices to provide evidence of product conformity with established requirements. The QM determines the measurements to be made and the accuracy required to assure the conformity of The Salt Company’s products with the specified requirements.

Prior to use, the QM verifies the ability of the devices to meet the requirements. The devices are used and controlled in a manner to ensure ongoing suitability, including the proper conditions for calibration and inspection. The measuring equipment is calibrated at prescribed intervals. If monitoring or measuring devices are found to be out of calibration, they are adjusted or readjusted as necessary, and the validity of the measurements up to that point is documented. All procedures are documented, including procedures to remedy deficiencies and preclude recurrence (see 8.5.2). The QM maintains all records on the results of calibration and verification.
Support Processes

8 Measurement, analysis and improvement

This section describes the methodology of The Salt Company in defining, planning and implementing the monitoring, measurement, analysis and improvement activities needed to ensure product and QMS conformity and to achieve ongoing improvements. These activities include assessments of customer satisfaction, internal audits, process monitoring and measurement and product monitoring and measurement.

8.1 General

The QM ensures that the applicable methods used to monitor QMS processes are identified during quality control planning and are included in quality control plans (see 7.1).

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

The Salt Company commercial manager has overall responsibility for identifying and reviewing customer requirements and for monitoring and measuring customer satisfaction (see 7.2.1 and 7.2.2).

Data collected by customer contact personnel during routine communications provide the company’s primary means of assessing customer satisfaction (see 7.2.3). A customer satisfaction survey form (hard copy or digital) is utilized to ascertain the overall perception of customers of how well the company is meeting customer requirements and to document any recommendations for improvement.

Customer complaints are immediately forwarded to appropriate sales personnel for action. If these personnel cannot resolve the issue to a customer’s satisfaction, then the complaint is transferred to the commercial manager for assignment to another appropriate manager or function for resolution.

Customer complaints are documented and monitored for resolution through the company’s management action system (see 7.2.3 and 8.5). Customer feedback is reviewed regularly by sales personnel to initiate any improvement or corrective or preventive actions needed (see 8.5). The QM periodically reviews customer satisfaction survey data and other customer feedback and provides relevant recommendations for review by top management at management review meetings (see 5.3).

8.2.2 Product and process monitoring and measurement
The Salt Company QM has overall responsibility for planning and implementing the inspection and test activities needed to verify that product requirements have been met at the appropriate stages of the product realization process (see 7.1).

The product characteristics to be monitored for compliance with internal and external requirements are selected. This determines the types of measurement, the suitable measurement instruments and the inspection and testing skills needed.

The Salt Company product monitoring and measurement system includes receiving quality control, in-process quality control and final product quality control (see 7.3.1).

The stages of in-process quality control are as follows:

- if applicable, raw salt after refining (crushing, washing and drying or any other technology application)
- salt after iodization, which depends on the process used by The Salt Company: either online in continuous operation or through measurement and analysis after batch operations (see the informative appendix 1: Control of product quality during production and SOP 7.4.1.a Procedure for the Control of Production Processes).

After packaging, final product quality control is carried out through controls on the quantity and the quality of the packaged material (see Procedure for the Control of Production Processes). Products are not released for further processing or for delivery until all requirements have been met. Any non-conforming final products are removed and set aside for control (see 8.3).

Testing and inspection records are maintained for a minimum of one year. See Procedure for Control of Records.

8.3 Quality Control of non-conforming products

The Salt Company ensures that all non-conforming products are identified and segregated to prevent their unintended use or delivery.

The Salt Company QM is responsible for implementing an effective process for identifying, documenting, segregating, evaluating and disposing of non-conforming products. The personnel responsible for product quality have the authority to stop production to correct quality problems in accordance with Procedure for the Control of non conforming Product (SOP 8.3).

8.4 Analysis of data
The Salt Company QM collects and analyses data using appropriate statistical techniques to determine the suitability and effectiveness of key business processes of The Salt Company and to determine areas for improvement. The analysis of data provides information related to the following areas:

- customer satisfaction (see 8.2.1)
- conformity with product requirements (see 7.2.1)
- trends in and characteristics of the processes and products of The Salt Company
- (internal) audit reports (see 5.4)
- corrective and preventive action records (see 8.5.2 and 8.5.3)
- management review (see 5.3).

8.5 Improvement

8.5.1 Ongoing improvement

Based on the quality control policy and objectives and on findings of the analysis of data, improvements are initiated (see 4 and 8.4). Appropriate improvement initiatives are established, supported and monitored for effectiveness through the management review process (see 5.3).

The Salt Company also considers corrective and preventive actions a vital part of its ongoing improvement programme. Corrective actions are initiated if the desired results are not achieved; preventive actions are initiated to prevent the recurrence of problems or to implement other improvement actions.

The QM has overall responsibility for establishing and implementing an effective management action system that includes improvement actions and corrective and preventive actions (see above and 8.5.2 and 8.5.3).

8.5.2 Corrective Action

Evidence on non-conforming products, customer dissatisfaction, or ineffective processes drives The Salt Company corrective action system, which is designed to reduce or eliminate the likelihood of recurrence. The management staff with responsibility and authority for corrective action is promptly notified of product or process non-conformities. Investigating and eliminating the root causes of these failures are a critical part of The Salt Company’s Procedure for Corrective and Preventive Action (SOP 8.5). Follow-ups are conducted through the internal audit process to ensure that effective corrective action is taken and that it is appropriate to the impact of the problem encountered (see 5.4). In addition, The Salt Company’s QM summarizes and analyses corrective action data to develop relevant
recommendations for improvement. The results of this analysis and the related recommendations are presented to top management for action during management reviews (see 5.3).

8.5.3 Preventive action

Data from internal audits, customer feedback and employee suggestions and other appropriate data are collected and analysed to identify the steps needed to eliminate the causes of potential problems and thereby prevent their occurrence (see 8.4). Based on the findings of the analysis, The Salt Company reviews and initiates relevant preventive actions through The Salt Company Procedure for Corrective and Preventive Action (SOP 8.5).

In addition, The Salt Company QM summarizes and analyses preventive action data to develop relevant recommendations for improvement. The results of this analysis and the related recommendations are presented to top management for review and action during management reviews (see 5.3).
Informative Appendices

1. Validation of ongoing mixing and packaging processes

The validation – performance testing of the equipment – is normally conducted through FATs whereby the vendor demonstrates that the equipment meets the specifications agreed with the customer.

To ensure that the salt is uniformly iodized, the following validation procedure is suggested for the continuous mixing process:

- By monitoring a number of batches (5 to 10) of iodized salt, sampled at regular intervals, while maintaining the salt flow system at constant speed and adding the iodine-source at a constant rate, the ideal speed for the conveyor in combination with the ideal addition rate of fortificant can be determined.

- The criteria for establishing the capability of the mixing process – i.e., the amount of acceptable variation in the iodine level – depends on the performance of the mixer. Ideally, the best operating conditions should result in a relative standard deviation in the samples of a maximum of 3 per cent, though a spread in values of plus or minus 10 per cent would still be acceptable.

- Validation of the packaging process should be conducted to ensure that packaged products are meeting the expected quality and quantity criteria. The validation method and procedure depend on the packaging equipment and packaging methods used; so, they are to be defined in consultation with the supplier.

An important consideration concerning the performance of the packaging equipment is the flow ability of the iodized salt. A poor flow ability of the product affects the output of the bagging and packaging lines.

2. Control of product quality during production

Adequate execution of this part of the QMS is essential to avoid off-specification products, which must be reprocessed. This is especially essential for large producers who may rely on iodization lines with large capacities.

The iodine content of the salt as it is being produced should be constantly controlled, preferably through "in line" product sampling and iodine content analysis at short intervals. It is recommended that products be sampled and analysed at least every hour because corrective decisions, if needed, must be made quickly.

Verification of the in line measurements in the laboratory of producers may be performed less frequently, for example, once every shift, depending on the amounts of the production output and the
available methods for in line testing and laboratory verification. The track record of a producer’s iodization facility may also mean that the frequency of laboratory verification should be adapted.

In line testing and laboratory verification should be based on quantitative methods. The previously recommended semiquantitative rapid testing kits (RTK) for in line analysis should be replaced by the WYD Iodine Checker at least. Iodometric titration also known as the “gold standard” is the recommended method for laboratory verification because of its accuracy.

To record the results of in line salt iodine measurements, a quality control chart with upper and lower control limits, representing the legally permitted range of variation, should be used. The control limits, usually three times the standard deviation above and below the central line, describe the output the iodization process should consistently produce. An example of such a control chart is shown below.

In addition, the example below also shows the upper and lower limits of product specifications as agreed upon with the customer. The figure shows that the control boundaries fall within the specification boundaries to ensure that, through quick response and proper corrective actions, the risk of off-specification production is minimized.

This daily chart is to be filled in by the person who undertakes the hourly iodized salt sampling and analysis. This chart should then be put in evidence for the persons who worked in the factory to visually see what they have accomplished during the working day.

**Figure 1: Example of a control chart for in line plotting of salt iodine content**

![Typical Control Chart](image-url)

*Source: Courtesy of Brian Dangerfield, South Africa.*
3. Control of the packaging process

To ensure that the iodized salt contains the recommended amount of iodine at the time of consumption, the product should be properly packaged, preferably in airtight bags or sacks. The recommended packaging materials are high-density polyethylene and polyethylene-laminated polypropylene for bulk packaging and low-density polyethylene bags for retail packaging.

The manual filling of retail bags, followed by heat sealing or by stitching (for bulk bags), is still common practice, determined by costs, labour vs. investment in packaging equipment. It is obvious that larger-capacity producers will rely on (semi)automatic packaging equipment, such as (semi)automatic filling and stitching and sealing or an automatic form fill-and-seal machine, instead of manual packaging. In large plants, the capacity of the packaging line can vary from 2 to 3 tons per shift for table shakers, from 20 to 30 tons per shifts for 1-kilogram polyethylene bags for retail packaging, and up to 150 tons per shift for 25-kilogram bags for processed foods.

The packaged product should be sampled and controlled regularly for quantity in the packaged product and for quality in the packaged material, i.e., the weight should be within the range as defined in the packaging standards, and the packaging material should be properly sealed. The best option for quantity control is a check weighing system located behind the packaging line. The frequency of the sampling and testing depends on the packaging equipment and method used. The check weighing system should be calibrated annually by a relevant national institution.
List of Procedures

- SOP 3.1.1  Control of documents
- SOP 3.1.2  Control of records
- SOP 5.4.1  Internal audit
- SOP 7.3.1  Supplier selection and evaluation
- SOP 7.3.3  Purchase and receipt of incoming goods
- SOP 7.4.1.a Control of production processes
- SOP 7.4.1.b Preventive maintenance
- SOP 8.3  Control of non-conforming products
- SOP 8.5  Corrective and preventive action

List of Records

See also SOP 3.1.2.
Procedure for the Control of Documents

SOP 3.1.1 Version 1

1.0 Scope

This procedure is applicable to all the types of documents used in the QMS of The Salt Company.

2.0 Objective

The purpose of the procedure is to ensure that documents are under management’s control and that every person in the organization uses the correct versions of the documents.

3.0 Procedure

3.1 Internal documents

Document approval

Prior to issue or release, all QMS documents shall be approved. The documents should be available for examination during the approval process.

The managing director has the authority to approve the quality manual, and the relevant management team member has the authority to approve the procedures and work instructions.

A document is certified approved if it bears the stamp “Approved Document” on the back of the last page and is signed by the approving authority.

A register of approved documents is maintained by the QM.

Document review, update (amendment) and reapproval

All documents should be reviewed for applicability by the approving authority at regular intervals after the initial release. If the document is found appropriate, it should be dated and stamped “Reapproved”.

Documents may be amended in the course of implementation through the issuance of a document amendment form or during the routine document review process. The amended document is approved by the relevant approving authority. The QM records the identifying details of amended documents during the process of issuing the revised documents.

Identifying changes and current revision status

The nature of changes and the reason for the changes are recorded in the document approval and revision control register maintained by the QM.
**Document issue**

Copies of the latest approved versions of all documents, either original or amended, are issued to all concerned persons. A record of issue should be maintained in a document issue record form. The copies of documents that are distributed according to a distribution list are considered controlled copies. They are stamped “Controlled”, and the copy numbers are indicated, along with the signature of the QM.

The clarity of documents should be checked at the time of the issue of the documents, as well as during all internal audits.

**Identifying obsolete documents**

After receiving the latest version of any document, the recipients should destroy any old copies. If they prefer to retain old copies, they should highlight the status of the documents by stamping them “Obsolete”. The QM should keep one copy of each earlier version of a document and appropriately identify the document with the “Obsolete” stamp.

**3.2 Document of external origin**

Standards documents and other documents that have been released by external agencies, including customers, are documents of external origin. The QM verifies the applicability of such documents once a year. A list of all relevant documents of external origin is maintained, along with a record of verification.

**4.0 Associated documents**

- document approval and revision control register
- document amendment note
- document issue record
- list of external origin documents

**5.0 Responsibilities**

This SOP has been written by the QM. It has been reviewed and approved by the managing director.

**Creation date**

**Approval date**
Procedure for the Control of Records

SOP 3.1.2 Version 1

1.0 Scope

This procedure applies to all the functions and operations of The Salt Company and encompasses all records used to demonstrate conformity with product and quality system requirements.

2.0 Objective

The purpose of this procedure is the control of all quality-related records to provide evidence of conformity with quality requirements.

3.0 Responsibilities

The staff and all personnel of The Salt Company are responsible for controlling all quality records they produce and process. The QM has overall responsibility for the record control system. The records are all listed on the records list.

4.0 Definitions

Records: documents stating the results achieved or providing evidence of the activities performed during the processes described in quality control system documents and retained as indicated in this procedure.

Retention: the time period during which the record shall be kept at The Salt Company before it is discarded, destroyed, or sent off-site.

5.0 Records

5.1 Key records, record holders and retention periods

Management review records: Outputs of management review meetings are retained by the QM or a management representative for a period of three years (see QM 5.3).

Competency records: Personnel qualification and training records are retained by the managing director for a period of three years after the termination of employment (see QM 6.2).
**Purchasing documents and purchased products review records**: Offers, quotes and other documents established in the course of negotiating and implementing contracts are retained by the commercial manager for a period of 10 years after contract completion (see SOP 7.3.3).

**Supplier evaluation and performance records**: Documents demonstrating ongoing supplier capability and performance are retained by the commercial manager while the supplier is active, plus three calendar years (see SOP 7.3.1).

**Production and process approval records**: All records and documents required for product or process approvals and validations are retained by the QM as long as the production is active, plus one calendar year (see SOP 7.4.1).

**Product quality records**: Inspection and test results, etc., are retained by the QM for one calendar year after the year in which they were created (see SOP 7.4.1 and QM 8.2.2).

**Calibration records**: Inspection, measurement and test equipment calibration certificates are retained by the QM for a period of three years (see QM 7.5).

**Customer satisfaction data and complaint records**: Files on customer complaints and related records, together with customer satisfaction data are retained by the commercial manager for a period of three years (see QM 8.2.1).

**Internal audit records**: Internal audit records are retained by the QM for a period of one year (see SOP 5.4.1).

### 5.2 Records storage

A record is normally stored within the department that initially established the record. Records are stored in a clean, dry environment. Records and other quality control documents may not be stored in private desk drawers or other obscure locations that are not generally known.

### 5.3 Disposal

Records retained beyond their specified retention period must be clearly marked “Archive or Obsolete Records” and placed in the archive location. Records not retained must be destroyed (i.e., shredded or deleted) as soon as practical after the retention period has ended.

### 6.0 Associated documents

- SOP 5.4.1 Internal audit
• SOP 7.3.3 Purchase and receipt of incoming goods
• SOP 7.4.1.a Control of production processes
• SOP 7.4.1.b Preventive maintenance
• SOP 8.3 Control of non-conforming products
• SOP 8.5 Corrective and preventive action.

7.0 Responsibilities

This SOP has been written by the QM. It has been reviewed and approved by the managing director.

Creation date

Approval date
Internal Audit Procedure

SOP 5.4.1 Version 1

1.0 Scope

This internal audit procedure applies to all key processes of The Salt Company.

2.0 Objective

The purpose of the procedure is to determine the effectiveness of the QMS of The Salt Company, identify opportunities for improvement and promote an awareness of customer requirements among the employees of The Salt Company.

3.0 Procedure

In consultation with the QM, the managing director appoints internal auditors for the various key processes. These auditors do not have direct responsibility for the processes to be audited. If needed, The Salt Company provides training to ensure the auditing capability of the auditors.

The QM establishes a schedule for the audits, which should be executed at least once annually. The schedule, including the frequency and scope of the audit, is distributed to the auditors and to the management of the key processes to be audited (the auditees). Each auditor notifies the relevant auditee on a timely basis about the commencement of the audit and performs a pre-audit investigation, including the study of previous audit reports and best practice research.

Prior to the audit, the purpose and scope of the audit are discussed with and approved by the QM.

During the audit, the auditor may use an internal audit checklist.

After the audit, a preliminary report is issued and discussed at the exit interview of the auditee and the auditor. The preliminary report requires a response within 10 working days. Upon receipt of the signed response to the preliminary report, a final report, including an executive summary, is prepared by the auditor and sent to the auditee's supervisor.

If recommendations for action have been made, the time frame for implementation must be indicated. Follow-ups are conducted to verify the implementation of the proposed action.

At least once every six months, the QM reviews the results of internal audits and provides related recommendations for review at management review meetings. The QM maintains all internal audit records and the results of internal audits and the related follow-ups.

4.0 Associated documents
• internal audit schedule
• internal audit checklist.

5.0 Records
• internal audit reports.

6.0 Responsibilities

This SOP has been written by the QA manager. It has been reviewed and approved by the managing director.

Creation date

Approval date
Supplier Selection and Evaluation Procedure

SOP 7.3.1 Version 1

1.0 Purpose

The purpose of this procedure is to select suitable suppliers who meet the requirements of *The Salt Company*.

2.0 Scope

This procedure applies to all suppliers of goods and services that may influence the quality of the processes and products of *The Salt Company*.

3.0 Procedure

*Request for proposal*

A request for proposal is drawn up for the product to be purchased, including specifications, time of delivery, quantities, warranties required, supplier evaluation definitions and requirements, as well as other needs that the supplier would have to cover (bank statements, industrial licenses, etc.).

*Selection of suppliers*

The first step is to collect information about potential suppliers. The sources of information may include the following:

- supplier catalogues
- direct contacts with suppliers
- introductions by other, related parties.

An initial list of potential suppliers is drawn up. The request for proposal is sent to these suppliers.

Once the suppliers submit proposals, the commercial manager, with the assistance of other departments of *The Salt Company* (e.g., accounting, technical, operations), prepares a comparative document, verifies that the comparisons are correct and decides who may become the supplier.

Only then, during the negotiations, does the commercial manager initiate the supplier evaluation procedure.

*Evaluation of the supplier*
The evaluation of suppliers is based on the following criteria:

- the relationship, if any, with the company
- Do the goods or service to be purchased meet the quality and environmental requirements?
- Is the price reasonable?
- delivery date
- payment method
- ability to supply the ordered quantity.

After examining and evaluating the potential suppliers, a list of selected suppliers is drawn up by the commercial manager.

**List of preferred suppliers**

The selected suppliers are listed in the order of the evaluation. The list is reviewed and approved by the commercial manager. After the approval, the list of preferred suppliers is considered final and is documented.

**4.0 Associated documents**

- SOP 7.3.3 Purchase and receipt of incoming goods.

**5.0 Records**

- list of selected suppliers
- criteria for suppliers
- list of preferred suppliers.

**6.0 Responsibilities**

This SOP has been written by the QA manager. It has been reviewed by the commercial manager. It has been approved by the managing director.
Procedure for the Purchase and Receipt of Incoming Goods

SOP 7.3.3 Version 1

1.0 Scope

This document applies to all material and supplies for use by The Salt Company.

2.0 Objective

This document describes the procedures for acquiring, purchasing and receiving raw materials and other supplies for the processing and packaging of iodized salt by The Salt Company.

3.0 Purchasing procedure

The materials to be acquired are raw salt (if The Salt Company does not have its own sources), free-flowing agent and anti caking agent, iodizing agents and packaging materials.

The supplier of the raw materials or other supplies to be acquired is assessed by the commercial manager using The Salt Company’s preferred supplier list on the basis of quality, cost and compliance with specifications (see SOP 7.3.1). The supplier offering the lowest purchase cost for the appropriate quantity and quality of material is selected.

The Commercial Manager ensures that the Warehouse Manager and Quality Manager are adequately and timely informed on the material and supplies to be delivered: the supplier, the product, its specifications and quantity and delivery date.

4.0 Procedure for the receipt of incoming goods

Upon receipt of the materials in a truck, container, or drum, the materials are inspected by warehouse personnel to verify the presence of the material ordered and to determine if there has been any damage in transit.

A log of the arrival date is kept in the warehouse information system. If a container or drum is opened or a seal is broken, the date this occurred must be recorded in the warehouse information system. If a container or drum with critical material (such as iodizing agent) is broken or damaged during handling, new material will be purchased or acquired to replace it so as not to compromise the purity of the material.

Once received, all materials are placed on hold pending release by the QM. Release by the QM occurs only after samples of each lot of raw material passes evaluation according to the raw materials
specification criteria. Testing includes physical characteristics, analysis to verify and approve, if applicable, the certificate of analysis for raw salt, iodizing agents and other relevant supplies. Complete certificates of analysis that meet The Salt Company’s specifications are mandatory for every lot that is received for use in production. Materials can be released into inventory only if they meet the applicable specifications. If materials do not meet specifications at any step in the process, they are rejected and returned to the materials supplier.

If the materials are not delivered within the agreed terms, the order is cancelled, and the supplier is placed on the supplier watch list.

The verification process for purchased equipment is described in the relevant procedure.

5.0 Documentation

- list of preferred suppliers
- material safety data sheet
- product information sheet
- certificate of analysis.

6.0 Safety

See the material safety data sheet.

7.0 Records

The warehouse manager maintains logs (digital and paper) of the materials received. The logs cover the supplier, quantity, cost, receipt date, opening date, and storage location after the materials have been procured.

8.0 Responsibilities

This SOP has been written by the QA manager. It has been reviewed by the commercial manager and the warehouse manager. It has been approved by the managing director.
Procedure for the Control of Production Processes

SOP 7.4.1.a Version 1

1.0 Scope

This procedure applies to all measures implemented by The Salt Company to control the quality of its production processes. The processes are the purification of raw salt, the batch or continuous iodization of purified salt and the packaging of iodized salt.

2.0 Objective

This document describes the procedure to ensure that the salt product is adequately iodized and packaged, that it complies with all standards and that it can reach the customer with adequate amounts of iodine.

3.0 Procedures

3.1 General

The three process steps that lead from raw salt to adequately iodized and packed salt are, if needed purification or refining of raw salt, iodization of (purified) salt and packaging of iodized salt.

These steps can be conducted batch wise or in a continuous operation.

In a batch production each process step is conducted stage by stage, whereas in a continuous production the purification and iodization process steps are conducted without interruption.

The Production Manager is responsible for proper execution of the process steps.

3.2 Refining of raw salt

Raw salt not meeting the quality requirements in the relevant (national) standards or the Codex Alimentarius is purified through crushing and washing with brine.

Crusher performance and washing cycles are determined according to the required product characteristics and quality. Crushed and washed salt is dried in a centrifuge to a maximum of 2.5 per cent water.

In the case of batch production, the dried salt is stored and put on hold. Per batch, two samples are taken of the dried salt for the measurement of the relevant product characteristics, including quality
(particle size, water content and impurities). After approval by the QM, the dried product is released for further processing.

In the case of continuous production, the proper verification of the performance of the washing and drying cycles is a prerequisite before the dried product is transferred for the next processing step.

Note: Dependent on quality of raw salt and/or on final product requirements The Salt Company might need further purification and drying methods, such as hydro milling and fluid bed drying.

3.3 Iodization of purified salt

In the case of batch production, the iodized product is stored in 50-kilogram polyethylene-laminated polypropylene bags and put on hold. (This process is described in the appendix.) Samples of the iodized salt are collected and sent to The Salt Company laboratory for analysis. (For the sampling method, see the relevant work instruction.)

Sampling of iodized salt and its analysis are conducted under the responsibility of the QM. After approval by or under the responsibility of the QM, the 50-kilogram bags of iodized salt are released for transfer to the packaging department.

In the case of continuous production, a sample is taken from the outlet of the iodization equipment every 30 minutes. The iodized salt is bagged in 50-kilogram polyethylene-laminated polypropylene bags, set aside and put on hold. From each sample, 10 grams are taken for analysis under the responsibility of the QM in The Salt Company laboratory. Analysis must be performed within 15 minutes after the sampling. After approval by or under the responsibility of the QM, the 50-kilogram bags of iodized salt are transferred to the packaging department.

In the case of incidental non-compliance with the quality requirements, the iodized product is to be reworked. In the case of a structural non-compliance with the product quality criteria, a corrective action is to be initiated by the QM (see SOP 8.3).

The QM is responsible for maintaining records of the results of the analysis of purified and iodized salt. To support the control of the iodized salt sampled online, the QM records the data using a quality control chart with upper and lower control limits, as well as upper and lower limits in the product specification.

3.3 Packaging iodized salt

Packaging takes place in a clean room under food-grade conditions. In the case of manual packaging, employees must wear gloves. In a sign of its concern for clean operations, The Salt Company provides clothing for this process.
At each shift, a sample is taken from each batch of packaged and sealed retail product to check the weight of the package and tight fit of the packaging. This check is carried out under the responsibility of the QM by the laboratory assistant. After approval, the batch is released for direct supply or for storage in the warehouse.

Weighing equipment is calibrated each day under the responsibility of the QM by the laboratory assistant. The weighing equipment is also calibrated once a year by the relevant national institution or through a service contract with the supplier of the weighing equipment.

Note: In the case of the use of packaging equipment, controls of the packaging, including sampling frequency and calibration, are determined in consultation with the supplier of the equipment.

4.0 Associated documents

- national standard for iodized salt
- Codex Alimentarius for food-grade salt.

5.0 Records

- analysis of purified dried salt and iodized salt
- control chart of the online analysis of iodized salt
- weight data on packaged salt
- calibration records.

6.0 Responsibilities

This SOP has been written by the QA manager. It has been reviewed by the production manager. It has been approved by the managing director.

Creation date

Approval date
Procedure for Preventive Maintenance

SOP 7.4.1.b

1. Scope

This document applies to all equipment and machinery required for the processes of The Salt Company.

2. Purpose

The purpose of this preventative maintenance (PM) procedure is to verify that all equipment and machinery are adequately maintained to ensure continuing process capability.

3. Applicability/Responsibility

The PM procedure should be completed during major downtimes or within production schedule when no shut down is required.

The Technical Manager is responsible for proper execution of the PM program.

4. Procedure

4.1 Planning and scheduling

In consultation with the Production Manager the Technical Manager defines the PM program and schedule taking into account the major down times in relation to production needs. PM work orders are prepared.

In case a PM work needs to be cancelled because of unplanned production needs, the Technical Manager and the Production Manager must approve the cancellation.

The Quality Manager maintains the corresponding documentation.

4.2. Preparation

On basis of a Work Order the relevant equipment is prepared for shut down.

After shut down the machine or process equipment is isolated from energy.
If applicable lock out devices are applied and subsequently released from lock out.

If the work order does not require equipment shut down, or will have no operational impact, the Technical Manager schedules the PM according to the availability of technician resources. He allocates the engineering resources to the work orders and generates (prints) work orders out of the PM program.

4.3. Execution Preventive Maintenance work

Before starting the PM work, the maintenance technician ensures that the equipment is released by production for maintenance. If the equipment is not released by production as per scheduled date, the technician informs the Technical Manager immediately.

The technician carries out the work as per the instructions on the work order, ensuring that the appropriate comments and codes are written on a hard copy of the document. When the work order is completed the technician signs and dates the work order.

If any extraordinary work has come up during the PM work the technician should inform the Technical Manager, referencing the work order and any other relevant paperwork needed.

The maintenance work is recorded by the person performing the maintenance on the appropriate log or check list after the work is performed.

The Technical Manager is responsible for filing and maintaining the records.

4.4. Release of equipment

The Quality Manager is informed and will verify that the maintenance has been performed and that the equipment has been prepared to “come on line”.

Notes:

1. If any repair is necessary, the technician records the problem on the maintenance repair log.

Any repairs performed on equipment shall be recorded on the appropriate equipment log.

2. Some repairs may be performed externally. These repairs will be documented same as above.

5. Associated documents

- Preventive Maintenance Program
• Production Planning and control.

6. Records

• Work orders
• Equipment check lists
• Repair logs.

7. Responsibilities

This SOP was written by: QA Manager
This SOP was reviewed by: Production Manager
This SOP was approved by: Technical Manager

Creation date:

Approval date:
Procedure for the Control of Non-conforming Products

SOP 8.3. Version 1

1.0 Scope

This procedure applies to all non-conforming products and materials detected within The Salt Company and produced in house or in company stock, i.e., in-process products and finished products not conforming to specifications and non-conforming products detected after delivery.

2.0 Objective

The purpose is to establish a procedure for the control and disposition of non-conforming products so as to prevent unintentional use or delivery.

3.0 Procedure

3.1 Non-conforming product detected at The Salt Company’s operations

When non-conforming product is detected through quality controls during in-process operations, it is immediately removed from the normal processing flow, and the production manager, the commercial manager and the QM are notified. The product or material is removed from the normal processing flow by being placed in a designated hold location. The non-conforming material is identified with a hold tag, which is filled out and attached to the item. The tag contains the part number, the quantity, a description, the reason for being on hold, the name of the employee who detected the non-conformity and the date. The disposition of the non-conforming product can be determined by any of the staff members mentioned above.

After reviewing all actions taken regarding the non-conforming product, the managing director determines the next step to be taken: whether the product is to be reprocessed or to be rejected and removed. The outcome of the review is recorded. After the product is properly disposed of, the disposition is noted on the hold tag. Completed tags are given to the QM and kept on file within the framework of the measurement of quality objectives. Depending on the nature of the non-conformity, it may be necessary to generate a corrective action request.

3.2 Non-conforming product detected after delivery

If non-conforming product is detected after delivery, a corrective action is taken that is appropriate to the reason for the non-conformity. Appropriate action may involve products or information sent to
customers, a recall of products, or other action deemed necessary by top management to correct the non-conformity and prevent a recurrence.

4.0 Responsibilities

This SOP has been written by the QA manager. It has been reviewed by the production manager and the commercial manager. It has been approved by the managing director.

Creation date

Approval date
Procedure for Corrective and Preventive Action

SOP 8.5 Version 1

1.0 Scope

This document applies to all process and product non-conformities observed and notified at regular operations, during internal audits, or through other evidence of non-conforming products, customer dissatisfaction, or ineffective processes.

2.0 Objective

The purpose of this procedure is to establish and outline the processes for identifying, documenting, analysing and implementing preventive and corrective actions aimed at eliminating or reducing the likelihood of the occurrence or the recurrence of non-conformities in processes and products.

3.0 Procedure

Corrective or preventive action may arise from:

- customer complaints recorded under the responsibility of the Commercial Manager
- internal audit results maintained by the Quality Manager
- any employee of The Salt Company, having observed or identified a non-conformity or ineffectiveness in the company’s processes or products.

Concerning the first two causes, the Commercial Manager and Quality Manager are responsible for initiating the corrective or preventive action process related to the reported non-conformities.

In the last case the relevant employee can and should bring a suggestion for a corrective and/or preventive action to the responsible authority (management team member).

The relevant authority reviews the (potential) non-conformity to determine the need for preventive or corrective action.

Once the need for action has been determined, the responsible management team member requesting a process or product correction should complete a corrective or preventive action form, including the product or process in which the (potential) non-conformity was identified and other pertinent information.

The form is then forwarded to the QM, who checks the information on the form for completeness and accuracy. The responsible management team member determines the person(s) responsible for the
action, the type of action and the date the action is due. The QM logs in the form for tracking purposes and forwards it to the individual(s) responsible for the corrective or preventive action.

The person(s) responsible for action completes the form by indicating the root cause and the action taken. By the date indicated on the form, the form is to be returned to the QM, who logs in the newly adjusted form. Once the proper resolution has been reached and the corrective or preventive action has been implemented, the QM finalizes the form and informs the employee who initiated the action about the results.

Corrective and preventive actions are reviewed at the management review meetings to ensure the effectiveness of the action and the procedure.

The form is kept by the QM.

4.0 Definitions

*Root Cause*: the fundamental deficiency that results in a non-conformity and that must be eliminated through a corrective or preventive action.

5.0 Associated documents

- corrective and preventive action form
- corrective and preventive action logs.

6.0 Responsibilities

This SOP has been written by the QA manager. It has been reviewed by members of the management team. It has been approved by the managing director.
III QUALITY MANUAL TEMPLATE FOR INSPECTION BODIES

Preface

This Quality Manual Template is designed for use by (governmental) inspection bodies charged with inspecting the products and facilities of producers and suppliers of iodized salt.

The template closely follows the outline of the ISO/IEC 17020 standard, *General criteria for the operation of various types of bodies performing inspection*. By following the ISO/IEC 17020 standard, inspection bodies show that they meet the requirements of expertise, independence and impartiality.

The template contains a cover page, a table of contents and complete documentation for a Quality Manual and Procedures for a quality management system of a hypothetical inspection body, *Inspection Body IB*.

Working through the template, an individual inspection body can tailor the sections to its specific needs and conditions.
Table of Contents

Purpose of the manual.................................................................................................................................

0. Description of Inspection Body IB..............................................................................................................

1.0 Scope......................................................................................................................................................

2.0 Definitions and conventions....................................................................................................................

3.0 Administrative requirements....................................................................................................................

4.0 Independence, impartiality and integrity....................................................................................................

5.0 Confidentiality........................................................................................................................................

6.0 Organization and management................................................................................................................

7.0 Quality control system............................................................................................................................

8.0 Personnel................................................................................................................................................

9.0 Facilities and equipment..........................................................................................................................

10.0 Inspection methods and procedures......................................................................................................

11.0 Handling inspection samples and items............................................................................................... 

12.0 Records.................................................................................................................................................

13.0 Inspection reports and inspection certificates.....................................................................................

14.0 Subcontracting.....................................................................................................................................

15.0 Complaints and appeals.........................................................................................................................

16.0 Cooperation........................................................................................................................................

Appendix 1. Organizational scheme ............................................................................................................

Appendix 2. Technical scope of activity........................................................................................................

Note: The numbering of this quality manual directly corresponds to the numbering in ISO 17020. Updates to this manual will be made by reissuing the relevant updated section of the manual and adjusting the issue level in the index.
Purpose of the Manual

The purpose of this manual is to assist Place name of Institution here, known as Inspection Body IB in this document, in performing the licensing, inspection and surveillance activities associated with its quality management system in accordance with the criteria defined in the relevant International Organization for Standardization–International Electrotechnical Commission (ISO/IEC) 17020 standard.

Through the adoption of this manual, inspection bodies demonstrate that they meet the requirements of expertise, independence and impartiality imposed in the standard.

0 Description of Inspection Body IB

0.1 Describe here the background, sector, activities, personnel and scope of Inspection Body IB

The inspections for which Inspection Body IB is authorized and competent are listed in appendix 2, Technical scope of activity.

Distinguish between the inspections that are part of the quality system and the inspections that are not part of the system, if any.

0.2 Describe the history of your inspection body

0.3 The position of Inspection Body IB within the government of (name of country) and its parent organization(s) is illustrated in the organizational diagram (see appendix 1, Organizational scheme)

1 Scope

This quality manual specifies the policies and procedures of Inspection Body IB that must be followed to meet national standards and the requirements for inspection work detailed in the management system standards of the International Organization for Standardization, ISO/IEC 17020.

All staff engaged in any work covered by Inspection Body IB are required to follow the relevant procedures. Staff must also ensure that any work carried out by sub-contractors shall be carried out so as to satisfy the same standards and requirements.

Analytical measurement (which must be performed inside a laboratory under well-controlled environmental conditions and using more sophisticated equipment or measurement procedures) is a laboratory activity and therefore does not come within the scope of ISO/IEC 17020. Inspection bodies wishing to undertake such laboratory-type analytical measurement as part of an inspection will need to do so in accordance with the relevant requirements in ISO/IEC 17025.
The scope of this manual does not cover the certification of quality management systems of producers and suppliers of iodized salt to be inspected.

It may, however, be necessary for *Inspection Body IB* to examine certain product aspects of the quality management system or other documented systems to justify inspection results, for example, the examination of production processes of the producers.

2 References and definitions

2.1 Normative references


ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 2:1991 *General terms and their definitions concerning standardization and related activities*

2.2 Other references

ISO 9001:2008 *Quality management systems: requirements*


2.3 Definitions

The quality manager is responsible for establishing and maintaining a list of definitions and conventions, as illustrated below.

<table>
<thead>
<tr>
<th>Audit</th>
<th>An internal quality audit: a structured and independent examination to determine whether activities and their related results comply with planned arrangements and whether these arrangements are implemented effectively</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auditee</td>
<td>The person being audited; the person must supply information to the auditor</td>
</tr>
<tr>
<td>Auditor</td>
<td>A person qualified to carry out the task of auditing the quality management system; wherever possible, the auditor shall be independent relative to the process or activity being audited</td>
</tr>
<tr>
<td>Calibrate</td>
<td>Correlate the readings of (an instrument) with a standard</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>Continual improvement</td>
<td>Recurring activity to increase the ability to fulfil requirements</td>
</tr>
<tr>
<td>Customer</td>
<td>Any organization that enters into a formal agreement with <em>Inspection Body IB</em> for the delivery of products or services</td>
</tr>
<tr>
<td>Customer complaint</td>
<td>Customer statement that <em>Inspection Body IB’s</em> products or services do not meet requirements or expectations</td>
</tr>
<tr>
<td>Customer satisfaction</td>
<td>Customer perceptions of the degree to which their requirements have been fulfilled</td>
</tr>
<tr>
<td>Inspection</td>
<td>Examination of a product design, product, service, process, or plant and determination of its conformity with specific requirements or, on the basis of professional judgment, general requirements</td>
</tr>
<tr>
<td>Inspection body</td>
<td>Body that performs inspections</td>
</tr>
<tr>
<td>Inspection body capability</td>
<td><em>Inspection Body IB’s</em> personnel, skills and expertise available for performing inspections</td>
</tr>
<tr>
<td>Inspection body management</td>
<td>Staff members of <em>Inspection Body IB</em> who manage the body’s activities</td>
</tr>
<tr>
<td>Management representative, quality manager</td>
<td>A member of the management team who, irrespective of other duties, has the authority to ensure that the quality system is established, maintained and implemented and who reports on the performance of the quality system as a basis for improvement</td>
</tr>
<tr>
<td>Measurement</td>
<td>Set of operations to determine the value of a quantity</td>
</tr>
<tr>
<td>Preservation</td>
<td>Measures taken to ensure that a product does not deteriorate</td>
</tr>
<tr>
<td>Quality policy</td>
<td>Overall intentions and directions of <em>Inspection Body IB</em> with regard to quality as formally expressed by executive management</td>
</tr>
<tr>
<td>Quality system</td>
<td>The organizational structure, procedures, processes and resources needed to implement quality management</td>
</tr>
<tr>
<td>Referral inspection body, subcontractor</td>
<td>External body providing inspection services (based on a MOU) to <em>Inspection Body IB</em> in meeting the quality requirements</td>
</tr>
<tr>
<td>Sample</td>
<td>One or more parts taken from a system and intended to provide information on the system and, often, serving as a basis for decision on the system or its output</td>
</tr>
</tbody>
</table>
Traceability

The property of the result of a measurement or the value of a standard whereby the result or value can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all of which have stated uncertainties.

3 Administrative requirements

3.1 Inspection Body IB is the government institution legally recognized and authorized under government statute XYZ (Note: enter the statute title and number or article number).

3.2 Inspection Body IB has documented its functions and the technical scope of the activities for which it is competent (see appendix 2, Technical scope of activity).

The precise scope and frequency of an inspection are determined by the terms of the underlying documentation on relevant national regulations issued by Government authorities. This ensures that there is a clear and demonstrable understanding between Inspection Body IB and its customers of the scope of the inspection work to be undertaken.

3.3 Inspection Body IB has liability insurance in accordance with the national laws or regulations.

4 Independence, impartiality and integrity

4.1 The personnel of Inspection Body IB are free from any commercial, financial, or other pressures that might affect their judgment. Procedures are implemented to ensure that persons or organizations external to the inspection body cannot influence the results of the inspections carried out.

4.2 Inspection Body IB is independent to the extent that this is required under the conditions within which it performs its services.

4.3 Inspection Body IB, in carrying out the inspection and testing of facilities and products of producers and suppliers of iodized salt, is independent of the parties involved.

4.4 Inspection Body IB and its staff who are responsible for carrying out inspection are not linked to any party directly involved in the design, manufacture, supply, installation, purchase, ownership, use, or maintenance of the facilities or products of the parties to be inspected.

4.5 Inspection Body IB and its staff who are responsible for carrying out inspection are not the designer, manufacturer, supplier, installer, purchaser, owner, user, or maintainer of the facilities or other items they inspect nor the authorized representative of any such parties.

5 Confidentiality
5.1 Inspection Body IB ensures the confidentiality of the information it obtains in the course of its inspection activities. Proprietary rights are protected.

Taking into account the relevant legal requirements, Inspection Body IB has a policy concerning the observance of the confidentiality requirements of customers by the inspection body itself or by any subcontractor engaged by the inspection body. Once hired, employees/inspectors of subcontractors must sign a confidentiality agreement with Inspection Body IB.

Access to the results of inspections, other than by the parties directly involved, is only allowed on the basis of relevant clauses, if any, as laid down in the regulations on the inspection of iodized salt facilities and the related products.

6 Organization and management

6.1 Inspection Body IB’s size, structure and composition are suitable for the adequate and competent performance of the body’s inspection and testing functions.

6.2 Inspection Body IB has defined and documented the responsibilities and reporting structure of the organization in an organizational scheme (see appendix 1). This organizational scheme shows the functions and lines of authority among staff within the inspection body and the relationship, if any, between the inspection function and other activities of the organization.

6.3 Inspection Body IB has a technical manager who is qualified and experienced in the operation of the inspection body and who has overall responsibility for performing inspections in accordance with ISO 17020. The technical manager is a permanent employee of Inspection Body IB.

6.4 Inspection Body IB provides effective supervision by persons familiar with inspection methods and procedures, the objectives of inspection and the assessment of the inspection results.

6.5 To ensure competent management in the absence of any manager responsible for inspection services, Inspection Body IB has named persons to deputize such managers.

6.6 Each position category in Inspection Body IB that could affect the quality of inspection services is described in job descriptions. These job descriptions include the requirements for education, training, technical knowledge and experience.

7 Quality Management System

7.1 The executive management of Inspection Body IB has established, documented and maintained a quality management system to implement quality management and ensure that the quality policy and objectives of the body are achieved so that:

- Customers are satisfied with the inspections performed
• Inspections are carried out adequately, correctly and efficiently in line all relevant legal and technical requirements.

This quality management system is understood, implemented and maintained at all levels in the organization.

7.2 To be a cost-effective aid in quality control, the quality management system should be adapted to the size of Inspection Body IB and the volume of the inspections performed.

7.3 The quality management system is fully documented in this quality manual, which contains the information required by ISO/IEC 17020.

7.4 The executive management of Inspection Body IB has appointed a management representative, the quality manager, who, irrespective of other duties, has the authority and responsibility for maintaining the quality system. The quality manager has direct access to top management.

7.5 The quality manager is free of any influences or conflicts of interest that may affect the proper maintenance of the quality system.

7.6 Inspection Body IB maintains a system for the control of all documents relating to its activities. This system ensures the following:

• The adequacy of documents is approved prior to issue
• Documents are reviewed, updated and reapproved as necessary
• Changes and the current revision status of documents are properly identified
• The relevant versions of applicable documents are available at points of use
• Documents are available and readily identifiable
• Documents of external origin are tagged and their distribution is managed using the documentation master list
• The unintended use of obsolete documents is prevented and suitable tags are applied to them if they are retained for any purpose (see standard operating procedure [SOP] 7.6 Document control)

7.7 To verify that the documented operational procedures of Inspection Body IB continue to comply with the requirements of the quality management system, internal audits of all elements of the system, both managerial and technical, are conducted according to a prearranged schedule. The quality manager is responsible for administering the internal audit system according to the documented procedure, SOP 7.7 Internal audit.

7.8 Inspection Body IB has documented procedures for dealing with feedback and corrective action whenever discrepancies are detected in the quality system or in the performance of inspections (see
SOP 7.8.a Identification and control of non-conformities, SOP 7.8.b Corrective actions, SOP 7.8.c Preventive actions, and SOP 7.8.d Customer complaints and feedback).

7.9 The management of Inspection Body IB reviews the quality system at appropriate intervals to ensure continuing suitability and effectiveness. Details of this review, how it is performed and recorded, and the associated responsibilities can be found in SOP 7.9, Management Review.

8 Personnel

8.1 Inspection Body IB has a sufficient number of permanent, competent personnel with the range of expertise necessary for handling the type, scope and volume of the work performed.

8.2 The staff responsible for inspection are appropriately qualified, trained and experienced and has a satisfactory knowledge of the requirements of the inspections to be carried out. The staff have the ability to make professional judgments and report on conformity with general requirements using the results of examinations. The staff also have appropriate knowledge of the technology used in manufacturing the products inspected and the applications of these products. The staff understand the significance of any observed non-compliance in the inspected products.

8.3 Inspection Body IB has established a documented training system to ensure that the training of its personnel in the technical and administrative aspects of the work in which they are involved is kept up-to-date (see SOP 8.3, Training).

8.4 Records of academic or other qualifications, training and experience of each member of its personnel are maintained by Inspection Body IB.

8.5 Inspection Body IB provides guidance for the conduct of its staff. This guidance may be in the form of a code of conduct, including issues relating to work ethics, impartiality, personal safety, the relationship with customers, company rules and other issues needed to ensure the proper conduct of the staff.

8.6 The remuneration of persons engaged in inspection activities does not directly depend on the number of inspections carried out and, in no case, on the results of such inspections.

9 Facilities and equipment

9.1 Inspection Body IB has suitable facilities and equipment at its disposal to carry out all inspection activities adequately.

9.2 Access to and use of Inspection Body IB’s facilities and equipment by unauthorized persons are not permitted.

9.3 Inspection Body IB ensures the continued suitability of its facilities and equipment for the intended use.
9.4 All equipment has been properly tagged (see SOP 9.5 Preventive maintenance).

9.5 Inspection Body IB ensures that all such equipment is properly maintained in accordance with the documented procedure, SOP 9.5 Preventive maintenance.

9.6 Inspection Body IB ensures that all equipment used for measurements the results of which have a significant influence on the results of inspections is calibrated before being put into service and thereafter according to an established programme according to SOP 9.6 Calibration.

9.7 Equipment identified under the criteria in 9.6 is calibrated according to national or international standards where possible and appropriate.

9.8 Reference materials are, where possible, in conformity with national or international standard reference materials.

9.9 Inspection Body IB has procedures for the following:

- the selection of qualified suppliers: SOP 9.9.a Supplier selection and review
- the issuance of appropriate purchasing documents: SOP 9.9.b Purchasing and verifying purchased products
- the inspection of received materials: SOP 9.9.b Purchasing and verifying purchased products
- ensuring appropriate storage facilities

9.10 Computers, software and automated equipment that Inspection Body IB uses in connection with inspections are maintained according to procedure SOP 9.5 Preventive maintenance.

9.11 Defective equipment is dealt with according to procedure SOP 9.5 Preventive maintenance.

9.12 Relevant information on all equipment is recorded. This includes identification, calibration and maintenance.

10 Inspection methods and procedures

10.1 Inspection Body IB uses the methods and procedures for inspection that are defined in the requirements and normally specified in regulations, standards and specifications.

10.2 Inspection Body IB possesses and uses adequate documented instructions on inspection planning and on standard sampling and inspection techniques. Where applicable, sufficient knowledge of statistical techniques is available to ensure statistically sound sampling procedures and the correct processing and interpretation of results.
10.3 If *Inspection Body IB* must use inspection methods or procedures that are non-standard, these methods and procedures are fully documented.

10.4 All instructions, standards, written procedures, worksheets, checklists and reference data relevant for the work of *Inspection Body IB* is, under the responsibility of the technical manager, kept current and is readily available to staff.

10.5 *Inspection Body IB* reviews each inspection work request to ensure the following:

- The body has the capacity and capability to conduct the inspection appropriately
- The work being undertaken is controlled through regular reviews and corrective action (see SOP 7.8.b *Corrective actions* and SOP 7.7 *Internal audit*)
- Completed work is reviewed to confirm that inspections have been performed properly and adequately.

10.6 Observations and data obtained in the course of inspections are recorded in a timely manner to prevent the loss of relevant information (see SOP 10.6 *Control of quality and technical records*).

11 Handling inspection samples and items

11.1 *Inspection Body IB* ensures that the samples and items to be inspected are uniquely tagged to avoid confusion regarding the identity of such items at any time (see SOP 11.1 *Sample receipt, identification and handling*).

11.2 Upon receipt, the samples are checked for suitability for the inspection to be carried out.

11.3 *Inspection Body IB* establishes whether the sample has already been properly prepared or whether the customer has requested preparation to be undertaken or arranged by the body.

11.4 *Inspection Body IB* takes steps to avoid the deterioration of or damage to inspection items while under its responsibility.

12 Records

12.1 Technical and quality assurance records are established and maintained to provide evidence of conformity to requirements and the effective operation of the quality system. Mechanisms are established so that records remain clear, readily identifiable and retrievable.

12.2 Documented records include sufficient information to enable satisfactory evaluation of the inspections performed.
12.3 All records are safely stored for a specified period, held securely and kept confidential for the customer. A documented records procedure has been established to define the methods needed for the identification, storage, protection, retrieval, retention time and disposition of records (see SOP 10.6 Control of quality and technical records).

13 Inspection reports and inspection certificates

13.1 Inspection Body IB ensures that, for all inspections, there is a retrievable inspection report (consisting of information for internal and audit purposes) and a product inspection certificate (legal evidence for the owner or operator that the product has been submitted for inspection).

13.2 The inspection report and inspection certificate include all results of examinations and the determination of conformity made from these results, as well as all information needed to understand and interpret the results.

All this information is reported correctly, accurately and clearly. If the inspection report or inspection certificate contains results obtained through subcontractors, these results are clearly identified.

13.3 Inspection reports and inspection certificates are signed or otherwise approved by authorized staff members of Inspection Body IB only.

13.4 Corrections and additions are not allowed on inspection reports or certificates. If any correction or addition is necessary, the spoiled report or certificate is withdrawn, and an updated replacement inspection report or certificate is issued.

14 Subcontracting

14.1 Inspection Body IB normally performs the inspections through its own staff.

Inspections under the responsibility of Inspection Body IB may be subcontracted in the case of an unforeseen or abnormal overload, if key staff members are incapacitated, or if key facilities or equipment are unfit for use.

Full responsibility for determining the conformity of inspected processes and products with the relevant requirements remains with Inspection Body IB even if part or all the inspection is subcontracted.

14.2 If Inspection Body IB subcontracts any part of an inspection, thereby relying on individuals or employees of other organizations to provide additional resources or expertise, these individuals are not considered subcontractors provided they are formally contracted to operate under Inspection Body IB’s quality system and have training and qualifications equivalent to the body’s permanent employees.

14.3 Inspection Body IB assesses the competence of subcontractors according to the requirements of ISO/IEC 17020 or ISO/IEC 17025, as applicable. It records and retains details of its assessment of the
competence and standards compliance of its subcontractors. Inspection Body IB maintains a register of all subcontracting (see SOP 14. Subcontracting).

15 Complaints and appeals

15.1 In the event of a complaint, adverse findings during audits, or any other circumstance that raises doubts concerning Inspection Body IB’s competence or compliance with required procedures, Inspection Body IB ensures that the areas of activity and responsibility involved are promptly investigated. A resolution of the adverse situation is promptly sought, and, where necessary, reinspection is conducted. A procedure for handling complaints is maintained (see SOP 7.8.d Customer complaints and feedback).

15.2 Inspection Body IB must establish a procedure for the consideration and resolution of appeals against the results of its inspections, where these are carried out under legally delegated authority.

15.3 A record is maintained of all complaints and appeals and of the actions taken by Inspection Body IB in response.

16 Cooperation

16.1 Inspection Body IB participates in exchanges of experience with other inspection bodies and in standardization processes as appropriate.
Appendix 1

Organizational Scheme of Inspection Body IB

Appendix 2

Technical Scope of Activity of Inspection Body IB

<table>
<thead>
<tr>
<th>General field of inspection</th>
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</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type and range of inspections</th>
</tr>
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<tr>
<th>Regulations, standards, or specifications containing the requirements according to which the inspections will be performed</th>
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List of Procedures

- SOP 7.6 Control of Documents
- SOP 7.7 Internal Audit
- SOP 7.8.a Identification and Control of Non-conformities
- SOP 7.8.b Corrective Actions
- SOP 7.8.c Preventive Actions
- SOP 7.8.d Customer Complaints and Feedback
- SOP 7.9 Management Review
- SOP 8.3 Training
- SOP 9.5 Preventive Maintenance
- SOP 9.6 Calibration
- SOP 9.9.a Supplier Selection and Review
- SOP 9.9.b Purchasing and Verifying Purchased Products
- SOP 10.6 Control of Quality and Technical Records
- SOP 11.1 Sample Receipt, Identification and Handling
- SOP 14 Subcontracting
Document Control Procedure

SOP 7.6 Version 1

1.0 Purpose

The objective of this procedure is to establish and maintain a method of controlling documents and data throughout Inspection Body IB.

2.0 Scope

This procedure deals with the development of and change in quality documents and their review, approval and distribution. This procedure also describes the method of protecting and saving computer files.

This procedure applies to all quality control documents (including external documents) and to other data required by ISO 17020.

3.0 Procedures

3.1 Control of changes in the manual

When the quality manager receives a document change request, he distributes it to the parties affected. The parties affected inform the quality manager of their remarks about this request. The requests and the associated remarks are discussed during a quality meeting. If necessary, the quality manager will redraft the request.

This method is repeated till the quality meeting accepts the request or definitively refuses it. If the document change request is definitively refused, the initiator of the request is informed accordingly.

The quality manager distributes the changed documents to the parties affected and ensures that versions and dates are updated, where necessary. If necessary, the quality manager can decide to reissue the entire quality manual so that there is one date and one version for all documentation.

3.2 Request for revision of a document

Any individual within the organization may request an addition, revision, or deletion in a quality document (procedure, process plan, or work instruction or form).

In this case, the individual submits, in writing, the request, along with appropriate attachments, to the quality manager.

3.3 Release of documents
If accepted, the new or revised quality document is approved and initialed or signed by the managing director and released after approval.

For procedures and instructions, approval always follows after the discussion of the document change request during the quality meeting, whereas documents can be approved at once by the managing director.

3.4 Control of internal and external documents

Control of internal documents:

Manual: the owner of a complete manual updates the appropriate documents and shows new revisions in his controlled copy.

Quality dossier: every owner of a quality dossier updates the appropriate documents and shows new revisions.

Control of external documents:

External documents that affect quality are documents on the regulatory and legal requirements, the analysis of products, safety data and technical data that are part of the quality management system. Software packages are also considered external documents.

External documents are dated and listed on the list of external documents.

The quality manager distributes the external documents and ensures that the latest version of the documents are distributed. Invalid external documents are destroyed.

3.5 Control, distribution and administration of manuals

The quality manager is responsible for the following:

- the control of the originals of all manuals and documents, including computer files and backups
- the creation and maintenance of reference lists
- the control of completed and obsolete documents
- the maintenance of the document control system.

The original documents (with the original signatures of the managers involved) are kept by the quality manager. Only the quality manager has the authority to make copies of these documents (or manuals).

Revised procedures, instructions and other documents are distributed by the quality manager.

Obsolete or invalid procedures, instructions, or documents are destroyed by the quality manager or by the owner.
In some cases (for example for legal reasons), the quality manager is allowed to keep invalid documents. These documents are identified by the word “Obsolete”.

The preservation of quality records is described in procedure SOP 10.6 Control of quality and technical records.

**Distribution of manuals:**

Integral manuals are distributed to the managing director, the quality manager and all managers who are mentioned on the quality manual distribution list. Procedures, instructions and documents are distributed in a controlled manner via the quality dossiers of the collaborators. The quality manager is responsible for the determination and, if necessary, the adjustment of the tables of contents of quality dossiers.

**3.6 Control of personal computers**

**Admittance protection:**

Each PC is protected by a password for each user. This password is only known by the user and by the quality manager. Passwords are changed once a year. The quality manager maintains the list of passwords.

**Data protection:**

To ensure that data are not accidentally lost, the quality manager is responsible for the daily backup of all altered files.

**3.7 Software changes**

Every request for a change in software is discussed by the quality manager during the quality meeting or during a special meeting of all users of the relevant software. The proposed changes and their potential impact are discussed.

The purchasing manager purchases new software according to SOP 9.9.b Purchasing and verifying purchased products.

The Quality Manager ensures that no software change is implemented without the following:

- training users
- writing or adjusting the necessary instructions
- undertaking a broad test run.

The quality manager evaluates the changes and reports his findings during the quality meeting.
4.0 Associated documents

- overview of procedures
- overview of processes
- overview of instructions
- overview of responsibilities
- overview of documents
- document change request.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Internal Audit Procedure

SOP 7.7 Version 1

1.0 Purpose

This procedure defines the methodology of Inspection Body IB in performing internal audits of the quality management system.

The purpose of internal auditing is to ensure that the quality management system is operating correctly and effectively. This is accomplished by performing planned and documented checks designed to ensure the following:

- The quality system documentation adequately defines the needs of inspection activities.
- The documented procedures and instructions are practical, clearly understood and properly implemented.
- The employees are experienced and well trained to perform their tasks adequately.

2.0 Scope

The procedure applies to all internal quality audits, which will generally be performed according to the requirements of ISO 17020, the inspection body's quality manual, procedures, process plans and work instructions.

The auditors must be suitably qualified and may be Inspection Body IB employees or external consultants. Inspection Body IB employees must not have direct responsibility for the processes to be audited.

3.0 Procedures

3.1 Audit planning

The quality manager is responsible for planning and conducting the internal audit programme, i.e., for the allocation and training of internal auditors and for preparing the internal audit schedule.

The internal audit schedule is a controlled document, which is authorized by the managing director. The schedule should cover all aspects of the quality management system at least once a year. Particular activities may be audited more frequently depending on their importance. For each audit, the schedule should define the auditor, the auditee and the audit date. At the planning stage, the month for the audit will be sufficient; as the audit date approaches, the auditor sets a firm date with the auditee.
3.2 Audit preparation

The auditor will prepare each audit as follows:

- by reading through previous audit reports covering the same area
- by becoming familiar with the requirements of ISO 17020 and the relevant documents
- by contacting the auditee and confirming the date and time of the audit
- by preparing an audit checklist.

3.3 Auditing

During the audit, the auditor will do the following:

- collect information concerning the subject being audited
- not respond to rumour or hearsay and avoid confrontational situations and argumentation
- collect documentary evidence of conformity or non-conformity
- note where current procedures may be improved
- keep the auditee informed on the progress of the audit and any findings.

3.4 Audit reporting

Soon after having performed the audit, the auditor will prepare an audit report that:

- reports and classifies the findings of the audit as follows:
  - acceptable: satisfies the requirements of ISO 17020 and Inspection Body IB’s standards, procedures, manual, etc.
  - major: fails to satisfy the requirements of ISO 17020
  - minor: satisfies the requirements of ISO 17020, but fails to satisfy Inspection Body IB’s internal standards, procedures, manual, etc.
- contains constructive suggestions for improvements and clearly identifies the areas where corrective actions are required, as well as who is responsible for carrying the actions out
- contains the names of the auditor and auditees and the location and date of the audit;
- is signed by the parties involved, who thereby attest that the audit is a true and accurate representation of the facts.

3.5 Follow-up
The auditor is responsible for verifying that follow-up actions take place. The actions should be structured in action plans to be executed by the auditee.

If an auditee persistently fails to carry out the assigned follow-up actions, the auditor informs the quality manager and managing director so as to ensure that the follow-up actions take place.

Once all follow-up actions have been completed, the auditor will sign the audit report to indicate that it is complete.

3.6 Audit records

Completed audit records are stored as quality records to

- enable the identification and analysis of problems so that preventive actions may be taken
- analyse response and correction times
- enable preparatory work by the auditor through reviews of the past reports for that area or function
- provide valuable summaries for use in management reviews of the quality system.

4.0 Associated documents

- internal auditors list
- audit planning and schedule
- audit questionnaire
- audit report and records.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Procedure for the Identification and Control of Non-conformities

SOP 7.8.a Version 1

1.0 Purpose

The purpose of this procedure is to describe the method of adequately handling non-conformities.

2.0 Scope

The procedure deals with the following:

- supplier non-conformities
- internal non-conformities
- customer complaints.

The procedure applies to every operational failure caused by a disregard of established arrangements.

3.0 Procedures

3.1 Registration of non-conformities

_Inspection Body IB_ employees who have ascertained an internal problem, a customer complaint, or a supplier problem complete a corrective action request (CAR) according to SOP 7.8.b Corrective actions.

This registration includes the following:

- the identification of the non-conformity: is it a customer complaint, a supplier problem, or an internal problem?
- the description of the ascertained non-conformity
- the immediate action taken.

If possible, the cause of the problem is indicated.

The initiator of the CAR contacts the quality manager immediately. The quality manager records the non-conformity on a CAR form and forwards the CAR to the responsible department manager.

3.2 Blocking non-conforming inspections
If an *Inspection Body IB* employee ascertains a non-conformity related to inspections, the relevant inspection is halted; the report is withheld (as necessary), and the relevant department manager is informed.

Non-conforming samples, installations and reports are tagged by the department manager and not processed or used until they have been released by the department manager.

### 3.3 Treatment of non-conformities

The relevant department manager considers the significance of the non-conformity and decides whether the inspection should be repeated. This decision is recorded on the CAR.

If the quality of an inspection is affected by the non-conformities, the customer will be informed (where appropriate).

If an employee is performing inspections incorrectly, the impact on previous inspections is assessed by the department manager, who decides on the measures to be taken.

The results of non-conforming inspections already released are recalled or appropriately tagged (if necessary).

The department manager is responsible for authorizing the resumption of inspections.

### 3.4 Eliminating the root cause

If it is determined that non-conforming inspections could recur or if there is doubt about *Inspection Body IB*’s compliance with its own policies or procedures as set forth in the quality manual, SOP 7.8.b *Corrective actions* is implemented to identify, document and eliminate the root cause of the problem.

### 4.0 Associated documents

- Corrective action request (CAR).

### 5.0 Responsibilities

This SOP was written by the quality manager. This SOP was approved by the managing director.

**Creation date:**

**Approval date:**
Procedure for Corrective Actions

SOP 7.8.b Version 1

1.0 Purpose
The purpose of this procedure is to establish and outline the system for the corrective actions that are to be taken to eliminate the occurrence of non-conformities and other conditions that adversely affect quality.

2.0 Scope
This procedure applies to the processes, procedures, resources, personnel and management of Inspection Body IB.

In particular, customer complaints, supplier problems, internal non-conformities, and the results of internal and external audits and customer satisfaction surveys are taken into account.

3.0 Procedures

3.1 Completion of the corrective action request
If an employee of Inspection Body IB observes or experiences a problem or non-conformity, the related inspection activities are suspended and the employee completes the first section of a CAR with as many details as possible. The CAR contains the description of the non-conformity and the proposed (immediate) action and sets out the responsibility for implementation.

After it has been completed, the CAR is submitted for review to the quality manager and to the relevant department manager, who makes a decision about the implementation of an (immediate) action.

For tracking purposes, the CAR is logged into the CAR log by the quality manager.

3.2 Corrective action
By means of a periodic analysis of the data registered in the CAR log, the department manager determines the frequency and gravity of reported non-conformities. The manager decides if a corrective action is necessary and therefore seeks to determine, along with the employee who reported the non-conformity, the root cause of the non-conformity.

If a corrective action is taken, the action is recorded in the CAR. The measure can lead to changes in procedures, instructions, or other elements of the quality management system.
Upon review of the action, the department manager ascertains the effectiveness of the corrective action implemented. The entire process is repeated if the initial action has proven ineffective.

### 3.3 Control of actions and measures

During quality meetings, the status of actions is analysed according to action plans. The execution dates are noted. If necessary, extra measures are taken if planned actions have not been completed on time or if unexpected problems have been encountered.

Process improvements and the long-term effects of corrective actions are reviewed during management reviews.

### 4.0 Associated documents

- corrective action request (car)
- corrective action plan.

### 5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.
Procedure for Preventive Actions

SOP 7.8.c Version 1

1.0 Purpose

This procedure describes the system to define the actions of Inspection Body IB that are intended to prevent the occurrence of problems and non-conformities.

2.0 Scope

This procedure applies to the processes, procedures, resources, personnel and management of Inspection Body IB.

In particular, customer complaints, supplier problems and internal non-conformities should be prevented and addressed.

3.0 Procedures

3.1 Preventive actions

The quality manager explores the potential causes of non-conformities and possible improvements with the help of audit results, quality results, customer satisfaction inquiries, customer complaints, and processes and activities that influence quality.

Structuring through projects

Upon identification of the causes of (potential) non-conformities and possible improvements, preventive measures are structured in projects led by a project manager appointed by the relevant department manager. The project manager completes a project document and forwards it to the department manager and the quality manager.

The project document contains the following:

- the name and number of the project
- the project manager and project team
- the purpose and expected results
- the planned date of effectiveness
- the method to be used to gauge the effectiveness of the project.
Each project is approved by the Managing Director.

*Action plan*

The project manager monitors the project action plan. The action plan lays out the various actions necessary for successful project implementation, as follows:

- analysis of the problem or current situation
- inquiry on alternative solutions and the selection of a solution
- implementation of the solution selected
- examination of effectiveness.

The project manager reports on the project to the relevant department manager and the managing director.

3.2 Control of action and projects

During quality meetings, the status of preventive actions is analysed on the basis of the action plans. The execution dates are noted. If necessary, extra measures are taken if planned actions have not been completed on time or if unexpected problems have been encountered. Executed projects are also reviewed for effectiveness during the quality meetings.

Process improvements and the long-term effects of preventive actions are reviewed during management reviews.

4.0 Associated documents

- preventive action plans
- project data.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.
Creation date:

Approval date:
Procedure for Customer Complaints and Feedback

SOP 7.8.d Version 1

1.0 Purpose

The objective of this procedure is to establish and maintain a method of receiving and adequately processing customer feedback and complaints.

2.0 Scope

This procedure addresses all complaints and other feedback received from customers or other parties involved in Inspection Body IB activities.

3.0 Procedures

3.1 Registration of customer feedback and complaints

Receiving and logging in customer feedback and complaints

All communications with customers after inspections, whether written or verbal, are forwarded to the customer service department. Telephone communications are documented in memorandums that are written during or immediately following any conversations with customers.

All customer feedback is recorded by the customer service department and, if necessary, redirected to relevant units. Customer complaints are recorded on CARs that are filled out by the individuals receiving the complaints. The record for each customer complaint includes the following:

- identification of the customer
- brief description and (possible) cause of the complaint
- immediate action and person responsible for the action.

The relevant department manager is informed of the complaint. The complaint is entered into the access database by the quality manager.

Classification of customer complaints

Customer complaints are classified according to cause. The purpose of this is to facilitate better tracking of trends and the evaluation of improvements in specific areas. Possible causes of complaints are as follows:

- a labelling problem
• non-conforming inspection results
• samples damaged during delivery
• transmission of incorrect inspection results
• late delivery to customers
• problems in communications or responses
• complaints regarding business practices, publicity, etc.

3.2 Handling customer complaints

The customer service department and the unit directly responsible for area that is the subject of the complaint decide how to respond to the customer and, if applicable, the action to be taken to correct the problem. The customer is informed of this decision.

The quality manager reviews every customer complaint to determine whether it should be discussed during the quality meeting. The quality meeting can decide whether to take corrective action. This decision is recorded on the CAR.

If a customer returns non-conforming inspections results, the inspection results are evaluated, reviewed and otherwise handled and processed in accordance with SOP 7.8.a. Identification and control of non-conformities. Depending on the nature of the non-conformity, the quality manager may follow up with requests for corrective and preventive actions.

If the investigation of customer complaints determines that remote operations, subcontractors, referral laboratories, or other external organizations have contributed to the complaint, the quality manager contacts these organizations and provides them with all relevant information.

Every customer complaint is recorded. The records are maintained by the customer service department. Copies of written communications, reports and other documents related to a complaint are organized into a file and tagged with the complaint number.

In general, records on complaint investigations are maintained by the department that conducts the investigation. For example, records of internal investigations may be merged with records of the corresponding corrective or preventive actions, which are maintained by the quality manager; records of investigations on test performances or other test characteristics are maintained by the inspection department, and records of investigations that involve referral laboratories or subcontractors are maintained by the purchasing department.

4.0 Associated documents

• customer complaints
• customer feedback.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Procedure for Management Review

SOP 7.9 Version 1

1.0 Purpose

The purpose of this procedure is to document the process and primary agenda related to the issues to be included in the management review meetings to evaluate the status of the Inspection Body IB quality management system.

The regular review by Inspection Body IB management ensures the following:

• The quality management system continues to be effective and suitable, fulfilling the changing current needs and the future needs of Inspection Body IB and its customers.

• The quality management system is updated as necessary.

• The results of internal audits are reviewed to ensure that the quality management system, as defined, is being implemented and used properly.

2.0 Scope

This procedure applies to all management review meetings conducted by the management of Inspection Body IB.

3.0 Procedures

3.1 General

The managing director has overall responsibility for conducting the review meeting, which takes place at planned intervals, but at least once per quarter, and which should be attended by all department managers and the quality manager.

3.2 Quarterly management review input

The quality manager prepares the agenda of the meeting. The input of the review should include information on and analysis of the following:

• follow-up actions after the previous review

• findings of internal and external audits

• customer feedback and complaints
• supplier-related topics
• non-conforming products
• training efforts
• the status of preventive and corrective actions
• recommendations for improvement.

3.3 Quarterly management review output

The output of the review meeting includes decisions and actions resulting from the review of the input topics.

3.4 Annual management review

At least once a year, all aspects of the quality management system are reviewed to ensure the continual suitability and effectiveness of the system in light of ISO 17020 requirements and the quality policy and objectives of Inspection Body IB.

All areas subject to ISO 17020 requirements are reviewed to assess the present situation, the progress achieved and possible improvements. Decisions are made about the effectiveness of the quality management system, ways to improve processes and methods to meet customer needs more closely.

3.5 Recording the management review

The minutes of the management reviews are taken by the quality manager and approved by the managing director. The minutes contain the following:
• calendar year and date of the review
• the review period
• a list of attendees
• actions resulting from the meeting.

A copy of the minutes, which are maintained by the quality manager, are distributed to the attendees and any employee assigned to take action. A copy of the minutes of the meeting is retained on file.

4.0 Associated documents
• Minutes of management review meetings.
5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.

Creation date: 

Approval date:
Training Procedure

SOP 8.3 Version 1

1.0 Purpose

This procedure describes the processes for the recruitment and training of new and existing inspections personnel so as to ensure that the staff responsible for inspection has appropriate qualifications, training and experience and a satisfactory knowledge of the requirements of the inspections to be carried out.

2.0 Scope

This procedure applies to all employees of Inspection Body IB who manage, perform, or verify work that affects the quality of inspections.

3.0 Procedures

3.1 Recruitment of personnel

Department managers determine the need for new personnel in consultation with the human resources manager. The managing director is responsible for the formal approval of vacancy announcements.

A vacancy announcement stating the minimum educational and experience requirements for candidates is written by the human resources manager. The vacancy announcement is made public.

The selection of candidates is based on their curriculum vitae and personal interviews. The candidate who best fits the job profile of the vacancy is accepted. Acceptance is approved by the managing director.

All candidates who are not selected receive a message.

3.2 Training (new) personnel

Background

The quality manager informs new employees on the following quality aspects of their work for Inspection Body IB:

- the impartiality of their work: they sign an employee impartiality agreement
- the quality policy
• the execution of the inspections and the use of equipment in accordance with relevant work instructions and procedures
• the importance of the customer, regulatory and statutory requirements.

Planning the training

The relevant department manager is responsible for establishing a concrete training plan and programme.

Besides ensuring that new employees have a satisfactory knowledge of the requirements of the inspections to be carried out, the training programme should also include specific quality-related aspects such as courses on the quality management system and the evaluation of its effectiveness, statistical techniques and problem analysis.

The training plan is submitted to the managing director for approval.

Changes in regulations, technologies and customer processes may generate the need for training among existing personnel.

Employee may also request specific function-related education or training.

Training records

The educational attainment and training of each employee are recorded and maintained in the employee's personal file by the human resources manager.

4.0 Associated documents

• organizational chart
• overview of functions
• employee file
• function description
• training programme.

5.0 Responsibilities
This SOP has been written by the quality manager. This SOP has been reviewed by the human resources manager. This SOP has been approved by the managing director.

**Creation date:**

**Approval date:**
Preventive Maintenance Procedure

SOP 9.5 Version 1

1.0 Purpose

The purpose of this procedure is to describe methods to maintain all test and inspection equipment adequately so as to ensure continuing availability.

2.0 Scope

The procedure applies to all inspection equipment of Inspection Body IB.

3.0 Procedures

3.1 Control of the maintenance system

The maintenance manager is responsible for the maintenance system. His tasks include the following:

- development, planning, execution and registration of maintenance activities
- advice on the purchase of inspection equipment
- analysis of maintenance results
- verification of the effectiveness of executed maintenance activities
- reporting conclusions during management review meetings.

3.2 Identification of equipment

All inspection equipment that requires maintenance must be properly tagged. The equipment is tagged, and the need for maintenance is noted on the maintenance card. This card contains all relevant information on the equipment (name, manufacturer, supplier, purchase date, number of spare parts and stock position), any maintenance instructions and the maintenance history.

*Note:* The maintenance manager manages the spare parts warehouse. He is required to keep a fixed minimum stock of parts on hand.

3.3 Preventive maintenance planning

Preventive maintenance is carried out at regular intervals, which depend on the type, material, construction and frequency of use of the equipment. The intervals are indicated on the maintenance card.
The maintenance manager decides whether equipment maintenance is to be executed in house or by an external maintenance firm.

3.4 The performance of (preventive) maintenance work

The maintenance manager ensures that the maintenance internal or external technician is adequately qualified to execute the maintenance work properly.

The technician carries out the work according to the instructions on the maintenance card or work order. When the work is finished, he signs and dates the work order and the card.

If an employee ascertains that equipment is defective during his activities, he notifies the relevant department manager or the maintenance manager. The defective equipment is removed from service and clearly tagged out of order.

The effect of the defect of the equipment on previous inspections, if any, is examined.

4.0 Associated documents

- maintenance card
- maintenance schedule
- maintenance contracts
- maintenance history.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been reviewed by the maintenance manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Calibration Procedure

SOP 9.6 Version 1

1.0 Purpose

The purpose of this procedure is to ensure that the measuring equipment of Inspection Body IB is accurate within the required parameters. The procedure describes how to tag, calibrate and maintain measuring and monitoring equipment in good condition.

2.0 Scope

The procedure applies to all equipment used for measurements that have a significant influence on the results of inspections.

3.0 Procedures

3.1. Responsibility

A staff member of Inspection Body IB should be named calibration manager. The calibration manager is responsible for ensuring that the necessary calibrations are conducted according to schedule. This includes the following:

- planning, execution and recording of calibrations
- evaluation of the results of calibration
- release of measurement devices after repair or calibration
- the provision of advice on the purchase of measuring equipment.

3.2 Registration and planning

The calibration manager makes an inventory of all Inspection Body IB measurement devices.

Each device has a calibration card showing the following data: name and identifier of the device, manufacturer or supplier, year of acquisition, measurement range and accuracy. The card also contains calibration data, including whether calibration is carried out by an internal or external technician, the frequency of calibration and the steps in calibration.

The calibration manager determines the frequency of calibration and develops a calibration plan on the basis of manufacturer guidelines, the operating instructions, the working condition of the devices and the required accuracy. The calibration manager records the effective calibration date. For every
measuring device, the calibration manager retains a calibration chart indicating all calibrations that have been performed, whether internally or externally.

### 3.3 Calibration

The calibration manager oversees the calibration, whether internally or externally, after the release of the device on the planned date of calibration. For calibrations performed in-house, the calibration manager follows the instructions for calibration. The calibration manager ensures that calibration is in line with national standards by using reference standards for measurements for which Inspection Body IB holds a current calibration certificate or equivalent from a competent body.

If the calibration is performed externally, the calibration manager follows SOP 9.9.b *Purchasing and verifying purchased products* to select appropriate calibration institutions that are ISO 17025 accredited.

For each calibrated measurement device, the calibration manager provides a label indicating the validity period.

If the calibrations involve a set of correction factors, these are correctly updated by the calibration manager (e.g., in the computer software).

### 3.4 Defects and inaccuracies

Each measurement device that is damaged, outside the tolerance limits, or shows any other non-conformity is immediately tagged with a red label and blocked from use. The calibration manager then fills out a CAR and decides either to repair and recalibrate the device or to scrap it. The calibration manager also contacts the relevant department manager to check on the measurements executed with the non-conforming device. The department manager decides if the measurements must be performed again. These actions are recorded on the CAR in line with SOP 7.8.b *Corrective actions*.

### 4.0 Associated documents

- calibration card
- list of measuring devices
- calibration planning
- calibration contracts
- calibration history.
5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been reviewed by the calibration manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Procedure for Supplier Selection and Review

SOP 9.9.a Version 1

1.0 Purpose

The purpose of this procedure is to ensure that the products purchased by Inspection Body IB and the services supplied to Inspection Body IB conform to specified requirements.

2.0 Scope

This procedure applies to all suppliers of products and services that may affect the quality of Inspection Body IB activities.

3.0 Procedure

3.1 Request for proposal

The purchasing manager draws up a request for proposal (RFP) for the product or service to be purchased. The RFP includes the specifications, time of delivery, quantities, warranties, supplier evaluation definitions and requirements, and other parameters to which the supplier must agree (bank statements, industrial licenses, etc.).

3.2 Selection of potential suppliers

The purchasing manager is responsible for selecting a supplier on the basis of the supplier’s ability to meet the requirements set out in the RFP. The first step is to collect information on potential suppliers and to create a list of potential suppliers. RFPs are sent to these suppliers.

Once suppliers have submitted written tenders, the purchasing manager prepares a comparative document that evaluates the tenders according to the requirements. Then, the purchasing manager verifies that the comparisons are correct and determines who might become the supplier.

The selection of potential suppliers is based on the following criteria:

- Do the goods or service to be purchased meet the quality requirements?
- Is the price reasonable?
- delivery time
- payment method
- ability to supply the quantity ordered.
The purchasing manager establishes the list of approved or preferred suppliers. This list is subject to approval by the managing director and is recorded and maintained by the purchasing manager.

3.3 Evaluation and review of suppliers

Registration of non-conformities among suppliers

Each non-conformity associated with a supplier that is observed and verified after the delivery of a product or service is noted on a CAR (see SOP 7.8.b Corrective actions). A supplier non-conformity may involve the quality of the product or service delivered, a late or mistaken delivery, the lack of sufficient documentation, poor packing, or damage during transport.

If immediate remedial measures are needed, the purchasing manager contacts the relevant supplier.

Resolution of non-conformities

The purchasing manager negotiates with the supplier about immediate and corrective measures, which are noted on the CAR. A follow-up on the corrective actions takes place during the quality meetings or earlier if necessary.

Supplier review

Once a year, a review of all suppliers of products or services affecting the quality of Inspection Body IB activities is undertaken by the purchasing manager. This review is based on supplier documents, the quality of the product or service at delivery and the performance during use. The observations are noted on the supplier review document.

On the basis of the yearly evaluation or supplier non-conformities identified outside the review process, the purchasing manager drafts a proposal on the actions to be taken against suppliers who do not meet Inspection Body IB requirements. The actions are subject to approval by the managing director.

The purchasing manager is responsible for any resulting modification necessary in the list of preferred suppliers.

4.0 Associated documents

- list of preferred suppliers
- list of supplier problems during the past year
- supplier reviews.
5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been reviewed by the purchasing manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Procedure for Purchasing and Verifying Purchased Products

SOP 9.9.b Version 1

1.0 Purpose

This document describes the procedures for acquiring and purchasing the products and services needed for the appropriate execution of Inspection Body IB’s inspection activities. It also describes the methods used by Inspection Body IB to test purchased products to ensure they meet the specifications and requirements determined during the ordering process.

2.0 Scope

The procedure applies to all products and services affecting the quality of Inspection Body IB processes and also to all subcontracting.

3.0 Procedures

3.1 Inquiry to tender

An inquiry to tender a product or service is sent to relevant preferred suppliers of those products or services. The inquiry to tender includes at least the name of the supplier, the date, a precise description of the product or service and the signature of the purchasing manager.

The received tenders are compared and evaluated by price, delivery time and former experience with the supplier. Based on the evaluation, the purchasing manager decides on the placement of orders.

3.2 Ordering

Orders can be placed only with preferred suppliers.

An order form is used that has been prepared by the department responsible for the purchase. This form includes a precise identification of the products or services sought, the name of the supplier, the identifier of the order form, the name of the person who is placing the order, the person who is to receive the order and the signature of the purchasing manager. Where applicable, standards and other relevant technical data are included.

If an order needs to be changed, a new order form is completed clearly indicating that the form is being issued as part of an order change. The new order form must mention the date or identifier of the original order form.

3.3 Verification of purchased products
The purchasing manager ensures that the warehouse manager and the quality manager are properly informed in a timely fashion about the order, including the supplier, the product, the product specifications, the quantity and the delivery date.

Upon receipt of the product, the warehouse manager, either through inspection or on basis of a certificate of conformity, verifies whether it meets the purchase specifications and requirements. The warehouse manager signs to accept the delivered product. If products do not meet order specifications and requirements, they are rejected and returned to the material supplier. A log of the product arrival is kept in the warehouse information system.

4.0 Associated documents

- list of preferred suppliers
- template order form
- product information sheet.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been reviewed by the department manager responsible for the purchase. This SOP has been approved by the managing director.

Creation date:

Approval date:
Procedure for the Control of Quality and Technical Records

SOP 10.6 Version 1

1.0 Purpose

The purpose of this procedure is to ensure that quality and technical records are adequately identified, collected, indexed, accessed, filed, retained, maintained, disposed of and stored.

2.0 Scope

This procedure applies to quality and technical records designated in the manual and in the procedures and to other quality and technical records identified in implementing documents.

3.0 Procedure

3.1 Determination of quality and technical records

The control, composition, alteration, announcement and distribution of the following quality records demonstrate the effective operation of the quality management system:

• records concerning contract reviews: orders, price quotations, etc.
• internal audit reports and the associated corrective and preventive actions
• evaluations and audits of suppliers (particularly for subcontracting)
• list of approved suppliers, purchase documents and other relevant purchase data
• records of customer complaints
• records of every non-conformity, including damaged customer property
• reports of quality meetings, including the periodic management review of the quality management system
• records of corrective and preventive actions
• training records
• maintenance records
• calibration records
• inspection reports.
All quality and technical records that are part of the quality management system are listed and appropriately identified by a descriptive title and a rotation number. The table of contents of each quality dossier mentions the quality and technical records that are to be maintained. Each dossier has an owner, who is a member of the management team. The dossier owner is responsible for the following:

- keeping the dossier updated
- correctly sorting and numbering the data
- the presence of the dossier at the agreed location
- the preservation in good condition during the agreed period
- the removal of outdated data (at least once a year) and the prevention of damage.

The dossier owner controls the distribution of the data. He also decides who is allowed to look at the records. The dossier owner is responsible for transferring the dossier and other documents to the records office. Once a year, current records are transferred to the records office. The dossier owner, records office and archive period of each record are determined by the quality manager.

All documents containing confidential information are clearly so tagged. They are maintained by the quality manager.

3.2 Control of quality records

The responsibility for the correctness and the completeness of quality and technical records is indicated in the relevant procedures and work instructions.

The relevant department manager is responsible for the use of suitable documents within the department. Therefore, the department manager regularly checks on those documents that are in use. The department manager ensures that all records used in the department are clear and accessible. Where possible, the recording takes place during the execution of the activities. Each record contains the name of the employee, the date and the identification of the activity.

Necessary corrections should be mentioned in the margin, be clearly identified and be initialed by the relevant employee.

3.3 Archiving

The quality manager maintains all completed quality and technical records in the archive. The records, their dossier owner, the depository and the retention period are mentioned on the archived documents. The quality manager is responsible for the appropriate measures to prevent damage or loss of the archived records and ensure that all outdated records are removed from the records office. The removal process takes place at least once a year.

All documents containing confidential information are kept by the quality manager.
4.0 Associated documents

- list of records.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Procedure for Sample Receipt, Identification and Handling

SOP 11.1 Version 1

1.0 Purpose

This procedure ensures that samples and items to be inspected are properly received, identified, handled, stored and preserved.

2.0 Scope

The procedure covers all samples taken and received by Inspection Body IB.

The warehouse manager is responsible for the proper implementation and execution of the procedure.

3.0 Procedure

3.1 Receipt of samples

All samples received are recorded in an accession book, worksheet, computer, or other system. (Describe the system used and refer to the relevant document.) The date and time of receipt, as well as the identity of the receiving officer, are recorded. Upon receipt, the samples are checked to ensure that they meet following acceptance criteria:

(Describe the acceptance criteria for the primary samples.)

The receiving officer establishes whether the item has received all necessary preparations.

Any apparent abnormality that is noticed should be recorded before inspection begins. If there is any doubt about the item’s suitability for inspection or if the item does not conform with the description provided, Inspection Body IB should consult with the customer before proceeding.

3.2 Sample identification

Primary samples can be tracked by their identification code. Primary samples are identified through the following code:

(Describe how the primary samples are identified.)
Samples lacking proper identification are not accepted and processed by *Inspection Body IB*.

If there is uncertainty about the identification of the sample and the sample is irreplaceable or critical, the responsible department manager may initially decide to process the sample.

Results are released only after the customer or individual responsible for the primary sample collection takes responsibility for identifying and accepting the sample or provides proper information on the relevant sample.

**3.3 Handling and storage**

Standard warehouse handling practices and storage conditions are considered acceptable unless special handling or storage is required. If special handling or storage is required, see section 3.6 of this procedure.

If storage areas other than the warehouse areas of *Inspection Body IB* are to be used to store inspection items, material, or products, the manager responsible should designate such areas and specify any applicable authorizations for delivery into and release from these storage areas. The warehouse manager should establish work instructions for the authorization of delivery into and dispatch from the warehouse.

If deterioration of the product or material could occur in storage, the warehouse manager should decide on the intervals and methods for assessing the condition of the stored product. The manager responsible shall ensure that this assessment is performed.

**3.4 Conserving products**

Standard warehouse environmental conditions should be considered acceptable for storage unless a special storage environment is required. If a special environment is required, see section 3.6 of this procedure.

**3.5 Delivery**

Common carriers should be considered acceptable for the delivery of material from *Inspection Body IB* to customers unless there are special delivery requirements. If there are special delivery requirements, see section 3.6 of this procedure.

If required by customer agreement, special means of ensuring the protection of the product until it reaches the destination should be specified by the warehouse manager.

**3.6 Special handling, storage, packaging, preservation, or delivery**

If special handling, storage, packaging, preservation, or delivery is required, the warehouse manager should define the special requirements either in reference to existing procedures covering the special requirements or by creating procedures to cover the special requirements.
The warehouse manager should ensure that relevant Inspection Body IB employees have access to procedures or work instructions any covering special requirements and should implement procedures or work instructions covering special requirements.

Examples of products that have special handling, storage, packaging, preservation, or delivery requirements include corrosive, reactive, or temperature-sensitive inspection items, materials and products.

4.0 Associated documents

- shipping document
- shipping request
- request for custodial storage.

5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
Procedure for Subcontracting

SOP 14 Version 1

1.0 Purpose

This procedure defines the method of evaluating and selecting subcontractors to ensure that subcontractors meet Inspection Body IB’s requirements.

2.0 Scope

The procedure covers all subcontractors providing inspection services to Inspection Body IB.

3.0 Procedure

3.1 Selection of subcontractors

The managing director of Inspection Body IB is responsible for selecting and monitoring the capacity, capability and quality of subcontractors and ensuring that the subcontractor is competent to perform the requested inspections.

The managing director reviews the arrangements with subcontractors to ensure the following:

- Requirements, including inspection procedures, are adequately defined, documented and understood
- The subcontractor is able to meet the requirements and that there are no conflicts of interest
- The selection of inspection procedures is appropriate for the intended use
- The respective responsibilities for the interpretation of inspection results are clearly defined.

The competence of a subcontractor can be demonstrated as follows:

- The subcontractor has ISO 17020 or ISO 17025 accreditation as applicable.
- Inspection Body IB’s assessment of the subcontractor’s competence as appropriate to the requirements of ISO 17020 or ISO 17025.

The managing director ensures that his staff is technically competent and knowledgeable in the application of ISO 17020 or ISO 17025.

Records of subcontractor reviews are maintained by the quality manager.
Agreements with competent subcontractors, including on the services to be provided and related terms, are laid down in contracts or memorandums of understanding and are signed by the managing director.

Contracts or memorandums of understanding with subcontractors, as well as a register of subcontractors, are maintained by the quality manager.

### 3.2 Reporting by subcontractors

The inspection reports of subcontractors responsible for examination results are provided to *Inspection Body IB*. A duplicate of the inspection report is retained in the permanent file of *Inspection Body IB*.

*Inspection Body IB* is responsible for ensuring that subcontractor inspection results and findings are provided to its customers. *Inspection Body IB’s* reports include all essential elements of the results reported by subcontractors, without alterations that could affect interpretation. However, it is not required that reports include every word and have the exact format of subcontractor reports unless local or national laws or regulations require this.

### 4.0 Associated documents

- list of subcontractors
- subcontractor reviews
- subcontractor contracts or memorandums of understanding.

### 5.0 Responsibilities

This SOP has been written by the quality manager. This SOP has been approved by the managing director.

Creation date:

Approval date:
IV MANAGEMENT OF THE QUALITY OF NATIONAL IODIZED SALT SUPPLIES

IV.A QUALITY ASSURANCE AND QUALITY CONTROL IN SALT FACTORIES

Quality Management Systems

Like other industries that manufacture goods, food companies and their associations commonly promote "Good Manufacturing Practice" (GMP) as a key measure for the development, protection and continuous improvement of the reputation of their products in the marketplace. In general, GMP requirements address all the aspects of production and testing in a factory that can affect the quality of the end product. GMP are not prescriptive instructions on how to manufacture products, but a set of principles to be complied with in the manufacturing process.

Typically, a GMP prescribes that the company must develop and execute a Quality Management System (QMS). Typical purposes of a QMS are (a) to document the company's best business practices; (b) satisfy the expectations and requirements of the customers; (c) ensure compliance with national standards; and (d) enable the continuous improvement of management performance. The scope and nature of the QMS of a company depends on the adopted GMP, its ambition in competing for market share, and the regulations for business registration, sales permission and product quality characteristics used by the national authorities and inspection agencies.

A complete QMS should cover all the measures adopted by the company to prevent any threat to the safety of the product, all the while ensuring proper quality of the product in agreement with customer demands and meeting the norms set in the national standards. As exemplified in the Codex Alimentarius for food-grade salt (Appendix i) and adopted in many national standards, the safety requirements for salt destined for humans include maximum permitted levels of potentially harmful contaminants and proper hygienic methods in the production, packaging, storage and transportation of salt. Thus, many companies which produce and sell foods that have or are potential sources of biological, chemical and physical contaminants conduct a Hazard Analysis Critical Control Point (HACCP) management system, which specifically aims to avoid such food safety issues. HACCP systems are premised on the principle that any preexistent threat of contaminants has been excluded or minimized by the proper choice of location, layout of premises, equipment and facilities, and in the control of operations (incl. incoming material, packaging, water quality, etc), maintenance of sanitation, cleaning routines, waste disposal and personal hygiene. The same prerequisite requirements are valid for Quality management Systems that are focused on assuring product composition characteristics, including the present manual.

Like HACCP management systems, the QMS measures described in this document should be understood as part of an overall system that aims at preventing or eliminating potential biological, physical and
chemical contaminants in the end product. Salt factories should respect proper sanitation, regular cleaning habits and personal hygiene measures to prevent and control biological hazards. Noteworthy, potential pathogenic bacteria cannot survive in salt for longer than 30 days and, therefore, iodized salt poses minimal biological risk. Potential physical contamination by employees or visitors (such as hair), foreign objects (e.g. glass, wood, metal) and insoluble materials (small stones, sand) must be prevented by adequate washing of the raw input salt, together with proper personal hygiene measures and routine cleaning of the production area. The most likely risk of chemical contamination in iodized salt is that of over-dosage with the fortificant, which should be controlled by regular quality checks during iodized salt manufacturing and storage of the end product, as described later in this document.

Salt manufacturing companies have a critical role in national salt iodization strategies, because they are responsible to make sure that the salt supply for human consumption is safe and contains the right levels of chemical substances in accordance with national standards. The use of QA/QC protocols in the production, warehousing and sale of iodized salt, as integral parts of the company’s QMS, is therefore vital. Carrying out QA and QC in iodized salt production and sale does not require the adoption of an entirely new program but only the incorporation of those activities in the warehouse, production area and the store which are specific to the provision of quality iodized salt. The development of a QA/QC system in a factory needs the support from general management to provide the resources to carry out and maintain adequate performance of the QA/QC protocols.

Salt Quality

Worldwide, raw salt is predominantly obtained by solar evaporation of sea water, inland lake or underground brine, including from solution mining of rock salt. Rock salt deposits are often clean and in many, but not all cases, the mined salt requires little purification. Gypsum (calcium sulphate) and other insoluble materials may be present, but these can be separated. Rock salt contains minimum moisture. Sea salt is manufactured by the progressive evaporation of sea water together with the naturally salt contents in large open ponds while using sunshine and wind. During evaporation, the sea water concentration (brine) continues to rise and different kinds of salts will form crystals in a set sequence depending on the increasing brine density. The ponds are arranged in a fixed sequence, and the brine is allowed to flow or pumped from the largest ponds (evaporation), through the mid-size ponds (concentration) to the smallest ponds close to the factory (crystallization), where the harvesting of solar salt takes place. The management of these consecutive stages is critical for obtaining as much and pure sodium chloride as possible, but along with the sodium chloride, some co-crystallization always occurs in the harvesting ponds of the chlorides and sulphates of magnesium, calcium and potassium.

The salt crystals form as a uniform crust on the bottom of the pond and are harvested by a variety of methods ranging from manual raking to mechanical scraping with dumpers or specialized equipment. The wet crystals can be either directly put on the side for drying and draining, or they are washed with saturated brine to remove insoluble matter such as clay and sand as well as the soluble impurities. After draining and drying at the sun, the salt can be crushed and/or sieved to a coarse or fine powder as
required. This is usually also the stage that additives may be mixed in and/or iodization takes place before the salt is packed for sale.

In a properly designed and managed solar salt factory, sea salt can reach up to 95% sodium chloride, 1% calcium and magnesium salts each, and approx. 5% humidity. If this salt is properly washed and dried, its purity can be improved to 98-99%, thus meeting the 97% minimum sodium chloride content recommended in the Codex Alimentarius for food-grade salt.

**Potassium Iodate**

Iodization of salt consists of the mixing of a chemical iodine compound, named “fortificant” or iodating agent, into crude salt. The preferred fortificant for salt iodization is potassium iodate (chemical notation: KIO$_3$), but other chemicals, in particular potassium iodide (KI), are also used especially in countries with a temperate climate and a short turn-over time between the manufacturing and purchase of iodized salt. Potassium iodate is preferred due to its superior stability in salt that is not highly refined, may contain moisture up to 5% and is sold in warm and humid climates. Usually, KIO$_3$ is sold in fiber drums with the chemical sealed in heavy-duty polyethylene bags.

In 1991, the Joint WHO/FAO Committee on Food Additives concluded that potassium iodate is a safe additive to food-grade salt in the commonly used concentrations. Also the Food and Drugs Authority of the USA has conferred GRAS status (“Generally recognized as safe”) to the use of potassium iodate as a food additive.

**Methods of Salt Iodization**

The most common method of iodating salt is called “wet mixing”. This involves the preparation of a fortificant (iodate) solution which is sprayed or dripped onto the salt as it moves along a conveyor belt or a screw conveyor. In a simpler set-up, which can be equally effective when carried out well, the iodate solution is sprayed onto a batch of salt that is mixed in a blender or roller mixer. The preparation and spraying of solution requires the fortificant, clean filtered water and a pump with a nozzle for spraying. Although dripping of the solution is satisfactory for coarse salt with a diameter less than 1cm and moisture levels up to 5%, the spraying method is more effective for situations where the particle size and moisture levels of the salt vary, which is the common case for salt industries in the less-developed world.

Typical concentrations of the iodate solution range from 50 to 100 grams of KIO$_3$ (30 to 60g of iodine) per Liter of water. The application rate or amount of solution to be mixed with salt depends on the flow rate in a continuous fortification process or on the batch size when fortification is done in a blender or mixer. In a "worst case" scenario, a solution that contains 30g KIO$_3$ per Liter (3% iodine, equal to ±5% KIO$_3$) increases the moisture content in the final product by less than 0.2%, which is minimal. Therefore,
the amount of water added in wet manufacturing of iodized salt barely affects the humidity of the final product.

Dry mixing is less common than wet mixing. Dry mixing is especially effective for pure salt that is fine and dry with grains of diameter less than 2 mm so that it can mix well with the fine grains of KI\textsubscript{3}. When iodized salt is manufactured by dry mixing, the KI\textsubscript{3} is first blended with an anti-caking agent to serve as the standard premix, which is then mixed with the input salt in a set proportion. Commonly permitted anti-caking agents are calcium carbonate, tricalcium phosphate and magnesium carbonate.

**Ensuring Proper Iodine Content**

Accurate preparation of the iodate solution and proper mixing of salt with iodate solution demand a QA/QC protocol that is carried out consistently. Importantly, when the salt iodine level during iodized salt manufacturing gets outside the prescribed range, the factory staff should identify the cause(s) of trouble and apply corrective measures as soon as possible. The related corrective measures put in place need to be documented and the records of QA activities updated, so that they can be available to inspection personnel that may visit the factory at any time. These quality demands have been described in detail in the Quality Manual Template for Salt Businesses, together with the Standard Operating Procedures that are pertinent for proper quality of iodized salt manufacturing.

The staff of the national regulatory authority has a duty to visit salt factories at regular intervals to carry out an inspection or technical audit of the salt manufacturing process and the chemical properties of the final product stored in the warehouse. One of the activities during these inspections consists of the examination of the factory’s records. It is important to keep in mind the principle that “what has not been recorded has not been done”.

**Salt Factory Personnel**

In many countries, large-scale salt factories have different senior management employees responsible for finance, commerce, input purchase, manufacturing, testing, storage and sales. For the QA/QC system to succeed, their respective roles and accountabilities in executing the company’s QMS must be clearly defined. And for job performance assessments, the expected accomplishments in a company’s QA/QC system should be included in the job descriptions of each officer directly involved with the respective quality characteristics of the end product - iodized salt.

In the following sections, for clarity and simplicity of the descriptions in large and medium-scale salt factories, the respective duties in the QA/QC system are distributed among a Warehouse Manager, a Production Manager, a Quality Manager, and the Managing Director who is the overall responsible employee for the operations in a factory.
In large factories, especially those specializing in a variety of salt products and packages (for coarse salt, refined salt, table salt, salt "specialties", etc), management responsibilities are typically distributed across a broader range of personnel. The Quality Manual Template lists seven different manager's titles, but in the largest factories, more specialists may have management responsibilities separate from, or in addition to those listed. Examples are Purchase, Marketing and Sales (in the Quality Manual Template we assume these positions are covered by the Commercial Manager), Electrical/Mechanical (covered by the Technical Manager), Laboratory (covered by the Quality Manager), and so on.

In small and some medium-sized salt factories, the various functions described above may be combined in fewer or even one single officer(s). Depending on the company, the procedures described below may therefore need to be combined and carried out by the respective company employee. As for large and medium-scale companies, these roles and accountabilities must be duly defined in the staff's job description(s).

The QA/QC protocols in this Chapter are described for large and medium-scale salt factories. Generally, the wet mixing method is used as basis for the detailed descriptions. The same principles apply for dry mixing.
QA/QC in Large and Medium-Scale Factories

This section describes the recommended QA/QC methods and protocols in large and medium-scale factories, while assuming that a separate manager is responsible for the four different parts in the overall QMS. In some smaller factories, these parts may be combined within the task description a fewer number or a single manager. In such cases, the factory management should adjust the descriptions accordingly.

(i) Fortificant receipt, storage and handling

Accountability

Proper warehousing involves management of the fortificant and its release from the storehouse. This is the responsibility of the Warehouse Manager. For measuring the iodine content in the fortificant, the Warehouse Manager works in close coordination with the Quality Manager.

Objectives

The purposes of QA/QC of fortificant receipt, storage and use are to ensure that:

- The fortificant has the correct iodine content
- The factory has always enough fortificant in stock for at least 3 months of production needs
- The fortificant is stored under adequate conditions and utilized on basis of the “first-in, first-out” principle.

Procedures

1. Handling and storage of fortificant:
   - Every time upon the arrival of a new delivery of fortificant, check that it is accompanied by a Certificate of Analysis (COA) and that the drums are hermetically sealed
   - Record in a form similar to Form A the manufacturer and the amount received, the COA number and the lot number(s), and other important observations. Attach the COA to Form A and provide a photocopy of both pages to the Managing Director
   - Mark each drum in sequence (A, B, C, etc) according to the expiration date(s) stated on the drum labels. Store the unopened drums in a clean dry area, away from chemical products or other potential contaminants. Arrange the storage in such a way that the first drums received will be used first, following the “first-in, first-out” principle
   - Only open a new drum when the fortificant is needed for iodized salt manufacturing.
2. Measurement of the iodine content in new fortificant:
   - Upon receiving a new fortificant supply, take two 10g samples at random from the drum(s), package them separately in a sealed bag and hand the samples over to the Quality Manager who will arrange for measurements of the iodine content in a laboratory
   - When the results of these analyses are available, compare them to the claimed content on the drum labels (Form A) or the COA. When the results of the iodine measurements are below the claimed content, notify the Managing Director for follow-up with the supplier.

3. When releasing the fortificant:
   - When fortificant is handed over for manufacturing iodized salt, record the date, the amount, and the name of the person who receives the fortificant, as shown in Form B. Each time, calculate the amount left over by subtraction, and enter this amount in column 4 and on the next line in column 2
   - Each time when a new drum is opened, start a new Form B. Always keep the record of the amount handed out (3rd column) and the amount left in the drum (4th column) up-to-date
   - Once the remaining stock of the fortificant falls below a pre-determined minimum stock amount (i.e., the amount needed for 3 months of production), inform the Managing Director that a new purchase order should be placed.

Records and Reporting

- The Warehouse Manager, working in tandem with the Quality Manager, should verify that the iodine content in each newly arrived fortificant shipment meets the specification (Form A). When the results of iodine measurements in a new delivery are below the claimed content, the Warehouse Manager should inform the Managing Director
- The Warehouse Manager should keep the stock records (Form B) up-to-date and ready for review by the Managing Director and any internal or external auditor
- The Managing Director should determine the minimum amount of fortificant that must remain in stock for 3 months of iodized salt manufacturing in the factory. When the remaining amount of fortificant in stock falls below this level, the Warehouse Manager should alert the Managing Director.
Form A

Receipt of New Fortificant

<table>
<thead>
<tr>
<th>Date: ..................................................................................</th>
<th>Received by: ...........................................................................</th>
</tr>
</thead>
</table>

1. Manufacturer name .........................................................

2. Certificate of Analysis ............................................ Yes/No Number .........................................................

3. Quantity ................................................................. Drums/kg

4. Lot number(s) .................................................................................................................................

5. Production date .................................................................

6. Integrity of drums ..........................................................................................................................

7. Iodine content claimed .............................................. ppm

8. Iodine content from laboratory measurement ................ ppm

9. Any other observation ....................................................................................................................

1 This form should be completed by the Warehouse Manager each time a new shipment of fortificant is received. Check that the shipment is accompanied by a Certificate of Analysis (COA) and enter the COA number on line 2. Check that the drums are hermetically sealed. Date and sign your name on the upper part of the form. Attach the Certificate of Analysis to this form. Provide one copy of both forms to the Quality Manager and the Managing Director, and file the originals.

2 Place a mark on each drum (A, B, C, etc) in order of the expiration date (First mark the drums that have the nearest expiration date, and so on)

3 Store the unopened drums in a clean, dry and safe area. Arrange the storage of drums in such a way that the first drums received are the first used. Only open a new drum when the fortificant is needed for the manufacture of iodized salt.
### Form B

<table>
<thead>
<tr>
<th>Supplier COA number</th>
<th>Drum Number</th>
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</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Form continuation number</th>
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<tbody>
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</table>

## Fortificant Inventory Control Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Amount in Drum (A)</th>
<th>Amount given out (B)</th>
<th>Amount left in the Drum (A-B)</th>
<th>Person receiving the fortificant</th>
</tr>
</thead>
<tbody>
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<td>1</td>
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</tbody>
</table>

This form should be completed and kept up-to-date by the Warehouse Manager. Start a new form each time a new drum is opened and complete the upper part of the form. When handing out fortificant, record the date and the amount handed out. Then, calculate the amount left in the drum and record it on the next row in column two. After the form is completed (line 25), start a next form and give the next form a higher continuation number. Keep the forms on file in sequence.

## Supervision sign-off by Quality Manager or Managing Director

<table>
<thead>
<tr>
<th>Date</th>
<th>Signature</th>
<th>Remarks</th>
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128
(ii) Manufacturing of iodized salt

Preamble

Methods of iodized salt manufacturing, including commonly used batch and continuous equipment, have been described extensively in the following publication:


For practical purposes and precision, metering pumps instead of compressed air pumps should be preferred for spraying iodate solution. Also, it is important that the mixing equipment and methods provide for adequate dispersion of the added fortificant in the end product. In salt factories using a continuous iodization process, this is most often accomplished by a screw conveyor.

Accountability

During iodized salt production, the preparation of the correct iodate solution, using proper amounts of solution and raw salt, and ensuring their adequate mixing are among the responsibilities of the Production Manager. Throughout the production shift, the Production Manager collaborates closely with the Quality Manager to obtain regular measurements of the iodine content in the final product.

Objectives

The purposes of QA/QC of iodized salt manufacturing are:

- The tools/equipment for measuring the fortificant amount and the water volume remain adequate and in good order
- The spraying or feeder equipment is functioning well
- Proper amounts of fortificant and water are used when preparing iodate solution
- The ratio of fortificant (g) used/iodized salt (kg) produced is according to the prescribed standard.

The responsible staff member is the Production Manager, working in the factory area where the iodization of raw food-grade salt and packaging of the final product take place. During the iodization shifts, the Production Manager coordinates with the Quality Manager for regular measurements of the iodine content in the resulting product. The Production Manager reports the results of QA/QC from manufacturing to the Managing Director.

In large-scale enterprises where iodized salt manufacturing is fully mechanized, the approach to QA/QC is principally based on ensuring proper function and maintenance of the equipment, accompanied with regular verification that the end product meets the expected iodine content. In
these cases, the Production Manager depends for adequate QA/QC on an engineer to keep the feeder, centrifuge, mixing equipment and conveyors functional, and on a chemist for regular and swift laboratory analyses of the samples of finished product.

**Procedures**

1. **Condition of the equipment (SOP 7.4.1.b Preventive Maintenance applies)**

   The Production Manager should regularly ascertain that the measuring containers and instruments (weight and volume) are in good order, that the electrical connections and mechanical parts of the manufacturing equipment remain functional and that all the parts of the plant, especially when not made of stainless steel, are kept clean from scale, grease and dirt.

   As explained in the Quality Manual Template, equipment should be purchased from certified suppliers and only put in operation after a successful Site Acceptance Test (SAT). The production team should adhere to a planned preventive maintenance schedule (SOP 7.4.1.b). Electrical cables, connections and control panels should always be kept clear from water and brine. The air compressor, iodate solution drum(s) and spray nozzle(s), and their connectors should be inspected each downtime.

   At a scheduled downtime each quarter, the Quality Manager should assist to ensure that the weighing equipment is calibrated, electrical connections and control points should be checked for corrosion, and all bearings should be greased to prevent jammed rollers and slow-moving belt or screw conveyors to give an unevenly iodized product. Each downtime, all the parts that are not stainless steel should be cleaned with rags. Anti-corrosive paint coating should be checked once per quarter, and paint re-applied in case that corrosion is discovered.

<table>
<thead>
<tr>
<th>Amount (kg) of salt for processing</th>
<th>20ppm</th>
<th>25ppm</th>
<th>30ppm</th>
<th>40ppm</th>
<th>50ppm</th>
<th>75ppm</th>
<th>100ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,000</td>
<td>333</td>
<td>417</td>
<td>500</td>
<td>667</td>
<td>833</td>
<td>1,250</td>
<td>1,667</td>
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<tr>
<td>2,000</td>
<td>667</td>
<td>833</td>
<td>1,000</td>
<td>1,333</td>
<td>1,667</td>
<td>2,500</td>
<td>3,333</td>
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<td>3,000</td>
<td>1,000</td>
<td>1,250</td>
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<td>1,667</td>
<td>2,000</td>
<td>2,667</td>
<td>3,333</td>
<td>5,000</td>
<td>6,667</td>
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<tr>
<td>5,000</td>
<td>1,667</td>
<td>2,083</td>
<td>2,500</td>
<td>3,333</td>
<td>4,167</td>
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<td>3,000</td>
<td>4,000</td>
<td>5,000</td>
<td>7,500</td>
<td>10,000</td>
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<tr>
<td>7,000</td>
<td>2,333</td>
<td>2,917</td>
<td>3,500</td>
<td>4,667</td>
<td>5,833</td>
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<td>6,667</td>
<td>10,000</td>
<td>13,333</td>
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<td>9,000</td>
<td>3,000</td>
<td>3,750</td>
<td>4,500</td>
<td>6,000</td>
<td>7,500</td>
<td>11,250</td>
<td>15,000</td>
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<td>10,000</td>
<td>3,333</td>
<td>4,167</td>
<td>5,000</td>
<td>6,667</td>
<td>8,333</td>
<td>12,500</td>
<td>16,667</td>
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</tbody>
</table>
2. Amount of fortificant required

The amount of fortificant depends on the process used and the dilution factors involved, as well as the final iodine content targeted within the legal standards. Amounts (mL) of standard KIO₃ solution are provided below for manufacturing iodized salt at given target iodine content, using a standard iodate solution of 100g KIO₃ per Liter of water. Other final iodine contents in iodized salt can be derived by proportional changes of the amount of iodate solution used in the processing.

<table>
<thead>
<tr>
<th>Amount (kg) of salt to be iodated</th>
<th>Amount (mL) of standard iodate solution required to realize a given iodine content in the end product</th>
</tr>
</thead>
<tbody>
<tr>
<td>100ppm</td>
<td>1000 mL</td>
</tr>
<tr>
<td>75ppm</td>
<td>2000 mL</td>
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<tr>
<td>50ppm</td>
<td>3000 mL</td>
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<tr>
<td>40ppm</td>
<td>4000 mL</td>
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<td>30ppm</td>
<td>5000 mL</td>
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<tr>
<td>25ppm</td>
<td>6000 mL</td>
</tr>
<tr>
<td>20ppm</td>
<td>7000 mL</td>
</tr>
</tbody>
</table>

Standard iodate solution

In calculating the amount of the fortificant that must be added to clean water, we use 0.595 for the fraction of iodine in KIO₃. A standard iodate solution of 60g iodine/L is recommended. This requires 100 grams (i.e. 60/0.595) of KIO₃ fortificant to be dissolved in one Liter of water. The water should be clean. The staff may need to filter the premix solution after preparation to prevent dirt particles from blocking the nozzles of the sprayer.

Spray mixing: Continuous and batch-wise processes

To calculate the amount of iodate solution to be added and mixed with food-grade salt, the following formula applies:

\[
\text{Amount of solution to be added (mL)} = \text{Mass amount of input salt (kg) \times National Standard / Iodine content in the solution (g/L)}
\]
For example, to manufacture 1,000kg iodized salt (One ton, or 20 standard 50kg bags) at 30 ppm, prepare a standard iodate solution of 100g fortificant/L (as explained above) and add 500mL of the solution to the input salt while mixing well. These calculations are also guidance for the proportional amounts of iodate solution and in any continuous salt iodization set-up that uses electricity-driven mechanical equipment (See examples in Venkatesh Mannar & Dunn, op cit).

From experience with batch processing of crude sea salt, it is most convenient for a team of two people to work together in arranging batches of one to three tons of salt (1,000 to 3,000kg; or 20 to 60 standard bags). An electro-mechanical method is preferred for spray iodization, e.g. a set-up of a sprayer with a salt grinder, with a screw conveyor or with a roller or rotary drum. A detailed example of manual batch mixing is described in: Assey VD et al, 2009. Improved salt iodization methods for small-scale salt producers in low-resource settings in Tanzania. BMC Public Health 9: 187-197. Larger quantities of salt may be iodized by a team of workers.

Whether iodization is done continuously or batch-wise, the release procedure should be controlled as described in the Quality Manual Template, SOP 7.4.1.a. This means that the final product shall not be released for storage or packaging unless the measurement of samples of the product have confirmed satisfactory iodine content.

Records and Reporting

During each shift, the Production Manager uses a record similar as Form C. This form should be kept up-to-date and ready to be shown to the Quality Manager for checking with the results from the measurements of iodine content in the final product. When Form C is completely filled-out, the Production Manager should send a copy to the Managing Director.

Production Record

After the end of a shift, use Form C to add up the amount of fortificant used (grams) and the amount of iodized salt produced (tons-1,000kg, or number of 50kg bags) during the shift. Record these amounts in Form C on the bottom line (marked TOTAL) and report them to the Managing Director.

Collecting salt samples for iodine measurement

At least once per hour during regular shifts, the Production Manager or machine operator should collect a 50g sample of the finished product. If the factory has an on-site laboratory, the sample should be processed without delay for iodine content. In other cases, place the sample inside a sealed bag in an opaque 1-kg container and bring all the individual samples (i.e. 8 samples from a typical 8h shift) after the end of the shift to the Quality Manager who will arrange for laboratory measurement of the iodine content. Only after the measurement results of the iodine content are satisfactory (See Quality Manual Template, SOP 7.4.1a Control of Production) can the bags of iodized salt be released for packaging and transfer to the warehouse storage.
The Production Manager should keep the records updated of the calculations done, amounts of iodized salt produced and amounts of fortificant used, as well as description of actions taken to inspect and keep all the equipment in the production area good working condition.
Form C

Iodized Salt Production Log

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Amount of fortificant used (g)</th>
<th>Amount of iodized salt produced (kg or bags)</th>
</tr>
</thead>
<tbody>
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<td>TOTAL</td>
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</tbody>
</table>

This form should be completed and kept up-to-date by the Production Manager. Use a new form for each new shift. Each time when a new iodate solution is being prepared, record the amount of fortificant (g) used. After the supply of iodate solution has finished, record the amount of iodized salt produced (in kg or bags). At the end of the shift, add up the total amount of fortificant used (g) and the total amount of iodized salt produced (bags), record these amounts at the bottom of the table (TOTAL) and report them to the Managing Director.

Supervision sign-off by Quality Manager or Managing Director

<table>
<thead>
<tr>
<th>Date</th>
<th>Signature</th>
<th>Remarks</th>
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</tbody>
</table>
(iii) Quality Analysis during Production and Storage of Iodized Salt

Accountability

Making sure that the salt iodine levels are adequate requires measurements of the iodine content in the fortificant and in the iodized salt during its manufacturing and storage before it leaves a factory. This is among the duties of the Quality Manager.

Objectives

The purposes of QA/QC of manufacturing and storing iodized salt are that:

- At least 90% of the samples taken during manufacturing have iodine levels within the $X$ to $Y$ ppm range required in the standards (the production minimum and maximum content, respectively)
- The Production Manager has continued ability to adjust the iodate solution for iodized salt manufacturing to ensure proper iodine content in the stock of finished product in the warehouse
- The iodized salt stored in the warehouse maintains a level above $X$ ppm iodine (the legal minimum).

Procedures

1. Making supervision visits
   - Make unannounced occasional visits to the warehouse to check that the fortificant stock is adequately stored and that the stock record is being kept up-to-date by the Warehouse Manager. Date and sign the lower part of Form B to confirm these supervision visits. Note any remarks on the form and in case of trouble, report to the Managing Director
   - During production shifts, make unannounced regular visits to the production area to verify that the production personnel are adequately following prescribed procedures (including taking a 50g finished salt sample each hour) and that the production records are being filled out correctly and on time. Date and sign the lower part of Form C to confirm these supervision visits. In case of finding trouble, report to the Managing Director.

2. Iodine measurements
   - In factories with a side laboratory, on receipt of the salt samples taken during a production shift, process the samples without delay if the production method is continuous. If the factory uses a batch-wise method, combine and thoroughly mix equal amounts of each sample (for example, 25g each) to obtain one single composite sample. Send part of the composite sample (for example 50-100g) to the laboratory for determining the iodine content with titration (see Appendix 2 for Analytical Method). Store the remaining amount of the composite sample in an air-tight opaque plastic container. Mark the container with the date and keep it stored safely for at least one month
- When a new supply of KIO₃ fortificant has arrived, the Warehouse Manager will take two samples of 10g each to verify the proper iodine content. Arrange for these measurements in the laboratory.

3. Sampling of finished product in the warehouse
- Once per month at minimum, take a random sample of approx. 50 g salt from the finished, stored product in the warehouse for quantitative measurement of the iodine content. Record the result with the date of sampling on Form D.

**Records and reporting**

The responsibility for arranging the salt iodine measurements is with the Quality Manager, who shares the results with the other management team members for reassurance or action.

When a new shipment of fortificant arrives, the Warehouse Manager will provide two 10g random samples of the new fortificant for laboratory analysis. Keep a record of the date of dispatch of the samples to the laboratory and the date when the results were returned. Since the iodine content in the fortificant is much higher than in iodized salt, the Quality Manager should work with the laboratory staff to ensure proper dilution of the fortificant samples. After the laboratory reports back of the fortificant analysis, record the two results on Form A (Form A is kept by the Warehouse Manager). Any gross deviation from the stated content (on the drum label or COA) should be discussed in the management team.

The Quality manager should use Form D for keeping a record of the measurement results of the salt iodine content during manufacturing. During the production season, share and discuss these results with the Managing Director at least once per week.

Use Form E for recording the laboratory measurements of the iodine content in iodized salt in the warehouse. Alert the Managing Director if the results fall drastically from previous measurement(s).

Record any corrective actions and any comments and share with the Managing Director.
<table>
<thead>
<tr>
<th>Date of Shift</th>
<th>Date sample sent to the laboratory</th>
<th>Date result received from the laboratory</th>
<th>Iodine content reported from the laboratory</th>
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</thead>
<tbody>
<tr>
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This form should be completed and kept up-to-date by the Quality Manager. Each time a shift has been completed, prepare a composite salt sample from the hourly salt samples received from the Production Manager and arrange for a quantitative measurement of the iodine content. Record the shift date, and the dates of dispatch of the composite sample to the laboratory and of receipt of the result from the laboratory. Finally enter the result of iodine content measurement in the last column of the Form. If a result falls outside the legally required range (40 - 80 ppm), discuss the reason(s) and corrective action(s) in a management team meeting.
## Warehouse Inventory Log of Iodized Salt

<table>
<thead>
<tr>
<th>Sampling Date</th>
<th>Date sample sent to the laboratory</th>
<th>Date result received from the laboratory</th>
<th>Iodine content reported from the laboratory</th>
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</thead>
<tbody>
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<td></td>
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<td></td>
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<tr>
<td>13</td>
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<td></td>
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<tr>
<td>14</td>
<td></td>
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<td></td>
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<tr>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This form should be completed and kept up-to-date by the Quality Manager. Once each month, take a random sample of 50-100 g salt from the store of finished product in the warehouse and arrange for a quantitative measurement of the iodine content. Record the date of sampling, the date of dispatch of the sample to the laboratory and the date the result is received from the laboratory. Finally, enter the result of iodine content measurement in the last column of the Form. If a result falls drastically below the previous measurement(s), discuss the reason(s) and corrective action(s) in a management team meeting.
(iv) **Overall quality management**

**Accountability**

The **Managing Director** (MD) is the overall responsible staff member in a factory. Based on the reports from the other managers in the factory, the MD can keep track of the company's overall performance in producing and supplying good quality iodized salt.

Typically in large companies, the management of the QA/QC system proceeds by a team approach, in which the respective managers share and discuss their findings with a senior manager. In this guidance, we use the Managing Director as the generic term for this role; in many large factories, the overall quality management task may be entrusted to a deputy MD or the Production Manager.

**Objectives**

The purposes of overall quality management are to ensure that:

- QA/QC of iodized salt production, storage and supply is established as an accepted, habitual activity within the manufacturing, warehousing and customer service activities of the factory
- The company maintains adequate documentation to demonstrate its compliance with the regulation and standards.

**Procedures**

1. **Fortificant purchase, stock and quality**

   The MD (through the Purchase Department, as the case may be) decides on the purchase of new fortificant (SOP 7.3.3 - Purchase of incoming goods). The purchase order should state that the shipment must be accompanied with a Certificate of Analysis (COA). On receiving the shipment, the Warehouse Manager uses Form A to record the details from the COA, including the results of a counter-analysis in the laboratory of the iodine content in the new fortificant.

   Each factory should keep a sufficient amount of fortificant in stock for a minimum of 3 months of iodized salt manufacturing. The MD (with the Production manager, as the case may be) should determine what the minimum amount is and inform the Warehouse Manager. The time period of 3 months is necessary for the completion of research in case the laboratory measurements in a newly arrived fortificant shipment show that the iodine content is seriously below the stated content on the drum label or in the COA.

   As described previously, the Warehouse Manager uses Form B to record the amount of fortificant handed out for iodized salt manufacturing, thus keeping a current record of the amount of fortificant remaining in stock. During unannounced visits to the warehouse at regular intervals, the MD should verify that the fortificant stock is adequately stored, that the fortificant inventory record
is up-to-date and that the remaining amount of fortificant in stock is adequate for the projected need of at least the next 3 months of production.

2. Iodized salt production

During the work shifts, the Production Manager uses Form C as the factory’s basic record for tracking the amount of the final product going into the warehouse. Each time when a new iodate solution is prepared, a new set of information must be entered in Form C, and each time after a shift has ended, the Production Manager uses the records in Form C to add up the total amount of the fortificant used (2nd column) and the amount of iodized salt produced (3rd column). These totals are reported to the MD who is accountable to check on the QA performance and to keep track of the amount of finished product in the warehouse.

The totals reported at the bottom in Form C are used to assess the QA performance during a manufacturing shift. For example, a target level of 60 mg iodine/kg in the iodized end product means that each 100g of fortificant used should correspond on average to a yield of 1,000kg (20 standard bags) of the iodized end product.

A simple method for checking the QA performance of iodized salt manufacturing is as follows. In this example, we assume that the target level is 60mg iodine/kg (100g KIO3 per 1,000kg) in the end product. First, divide the total kilograms of end product reported in the TOTAL of column 4 by the total grams of used fortificant reported in the TOTAL of column 2, and then, multiply this fraction with 100. The result of this calculation tells the amount of finished product (kg of iodized salt) that was obtained per each 100g of fortificant that was used during the particular shift. When the calculation result shows more than 1,000kg, the shift has been under-iodating salt and the iodine content in the end product is expected to be below the target of 60. Conversely, if the calculation result falls below 1,000kg, this means that over-iodized salt was produced and the iodine content in the end product will be above 60. The MD can use the results of laboratory measurements obtained by the Quality Manager and reported in form D to ascertain that the calculations from a shift’s record (Form C) were correct.

It is recommended that the management team reviews the amounts, method, equipment and procedures of iodized salt manufacturing when the calculated amount of finished product deviates more than 15% from the expected amount (i.e. in the example, when the factory targets the 60 ppm level, but the finished product from a given shift was below 850kg or above 1,150kg per unit of 100g fortificant). The MD should record the details of this review and the decision(s) taken, and then the MD should document that any corrective measures that were agreed-upon during the review have been adopted in the subsequent manufacturing shifts.

3. Iodized salt storage in the warehouse

It should be a corporate rule in salt factories that only the salt, stored as end product (i.e. after it has been iodized) leaves a factory. Everyone in the salt company should know that this is the proper salt for human consumption. The same store of iodized end product can also be used for bonuses or payment in kind to day-laborers or other factory workers. Salt handouts, for example given as a
bonus or for in-kind payment should not occur in the form of crude, non-iodized salt, but as iodized salt after proper manufacturing. It is important to remember that these handouts, however well-intended and practical they may be, can add up to a sizable amount of salt that can be bartered, exchanged or sold onward, and thereby can affect the health and brainpower of the communities who consume it.

Form E, which is kept by the Quality Manager, offers a track record over time of the iodine content of the end product in the warehouse store, ready for dispatch to customers. Importantly, the KIO₃ fortificant has proved to be very stable in the iodized end product when properly packaged and stored. Nevertheless, some natural loss of iodine content may always occur, particularly with poor quality input salt, as may be the case in unrefined sea salt. High humidity and high temperature in the warehouse combine in the course of time and, thus, some loss of salt iodine content will occur with the increasing storage time. This is the reason why monthly laboratory measurements of the stored product must be obtained. The results of these monthly measurements should not fall below the minimum prescribed in the national regulations (i.e. the lower control limit in the control chart, illustrated on page 37).

4. Product quality management
The MD depends on the performance of the respective line managers for the practical execution of QA/QC in the factory. The first and key important step is to ascertain that the fortificant is good quality. For successful quality of the end product, ensuring the proper iodine content (Form A) and an adequate stock (Form B) of the fortificant are essential pre-conditions, because the next steps of manufacturing, warehousing and customer sales depend on it. Assurance of this “incoming material” also plays a critical role in the registration and licensing of a salt factory by authorities. It is therefore important that the management team first gives keen attention to the need to ascertain proper performance of this part of the QA/QC protocol.

Once the purchase, storage and handling of the fortificant have been secured, the management team should consider the protocols for the subsequent steps of manufacturing and storage. In these steps, successful management of QA/QC performance arises from the realization that a company is accountable to their customers (and to authorities) that the product when it leaves the factory always meets the prescribed X to Y range of iodine content defined in the standard. In order to meet that standard at all times when iodine may be lost during the time that the end product is stored in the warehouse, the management team should examine and, if needed, adjust, the amount of iodate solution that is being added during the manufacturing of iodized salt. An upward adjustment of the amount of iodate solution added during iodized salt manufacturing is called "overage". The approach is explained in the next section.

Finally, to minimize the loss of iodine content (and prevent the need for re-processing), the factory should strive to ensure the best possible conditions and procedure of storage in the warehouse.
Adjustment of the amount of iodate solution in manufacturing

The monthly record of the iodine analyses in the salt stored in the warehouse (Form E) is expected to show that the iodine content in the iodized end product always remains within the $X$ to $Y$ range. When the month-to-month measurement results indicate a continuously diminishing trend, however, a preventive scenario would be to increase the amount of iodate solution added in the manufacturing step accordingly. The effect of such an increase would be that the stored iodized salt starts out at a higher initial iodine content and, therefore, the product ready for purchase by customers can be expected to remain within the prescribed standard range for a longer time period.

The various amounts of standard iodate solution that may be used in iodized salt manufacturing to achieve different iodine contents in the finished product are shown in the section (ii) on iodized salt manufacturing. This Table, and the accompanying formula for the calculation of standard iodate solution volume, may be used for decisions on varying and, as and when needed, increasing, the iodine content in the product at the point in time when it enters the storage.

Preservation of the iodine content during storage

Suggested ways to prevent and reduce the erosion of iodine content in the finished product during its storage in the warehouse include:

- Use good quality input salt. This may not be a major issue when underground rock salt is sourced. Sea salt, however, demands accurate brine management, washing of the fresh salt with brine after harvesting and sufficient air-drying prior to iodized salt manufacturing. Sea salt harvesting from single-pond solar evaporation cannot yield raw salt of adequate purity without further processing, for example by hydro-milling. A proper sea salt factory should only yield sea salt that meets the specifications for food-grade salt
- Pack the manufactured iodized salt in poly-ethylene bags prior to storage, i.e. packaging should not be postponed until the time that a customer collects the product
- Store the warehouse stock on raised pellets. Prevent rain, heat and dirt from entering the warehouse with permanent roofing, adequate air ventilation, and proper floor finish with sound water drainage
- Practice turn-over of the stock on basis of “first-in-first-out”.

Records and Reporting

The details provided above makes clear that each of the different managers who make up a factory’s management team are responsible for recording and documenting the particular aspect(s) of the overall QA/QC system that they are responsible for. The Warehouse Manager, Production Manager and Quality Manager each report on their experiences and findings to the MD.

The major critical task of the most senior manager is to use the information for the provision of leadership in upholding the habit that quality management in the factory remains focused on the supply of quality products that delight the customers and meet the prescribed standard of the country of use.
In terms of records and reporting, the MD is responsible that:

- Each member of the management team keeps his/her own record forms and documents accurate and current (SOP 3.1.2 - Control of Records)
- The management team’s decisions on each aspect outlined above are recorded and documented in sufficient detail, and
- The overall documentation demonstrates the factory's conformity with customer demands and the stipulations in national regulations and standards, and that it offers a track record of the company’s ambition to continually improve its quality performance.
IV.B INSPECTION AND CONTROL OF NATIONAL IODIZED SALT SUPPLIES

Legislation and Regulations

Governments play a leadership role in effective national strategies to overcome micronutrient deficiencies. Once salt iodization is selected as the national strategy to eliminate IDD, it is necessary that Government first enacts national regulations to establish the legal authority and a regulatory framework for the iodized salt supply. The first reason is that effective regulatory control of the salt supply protects the consumers against the risk of purchasing impure, nutritional inadequate, deceptively mislabeled, misbranded, impure and unsafe salt. Secondly, by enforcing a strong regulatory framework, non-compliant manufacturers and sellers will not be able to profit from supplying inferior products that do not comply with the official standards. Legislation and regulations aim at creating a "level playing field" for industry and trade (Rose Nathan, Handbook on Legislation for Food Fortification. Ottawa, Canada, The Micronutrient Initiative, undated. ISBN 1-894217-10-1).

In virtually all countries of the world, the regulatory control of the safety and quality of the food supply, including iodized salt, is vested in a national Food and Drugs Authority (FDA) or Board, which most often operates as an independent executive body under the Ministry of Health. In the delivery of food control services, when it has sufficient personnel the FDA may conduct all the necessary controls by itself or, in other cases, it may delegate any part of the inspection procedure to staff officers employed in other organizations (e.g. Local Government, Customs, private service providers, etc). This delegation of tasks may take place by sub-contracting for example, but the full responsibility for determining the conformity with the relevant regulatory framework always remains with the national FDA.

VIGNETTE: An example from Tanzania

The Tanzanian Food and Drugs Authority (TFDA) has delegated the task of food inspections to District, Town, Municipal and City Authorities. In regard to salt iodization, health officers employed by the Local Government Authority in Districts, Towns, Municipalities and Cities have the duty to provide inspection services to the salt production and sale outlets within their area of jurisdiction, thereby helping to ensure that all the salt provided to the households, food services (restaurants and catering units) and food processors continuously meet the specifications prescribed under the Tanzania Food, Drugs and Cosmetics (Salt Iodization) Regulations, 2010. From time to time, TFDA officers conduct audit inspections of the Local Health Departments to ensure the effective implementation of the salt inspections by local health officers. These “audit inspections” are systematic, independent examinations to ascertain that the inspection services provided by the Local Health Departments and their related results are in compliance with the national standard. The results of audit inspections inform the TFDA whether the inspections are provided effectively and whether they are suitable to achieve the ultimate objective that all the citizens of Tanzania have continuous benefit from safe and proper quality iodized salt in their
In view of the significant variety of scale and professional capacity across salt companies, the criteria for inspection should realistically align themselves along the salt industry classification described in the previous Chapter. Because large salt companies are capable to meet more challenging requirements than the smaller companies and so-called "foothill producers" or "salt winners", the observation criteria used for determining the proficiency of QA/QC systems are staggered by category. Also, the guidance recommended for conformity assessment of salt manufacturing facilities includes a varying number of "critical control points", which, if they are not met, are considered disqualifying defects regardless of the size or capacity of the facility. The number of critical control points differs by category and they become more demanding with the greater scale and sophistication of the facilities inspected. Any disqualifying defect(s) should routinely lead to follow-up requirements that must be satisfactorily addressed by the company before a next inspection visit.

The guidance in this section is derived from the text in ISO/IEC 17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection (2012). Chapter III provides the Quality Manual Template based on this standard. The guidance text on the quality system elements is intended to be used in combination with the relevant elements of ISO 9001:2008: Quality management systems - Requirements, of which the Quality Manual Template is provided in Chapter II.

The guidance in the following pages intends to assist in the development of inspection protocols in iodized salt establishments, and of audits of inspection services delivered by local health officers, customs officers and other sub-delegated staff as the case may be. The guidance highlights the areas and aspects that the food inspectors, health officers and the auditors should focus on, as well as the inspection results which should be consolidated and reported in accordance with national regulations.
(i) Salt Manufacturing Facilities

These inspections intend to ensure that the salt supplies of domestic origin are safe and continue meeting the specifications. An examination of the performance record of the iodized salt QA/QC system of the facility is among the aspects for attention during the inspection of salt manufacturing facilities. As required, the guidance for inspection should also provide for proper warnings and legal actions to be taken when non-compliances are discovered.

Objective

The objective of inspecting the premises of salt manufacturers is to confirm and enforce that their facilities continuously implement effective QA/QC in the production, storage and sale of salt products.

Responsibility

Officials authorized to inspect salt manufacturing facilities are FDA officers or, as the case may be, health officers of Local Government Health Departments in their areas of jurisdiction. They report their findings to their respective Chief Inspector or Chief Health Officer (CHO). FDA is responsible for preparing and providing the technical training, the detailed guidelines and other legal instruments required for these inspections.

Planning

In principle, visits to salt manufacturing sites should be done on a monthly basis. The frequency of such visits can be scaled down or up depending on the performance of the salt facility, however. Inspections of a site may take two to three hours to allow for thorough examinations.

Procedure

Conduct an opening session

When visiting a facility, the inspector conducts an opening meeting with senior management, including the Quality Manager. During this opening meeting, the purpose, approach and approximate duration of the inspection visit is explained briefly, the need stated for reviewing written procedures and records, personnel interviews, observation of the iodized salt manufacturing process and salt sampling for iodine determinations.

Conduct the inspection

i. Use the inspection form and checklist for salt manufacturing facilities and record in detail any deviation, defect and/or non-compliance observed

ii. Review the non-compliances and/or defects discovered during the last inspection visit, the recommendations made, evaluate the corrective actions taken, and record the findings appropriately.
Salt iodine determination
Near the completion of inspection, take a salt sample from the warehouse store for measurement of iodine content in a certified laboratory.

Conduct a closing session
Finish with a closing meeting to share feed-back on the findings. Explain the critical findings that require follow-up in the facility. If non-compliances are found, inform the management about the actions that must be taken and leave a copy of the report with the Managing Director.

Record and report the findings
Once the laboratory results are received, analyze them against the required norms and send a report, with suggestions for corrective action where necessary, to the Factory Manager. If a non-compliance is found, enclose a warning letter stating what shall be corrected by a specified date or before the next visit. Send a copy of the full report to the Chief Inspector or CHO.

Suggested critical defects
Aside of the QA/QC performance records, the inspector will examine a range of physical items. The Table on the next page suggests various aspects that may be considered to be a "critical defect" when absence, lack of functionality or non-compliance is discovered. As determined by a country's FDA, some but not necessarily all critical defects may be considered as a disqualifying discovery in terms of a facility's registration, licensing and/or permission for operation.

In any given country, FDA should develop the criteria and decisions for decisions on the proficiency in the facility's QA/QC system; FDA should define the kinds and number of critical control points related to an agreed-upon salt industry classification, and it should provide criteria for decisions by the inspectors on the qualification of a facility based on the physical discovery.
### Salt Manufacturing Facilities:
#### Suggested critical defects specific to salt iodization

<table>
<thead>
<tr>
<th>Inspection items</th>
<th>Large factories</th>
<th>Medium-scale factories</th>
<th>Small enterprises</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Site</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>2. Building(s)</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>3. Water supply</td>
<td>Permanent water source</td>
<td>Permanent water source</td>
<td>Permanent water source</td>
</tr>
<tr>
<td></td>
<td>Water is potable</td>
<td>Water is potable</td>
<td>Water is potable</td>
</tr>
<tr>
<td>4. Raw materials</td>
<td>Copy of valid COA present</td>
<td>Copy of valid COA present</td>
<td>Copy of valid COA present</td>
</tr>
<tr>
<td></td>
<td>KIO$_3$ not expired and properly stored</td>
<td>KIO$_3$ not expired and properly stored</td>
<td>KIO$_3$ not expired and properly stored</td>
</tr>
<tr>
<td></td>
<td>Valid KIO$_3$ counter-analysis</td>
<td>Valid KIO$_3$ counter-analysis</td>
<td></td>
</tr>
<tr>
<td>(If iodization is mandatory)</td>
<td>No non-iodized salt stored</td>
<td>No non-iodized salt stored</td>
<td></td>
</tr>
<tr>
<td>5. Equipment</td>
<td>Spray nozzles properly functioning</td>
<td>Spray nozzles properly functioning</td>
<td>Spray nozzles properly functioning</td>
</tr>
<tr>
<td>6. Hygiene</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>7. Salt processing, product storage and release</td>
<td>QA/QC system proper, adequate and documented</td>
<td>QA/QC system proper, adequate and documented</td>
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</tr>
<tr>
<td></td>
<td>On-side laboratory for salt iodine content</td>
<td>Uses service laboratory for salt iodine content</td>
<td>Uses service laboratory for salt iodine content</td>
</tr>
<tr>
<td></td>
<td>Lab results of at least two salt samples recorded</td>
<td>Lab results of at least two salt samples recorded</td>
<td>Lab results of at least two salt samples recorded</td>
</tr>
<tr>
<td></td>
<td>No non-iodized salt on offer or given out</td>
<td>No non-iodized salt on offer or given out</td>
<td>No non-iodized salt on offer or given out</td>
</tr>
<tr>
<td>8. Labeling</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>9. Transportation</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>10. Sanitation</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>11. Licensing</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
(ii) Salt Sales Outlets (Wholesale and Retail)

Inspection of salt sales outlets aims to validate that the quality and safety of the salt varieties and brands, offered for purchase in the wholesale and retail markets and stores, are in agreement with the specifications. Importantly, the examination of sales outlets permits the detection of salt suppliers and brands that may not be approved by FDA. Finally, checks at sales outlets (shops and markets) also help find out whether brands that have previously been inspected in factories and at ports of entry are in accordance, or not, with the specifications.

Furthermore, inspections in sales outlets can serve as an opportune means to provide education to salt dealers about the national salt iodization strategy and its benefits for the population, and about their role as salt dealers in the promotion and upholding the rights of consumers.

Objective

The objective of inspection of salt sales outlets is to confirm and enforce that the salt for purchase to consumers is in compliance with the requirements established under the national regulatory framework.

Responsibility

Carrying out inspections of salt sales outlets is a responsibility of Local Government Authority health officers, to whom the FDA has delegated this function. FDA is responsible for preparing and providing sampling plans and the technical training required for these inspections.

Planning

Where possible the inspection visits for an outlet should be done once every three months and be scaled down or up depending on the compliance of the dealership. Health officers (food inspectors) should plan to spend up to two hours for an inspection of a sales premise.

Procedure

- In the area of authority, visit the most popular stores, markets, supermarkets and distribution centers where people commonly buy their livelihood supplies
- Show your credentials to the salt dealer or owner of the sales outlet, and make sure they identify you as an inspector
- Give a brief explanation about the purpose of your visit
- As a pre-test in rural, low-resource areas, the RTK may be used to test whether salt contains iodine. When a salt brand tests negative, always obtain a sample for laboratory analysis
- Record observations in the format and form provided by FDA
- Finish the visit by reporting your major critical findings to the dealer/owner
- Report the results of inspection to your CHO.
(iii) Ports of Entry

The purpose of inspections at the ports of entry (national border) is to verify that imported salt complies with the requirements set under the national regulations on the import of foods, their safety and their composition. This inspection also permits the detection of salt brands that are not registered with FDA (Typically in salt importing countries, FDA requires that all the imported prepackaged salt products must be registered before they are permitted entry into the country).

Objective

The objective of inspecting salt import consignments at the ports of entry is to ensure that the salt product is registered and that the consignment complies with the Food Law and regulations made thereunder, including requirements for iodine content.

Responsibility

Inspection of imported salt is the responsibility of FDA. Any delegated staff, e.g. Customs Officers, assigned to inspect food imports is answerable for these inspections to the Main or Zonal Office of FDA.

Procedure

- Review the documents, including the Certificate of Conformity (Analysis), which must accompany the consignment of salt. Verify that the salt is approved for use in the country of origin
- Review the import permit issued by FDA to verify that the salt is registered and complies with the national food importation regulations
- Examine the labeling to make sure that it indicates the brand name, the name “Iodized Salt”, a batch number, country of origin, name and address of manufacturer and any other requirements under the Food Law of the importing country
- Take appropriate legal action in case a consignment does not comply with the above requirements
- Under time pressure, the RTK may be used to test whether salt contains iodine. When a salt brand tests negative, always obtain a sample for laboratory analysis
- Record your observations in the Inspection Form provided by FDA
- Once every three months, submit a summary report to the FDA Headquarters or Zonal Office, indicating the dates of inspection, the brand(s) and amount(s) of imported salt, as well as legal action(s) taken for each consignment, if any.
(iv) Food processing industries and food services

In more industrialized countries, the majority of the salt intake of populations, sometimes up to 80%, consists of food-grade salt used by the food industry as ingredient in manufacturing of processed foods. Typical examples of commercial foods, manufactured with salt as an ingredient in the recipe, are bread and bread products (biscuits, crackers, knackebrod, etc), (cured) meat, meat siege, cheese, and salted snacks (salted peanuts, potato chips, etc). In countries where iodization of all the food-grade salt is mandatory or practically widely accepted (examples include Austria, Belarus, Bulgaria, Czech Republic, Germany and Switzerland), or where the regulations mandate that the bakery salt should be iodized (for example, Denmark and the Netherlands), the FDA should perform an examination of the salt used in the respective food industries as part of the general food safety/quality inspection of these facilities.

Food service establishments, whether public (for example, factory worker's canteens, student eateries, food services of hospitals, prisons, etc) or private (café’s, restaurants, eateries, etc), also use salt in the preparation of foods and meals. As appropriate, an examination of the salt used in these facilities should be part of the inspections of food safety/quality in these establishments.

Typically, an examination would verify the provenance (brand origin, name/address of manufacturer, and any other requirement under the Food Law or regulation) of the salt used and, if needed, salt sampling for lab measurement of the iodine content.

Vignette: An example from Egypt

Since the large majority of Egyptians consume Baladi bread, it has a central place in the common diet of the population. Supported through a collaboration among the UN World Food Programme (WFP), GAIN and the Ministry of Social Solidarity (MOSS), the flour for baking Baladi bread in Egypt is fortified with iron and folic acid, thus helping to prevent iron deficiency anaemia in young children and neural tube defects among newborns. Officials of MOSS are conducting inspections of the bread bakeries to ascertain that the micronutrient levels in flour match the national standards.

Working with MOSS, GAIN has promoted that the MOSS inspectors should also examine the label on the salt bags in the bakeries to check for compliance with the Ministerial Decree of 2003 that all the salt used in bread baking must be iodized. A pilot protocol was developed for the bakery salt inspections on the principle that for first screening, the RTK is reliable to identify non-iodized salt, in which case the baker would be encouraged to insist on obtaining iodized salt from a reputable supply source. In case the bakery salt tested positive, the MOSS official would proceed with taking a salt sample to ascertain the conformity of the salt iodine levels with the national standard.

Form F (next page) illustrates the draft document used in these pilot inspections.
## FORM F: Draft check list for Bakery Iodized Salt Inspection in Egypt

<table>
<thead>
<tr>
<th>Bakery Name:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Person interviewed:</th>
<th>Work Title:</th>
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<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>When was the previous inspection undertaken?</th>
<th>Date-</th>
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</table>

<table>
<thead>
<tr>
<th>Questions asked and Issues reported by the person interviewed:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Salt storage:</th>
<th>Dry place?</th>
<th>Clean area?</th>
<th>Goods kept in order?</th>
<th>Comments-</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ If correct</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Add comment if not correct</td>
<td>N</td>
<td>N</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bags:</th>
<th>Conditions:</th>
<th>What is printed on the bag?</th>
<th>Comments-</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>RTK Test:</th>
<th>Sample/s I.D.</th>
<th>Color spot test?</th>
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<tr>
<th>Delivery Notes:</th>
<th>Type of supplier:</th>
<th>Name and contacts of supplier:</th>
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<td></td>
<td>✓ Correct one</td>
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<td>General good supplier?</td>
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<td></td>
<td>Salt producer?</td>
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## Comments and Recommendations of inspector:

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<tr>
<th>Name and Signature of person who did the inspection:</th>
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Audit of Inspectorate Services (Sub-contracted agencies)

FDA-employed food inspectors are authorized and have the duty to conduct audits of the inspection services delivered by officers of delegated sub-contractors, e.g. personnel of the Customs, the Local Government Health Departments, etc. These audits are performed with a view to ascertain the degree to which the functions delegated by FDA are yielding the expected results. With the audit inspections, FDA performs an independent, systematic investigation to determine whether the inspection services from sub-contractors comply with the set standards. Specific to salt iodization, these audit inspections are intended to inform the FDA whether the sub-contracted inspections are effective in helping to ensure that the population's common food supply continuously contains safe, good quality iodized salt.

This part of the guidelines highlights areas that audit inspectors should examine to obtain information of the inspection performance by health officers of Local Government Authorities. The description illustrates the approach that can be taken for inspection audits of any other sub-contracted agency, including private firms.

Objective

The guidelines shall be used for audit inspections of the salt iodization inspection services in all the Health Departments of Local Government Authorities of (insert country name).

Responsibility

Audits of salt inspections are a sole and full responsibility of the FDA.

Planning

The Chief Inspector at FDA shall set the required frequency of audits for all the Health Departments of Local Government Authorities, while giving priority to those areas known or suspected for low or failing iodized salt supplies. Ideally, one audit visit to each Local Health Department should take place at least twice a year. Officers of FDA should plan to spend up to two days in a given Local Health Department to complete an audit.

Procedure

a) Prepare for audit inspections
   • Make a list of Local Health Departments to be audited (by their areas of authority)
   • Collect and check the necessary auditing forms, checklist(s), equipment and tools
   • Make sure of adequate time allocation for each audit inspection based on the size and location of the Departments and number of FDA audit inspectors available
   • Communicate with the Chief Health Officer(s) of the Local Government Health Department(s) to ensure that the host officers are available, and plan your audit schedule accordingly
• Review previous audit inspection records in order to detect trends of compliance in each Local Health Department.

b) Conduct the audit inspections

• Conduct an opening meeting with the appropriate Food and Drugs Committee (or similar authority) of the Local Government Health Department. Explain the purposes of the audit inspection and request for cooperation

• Perform the audit inspection with guidance of the forms, checklist, tool(s) and equipment brought from FDA

• Conduct a physical inspection of a few selected salt manufacturing or wholesale/retail facilities in the area, in the company of the CHO, to verify that the findings obtained at the CHO office are reliable

• Hold a closing meeting with the Food and Drugs Committee to inform it of the results of the audit inspection, emphasizing any recommendation(s) for improvement and their justification

• Take appropriate actions including scheduling of follow-up meetings or audit inspections

• Prepare and submit an audit inspection report to the FDA Chief Inspector as soon as possible.
Typically, the food legislation or regulation requires the FDA to prepare an annual report of its main findings of the food inspection activities. The annual report may be posted on FDA’s (or parent Ministry) website for transparency and public accountability.

In countries where FDA subcontracts or otherwise delegates (part of) the inspection tasks to other agencies, it depends on these partners for reporting. It is suggested that sub-contractors -e.g. the CHO in case of the Local Government Health Department - should prepare a consolidated report once every three months of the inspection report from its officers. The consolidated report should show the status of approval for the salt manufacturing and sales premises as well as the percent compliance in the inspected salt manufacturing premises. The percent compliance is calculated as the number of premises complying with the regulations divided by the total number of premises inspected during the quarter.

It is further suggested that, on its side, FDA should prepare an annual report that describes the status of the salt iodization strategy in the given country and publish it on the FDA website for public view. FDA is also encouraged to share the report with a national Council or Committee concerned with oversight of the salt iodization strategy for elimination of iodine deficiency.