

Responsible Fisheries Management Chain of Custody Standard

A Tool for Voluntary Use in Markets for Certified Products of Marine Capture Fisheries

Unified version

Draft 1

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Standard Genesis

Iceland took the initiative to develop the original version of this Standard, which was presented for public and stakeholder comments, and subsequently adopted for certification in 2011.

The standard framework was used in cooperative fashion by Iceland Responsible Fisheries Management and Alaska Responsible Fisheries Management, allowing both programs to introduce minor but meaningful modifications.

About this document

The present version, finalized in 2021, is the result of the unification of those two versions. It is intended to be applied in both certification programmes, as well as in other responsible fisheries management certification programmes including those currently under development.

This Chain of Custody Standard is based on the 1995 FAO Code of Conduct for Responsible Fisheries and the FAO Guidelines for the Ecolabelling of Fish and Fishery Products from Marine Capture Fisheries adopted in 2005 and amended/extended in 2009. These in turn are based on the current suite of agreed international instruments addressing fisheries, in particular the 1982 UN Convention on the Law of the Sea, the 1995 UN Fish Stocks Agreement, as well as related documentation including the 2001 Reykjavik Declaration on Responsible Fisheries in the Marine Ecosystem, as well as various other relevant documents from ISO and other sources. This document is also based on the EA-6/04 M: 2011 EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites.

The programme is the direct result of pro-active discussions and interaction with fishermen, packers, processors, markets, regulators, standards, and certification experts.

This document contains mandatory requirements for supply chain organisations seeking Responsible Fisheries Management Chain of Custody Standard certification.

General introduction

Chain of Custody (CoC) certification provides credible assurance that products sold through licensed use of the certification ecolabel or trademark will communicate to customers and consumers the provenance of fish from a certified Alaska and Iceland fishery and can be traced throughout the supply chain to a certified source. Organizations certified against the CoC Standard are audited by a third-party accredited Certification Body and are subject to periodic surveillance audits over the three-year period of a CoC certificate.

Through the programme framework, the requirements for CoC certification will be subject to continual review and improvement to ensure that it continues to serve stakeholder and consumer needs.

Scope and options for CoC certification

Any organisation trading or handling products from a certified fishery is eligible to have CoC certification. CoC certification is a requirement for each organisation in the supply chain taking legal ownership of certified products that wishes to make a claim on the certified source, up until the point where products are packed into consumer ready packaging.

Principles of the Process

To become certified as meeting the joint RFM Chain of Custody Standard applicants must be able to demonstrate compliance with this standard, through an independent audit by an approved Certification Body.

The Certification Body must be approved and be accredited to ISO/IEC 17055:2012 (Conformity assessment - Requirements for bodies certifying products, processes, and services) by an accreditation body who is a member of the International Accreditation Forum (IAF).

The chosen Certification Body will formulate a contract between the company and the certification body detailing the requirements and commitments needed from the company.

The objective of RFM chain of custody certification is to provide an assurance to a certified claim on a seafood product that the product originates from a certified 'Responsible Managed Fishery'.

Definitions

Chain of Custody (FAO Definition): *The set of measures which is designed to guarantee that the seafood product put on the market and bearing the ecolabel logo is really a product of designated origin and coming from the certified fishery concerned. These measures thus cover both the tracking/traceability of the product all along the processing, distribution, and marketing chain, as well as the proper tracking of the documentation and control of the quantity concerned.*¹

Additional Sites: A new site or group of sites that will be added to an existing certified Multi-site Organization.

Applicant: A company or group of companies in the supply chain that has formally applied to meet the RFM Chain of Custody Standard through the formal Application Form.

Certified Member: A company or group of companies in the supply chain that have been formally certified by the Certification Body as meeting the RFM Chain of Custody Standard.

Certified Fishery: A fishery that has been independently certified as meeting the **Alaska Responsible Fisheries Management (RFM) Standard or Iceland Responsible Fisheries Foundation Responsible Fisheries (RFM) Management Standard.**

Chain of Custody Standard: The list of requirements that the applicant must meet to claim certification to the RFM Chain of Custody Standard and /or use the certified claim.

Certified Chain: A Certified Member in the supply chain that can demonstrate all certified stages back to the Certified Fishery.

Certification Mark: A distinctive logo, trademark or seal which has been approved by the standard owner and verifies that the fish has been sourced from and is traceable back to a Certified Fishery.

Chain of Custody Registration Number: An RFM Chain of Custody Standard certificate registration number issued by the Certification Body to each company certified to the RFM Chain of Custody Standard.

Site: A site is a permanent location where an organization carries out work or a service.

Stage: A handling / transfer point in the supply chain e.g., vessel, packing, processing, distribution, sales.

Single-site Organization: A sole applicant for certification at a single discrete physical location, that complies with sections 1.0 to 4.0 of the RFM Chain of Custody Standard Requirements.

¹ FAO Guidelines for the Ecolabelling of Fish and Fishery Products from Marine Capture Fisheries.

Multi-site Organization: An Applicant that has more than one site under its direct control and applies for certification for these sites. This certification is applicable to any multi-site organization handling or trading certified products where the organization has identified a designated central office function which operates in conformity with requirements of sections 5.0 to 7.0 of the RFM CoC Standard. In this case every site under the scope of certification conforms with sections 1.0 to 4.0 of the RFM Chain of Custody Standard Requirements.

Subcontractor: A third party or affiliate that is appointed to carry out work for the applicant company (includes contract processors, packers, labelling and any other product processing facilities).

Service Provider: A third party or affiliate that is appointed to carry out work for the applicant company (includes contract transportation companies, distribution companies and any other storage facilities).

Temporary Site: A temporary site is one set up by an organization in order to perform specific work or a service for a finite period of time and which will not become a permanent site.

Outline of the Chain of Custody Process

The RFM Chain of Custody Certification process is managed by the approved independent Certification Bodies listed on the [ARFM](#)² and the [IRFM](#)³ websites.

The certification process has a number of distinct stages which are described below.

Single-site or Multi-site Organization

The initial step for applicants is to determine which category of organization they are: *Single-site or Multi-site*.

Single-site Organization

A site is a permanent location where an organization carries out production processes – as defined by IAF MD1:2007 clauses 1.2 & 2.1.1.

A site could include all ground or water areas on which activities under the control of an organization at a given location are carried out.

Multi-site Organization

A Multi-site Organization is defined as an organization having an identified central function (but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed and a network of local offices or sites at which such activities are fully or partially carried out – as defined by IAF MD1:2007.

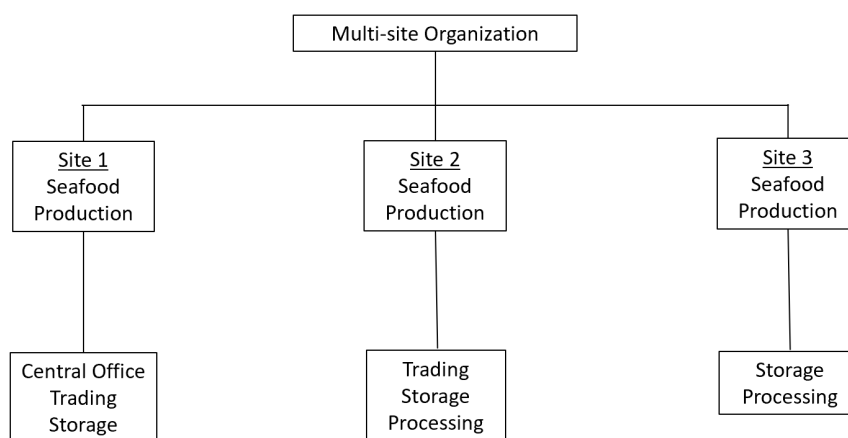


Fig. 1. Example of a multi-site organization

A Multi-site Organization may be considered as such only if it complies with the following criteria. All sites within the organization:

- shall have a legal or contractual link with a central office of the named and designated coordinating organization.
- Shall perform operations and related activities;

² <https://www.alaskaseafood.org/rfm-certification/chain-of-custody/coc-certification-bodies/>

³ <https://www.responsiblefisheries.is/certification/the-programme/certification-body>

- shall be subject to a common management system that oversees the traceability operations, which is laid down in a centrally controlled documentation system.
- shall be subject to continuous surveillance and internal audits by the central office of the designated coordinating organization.

Stage 1. Information Request

Information shall be requested from an applicant within the supply chain. An applicant could be a:

- processing vessel or processing vessel group.
- primary processor.
- secondary processor.
- sales and marketing (trader); or
- market, retailer, restaurant.

In turn, applicants may request information from the Standard owner organization or the Certification Body about the certification process, the Standard requirements, the estimated costs, or timeframes to gain certification.

Applicants are advised to carry out a self-assessment against the standard to ascertain their readiness for external audit prior to submitting their application.

Applicants are advised that all information given to the Certification Body will remain confidential.

It is not a requirement for the transport or storage / distribution companies to hold certification to the ARFM - IRFM Chain of Custody Standard, as these companies are classified as entities within supply chain which do not take physical control or only handle storage and distribution in packaging or containers that prevent tampering with certified seafood.

Stage 2. Completion of Application Form

Applicants will be requested to formally provide information on their product handling details and their product supply chain to the Certification Body, using the RFM Chain of Custody application forms.

Single-site Organizations may apply here: [Insert hyperlink to application form](#)

Multi-site Organizations may apply here: [Insert hyperlink to application form](#)

Note that Multi-site organizations must provide the details of **all sites** to be included within the scope of certification in the application.

Multi-site Organizations are also subject to additional application requirements:

- The organization's central office shall carry out an initial inspection visit of each site and review the implementation of the documented systems, prior to their application for certification; and
- The central office will be required to have a contractual agreement with the Certification Body to ensure that the RFM Chain of Custody Standards are fully implemented and enforced at all of the participating sites.

When the completed application form is received by the Certification Body the applicant is allocated a unique chain of custody registration number.

Stage 3. Certification Body prepares an Audit Plan.

Each organization and its supply chain are different and therefore the Certification Body will create a relevant audit plan to validate the chain of custody for the applicant's relevant product and supply chain as detailed in their application form.

The Applicant will be required to ensure that they can source product traceable back to the Alaska RFM or the Iceland RFM certified Fishery, from an organization(s) that hold valid RFM Chain of Custody Certification.

The Certification Body will provide the Applicant with an audit plan and audit cost based on the information provided in the application form.

Additional requirements for Multi-site Organizations

The audit plan considers the number of sites to be included within their scope of certification and their respective risk according to the activities conducted at each.

The resultant Audit Plan will be based on a representative sample of sites detailed in the application or the site register if the organization is already certified.

The selected sites will be audited first; followed by the central office last of all. The audit at the central office will include the results and evidence of the audits of the sites selected in the Audit Plan.

The full details of Audit Plan for Organizations can be found in the respective Application form.

Stage 4. The Audit(s)

The assessment of the applicant company's facility/facilities is carried out by an independent auditor(s) approved and acting for the Certification Body. The audit is against the RFM Chain of Custody Standard; and should be approximately 0.5 days or 4 hours in duration for a single site. Multi-site audits could require additional time, with some efficiencies across the additional sites.

It is the applicant's responsibility to ensure that the information supplied in the application form is factual and accurate so that the Audit Plan remains relevant.

The Certification Body's assessor will carry out the assessment in an independent, professional, and courteous manner.

Key components of the Chain of Custody standard include requirements for:

- product identity system.
- traceability system; and
- segregation system.

Stage 5. Audit Report

During the assessment process the assessor will compile an audit report on how the Applicant does/does not meet the RFM Chain of Custody Standard.

If more than one auditor is involved in the Assessment Stage, the Certification Body shall designate a lead auditor whose responsibility is to consolidate the findings from all the auditors and to produce a synthesis report.

The RFM Chain of Custody Standard will require specific interpretations of the clauses by the auditor to ensure they relate accurately to different sectors including packing, processing, distribution and selling of seafood products and materials.

The assessment report will identify any non-conformities against the RFM Chain of Custody Standard. The Applicant will be required to provide corrective action evidence to the assessor for identified non-conformities within 28 calendar days from close of assessment.

The certificate will not be issued if non-conformities found during an initial audit are not corrected or downgraded within the 28-day calendar period.

Non-conformity Classification

Minor non-conformities: raised during surveillance or re-certification audits (or any other time after initial certification) shall be closed or downgraded *within 28 days of detection*.

If the minor non-conformity is not corrected *within 28-day maximum timeframe*, the non-conformity shall be re-graded as a major non-conformity; and resultant conditions apply.

Major non-conformities: raised during surveillance or re-certification audits (or any other time after initial certification) shall be closed or downgraded *within 28 days of detection*.

If the major non-conformity is not addressed within the 28-day maximum timeframe, *suspension or withdrawal of the certificate and a full re-audit may be initiated*.

Suspension: raised during surveillance or re-certification audits (or any other time after initial certification) as a result of selling non-certified product as certified is a cause for suspension.

Non-conformities at Multi-site Organizations

For multi-site CoC clients, non-conformities found at different sites are all raised against the certified entity (the organisation which holds the CoC certificate).

Stage 6. Certification Decision

The Applicant's audit report and any necessary corrective actions will be submitted to a certification committee for a certification decision.

The certification committee is composed of persons with equal competence to the auditor and with expertise in certification.

Additional conditions for Multi-site Organizations

If any site has a non-conformity during an initial audit, certification shall be denied to all sites included under the scope of certification by the Applicant pending satisfactory corrective action.

Stage 7. Certification

When certification has been approved, the Applicant shall be notified within 10 working days of the certification decision. Following this notification, a Certificate of Approval will be issued to the applicant company.

The Certificate of Approval remains the property of the Certification Body and the control and management of the status of a certificate shall be in place.

Certificates are valid for three years with annual surveillance audits.

Sales and marketing companies (traders) will be subject to surveillance audits every 18 months.

The scope of certification covers:

- an Organization's activities.
- only those RFM certified fisheries and suppliers nominated by the Organization and notified to the Certification Body; and
- only those RFM certified stocks under consideration nominated by the Organization and notified to the Certification Body.

Following an initial audit, the Applicant will be awarded certification for its facility/facilities if it meets the RFM Chain of Custody Standard and all non-conformities are satisfactorily closed and/or addressed.

Eligibility for continued certification is maintained where there is substantive and demonstrable evidence that the company continues to conform to the criteria of the Standard. Any non-conformities raised shall be verified as closed, with objective evidence within the defined timescales.

Scope of certification for Multi-site Organizations

- the scope of certification applies only to those sites that have been notified and included in the site register submitted to the Certification Body by the Organization *and* have been eligible for inspection.
- sites identified in the certificate document, are also issued sub-certificates; and
- sites identified in the certificate document may trade products with claims of being certified.

Stage 8. Access to Certification Mark and Statement

Certified Members can apply to the standard owner for a permit to use the RFM certification marks, as applicable.

Appeals

The Applicant has the right to appeal the certification decision of the Certification Body. Appeals shall be made in writing within seven days of the certification decision.

A full response will be given by a Certification Body representative independent of the assessor and certification committee.

Further information

Further information regarding application, rules and regulations can be obtained from the Standard owners or the Certification Bodies:

Iceland Responsible Fisheries Foundation
Borgartún 35,
105 Reykjavik,
Iceland
www.responsiblefisheries.is

Certified Seafood Collaborative
311 N. Franklin Street Suite,
Juneau, AK 98801-1147,
United States of America
www.rfmcertification.org

SAI Global/Global Trust Certification Ltd.
Quay Street Business Park,
Dundalk,
Ireland

SCS Global Services Headquarters
2000 Powell Street, Suite 600,
Emeryville, CA 94608
United States of America

Chain of Custody Standard Requirements

*“The set of measures which is designed to guarantee that the product put on the market and bearing the ecolabel logo is really a product coming from the certified fishery concerned. These measures should thus cover both the tracking/traceability of the product all along the processing, distribution and marketing chain, as well as the proper tracking of the documentation (and control of the quantity concerned)”.*⁴

1.0 General Principles of Traceability for Chain of Custody

- 1.1 The Applicant shall have a documented policy to state that it is committed to the RFM Chain of Custody Standard. This must be:
 - signed by the person with overall responsibility for the site; and
 - communicated to all staff.
- 1.2 Only seafood products that originate from an RFM certified responsibly managed fishery may carry the RFM certification mark.
- 1.3 RFM certified seafood products shall be kept readily identifiable and where necessary kept clearly separated from non – certified seafood products.
- 1.4 The Applicant shall have a traceability system that can identify the certified seafood products enable tracking from receipt, during intake, processing, storage, dispatch handling and delivery to customer.
- 1.5 The Applicant shall comply with the applicable national federal and/or regional/state regulations on labelling and traceability.
- 1.6 The company shall have a system in place to ensure that purchased seafood carrying the RFM certification mark is not mixed with non-certified seafood during transportation to and from the site and in third party storage if applicable.
- 1.7 Where the Applicant utilizes the services of a subcontractor (carrying out contract processing, packaging, or labelling activities), the Subcontractor shall be certified to the RFM Chain of Custody Standard.
- 1.8 Where the Applicant utilizes the services of third-party service providers, a contract or equivalent documentary evidence shall be in place demonstrating that product traceability and tamper proofing are ensured during storage, distribution, or transportation.

⁴ FAO 2005/2009 Guidelines for the Ecolabelling of Fish and Fishery Products from Marine Capture Fisheries, 16. Chain of Custody, page 4.

2.0 Traceability within the Supply Chain

- 2.1 Each seafood consignment shall be traceable back to the certified fishery and should have the following minimum information available:
- species name; and
 - catch area.
- 2.2 Certified seafood products shall be kept separate from non-certified seafood products throughout all stages such as receipt, storage, processing, packing, labelling, sales, and delivery if they are to carry the official certification ARFM/IRFM mark. This may be achieved by:
- physical separation; and
 - temporal separation.
- 2.3 Where certified and non-certified seafood is mixed the final product is not eligible to carry the RFM certification mark unless:
- compound products, including ready meals, may contain non- certified seafood ingredients within the final product where the non – certified seafood ingredients shall be 5% or less by weight of the total seafood ingredient in the final product.
- 2.4 The Applicant shall operate a system that allows any product or batch of products sold/marked by the organization as originating from a certified fishery to be verified through documentation.
- 2.5 Procedures shall be established by the Applicant to deal with any non-conformities in the traceability system.
- 2.6 The Applicant shall operate a product recall system that will be activated if certified seafood is mixed with non- certified seafood. The relevant certification body shall be notified within 3 working days in the event of a certified product being recalled. The product recall system shall be tested annually with documented results for inspection.

3.0 Traceability and Labelling

- 3.1 The Applicant shall test the efficacy of their batch control and traceability system through a thorough documented internal assessment carried out annually and the results shall be retained for inspection. The test shall include a traceability challenge (backwards and forwards) and a quantity check/ mass balance.
- 3.2 Documentation must be available that verifies the identity of the certified seafood as originating from an RFM certified fishery.
- 3.3 Certified seafood products shall be labelled or otherwise be identified in a manner that ensures traceability is maintained during packaging, storage, handling, and delivery.
- 3.4 The Applicant shall be able to track and trace the certified product one step forward and back to the certified fishery.

- 3.5 Each certified product shall be labelled with all necessary information which is appropriate for the Applicant's stage in the supply chain. The information should at minimum include the following:
- commercial species name.
 - country of origin.
 - fishing/catch area.
 - product description and/or code number; and
 - manufacturing lot or batch number.
- 3.6 In addition, each outgoing batch/lot of certified seafood product sold as certified, shall be identified as RFM certified on product packaging or associated documentation (e.g. sales invoice, dispatch documentation).
- 3.7 The Applicant shall operate a secure system for the production, storage and application of product labels bearing the RFM certification mark; and will ensure that only certified seafood product is labelled as such.
- 3.8 A record of all certified incoming products shall be maintained, showing the name of the supplier, their unique chain of custody certificate number, evidence of RFM Chain of Custody certificate validity, and sufficient other details to allow the tracing of those inputs back to their suppliers and the Certified Fishery.
- 3.9 Traceability records shall be kept for a reasonable period to correspond with the shelf life of the product and/or a minimum of three years. Traceability records shall be accurate, legible and unadulterated.
- 3.10 The applicant company shall have a documented procedure for handling non-conformities to this Standard. Records of non-conformities shall include:
- clearly documented details of the non-conformity.
 - identification of the person responsible for addressing non- conformity.
 - clearly documented corrective action.
 - documented verification that the corrective action has been implemented and the non- conformity closed.
- 3.11 Non – conformity procedures shall include documented corrective actions, within 28 days.
- 3.12 The Applicant shall keep a documented record of customer complaints or feedback concerning the labelled certified seafood and take appropriate action with respect to such complaints.
- 3.13 The Applicant is only allowed to use RFM certification mark if it has valid certification to the RFM chain of custody standard; and has been granted approval to do so by the standard owner.

4.0 Training

The Applicant shall put in place documented programmes covering the training needs of all relevant personnel.

- 4.1 Records of all training must be available. This must include as a minimum:
- the name of the trainee and signed confirmation of attendance.
 - the date of the training.
 - the title or course contents, as appropriate.
 - the training provider.
- 4.2 The Applicant shall routinely review the competences of its staff, at least annually; and provide appropriate training in the form of refresher training or coaching, mentoring or on – the – job experience.

Additional Multi – site Chain of Custody Standard Requirements

This section details the set of requirements that shall be certified as being in place where the Applicant is a Multi-site Organization; these requirements apply to the designated central office.

5.0 Organizational Integrity

- 5.1 The Multi-site Organization shall either:
- be a legal entity with direct control over the sites and that takes ownership of the certified product, or.
 - have a signed contractual agreement between the central office and each member site that is included in the application.
- 5.2 The Multi-site Organization’s central office shall have a signed contractual agreement with the Certification Body for ensuring that the RFM Chain of Custody Standard are fully implemented and enforced at all of the participating sites.
- 5.3 There shall be a documented company policy stating the organization’s commitment to the RFM Chain of Custody Standard.
- 5.4 There shall be documented evidence to demonstrate that this policy has been communicated to all the Chain of Custody member sites within the Multi-site Organization.
- 5.5 The Multi-site Organization’s central office shall provide each member site with ready access to updated documentation and information, specifying the relevant terms and conditions of certification.
- 5.6 There shall be a documented organizational structure showing relevant positions, and their interrelationship and responsibilities with respect to the RFM Chain of Custody Standard.
- 5.7 There shall be a designated appropriately trained person within the organization who is responsible for coordinating multi-site chain of custody activities to ensure they meet the requirements of the RFM Chain of Custody Standard.

- 5.8 Where a Multi-site Organization utilizes the services of a subcontractor (carrying out contract processing, packing or labelling activities), the subcontractor shall be certified to the RFM Chain of Custody Standard.
- 5.9 Where a Multi-site Organization utilizes the services of third-party service provider, a signed contract or equivalent documentary evidence shall be in place demonstrating that product traceability and tamper proofing is ensured during storage, distribution or transportation.
- 5.10 The Multi-site Organization's central office will ensure accurate collecting and reporting of purchases and sales of volumes of RFM certified materials at the site level.

6.0 Management of members

- 6.1 The Multi-site Organization shall have a register of all sites included under its control/contractual agreement which details the following information as a minimum:
- name of each site;
 - full address (physical and postal);
 - contact details (phone/email);
 - product handled; and
 - date of last internal audit and result.
- 6.2 The Certification Body shall be formally informed of the addition of any new sites to the multi-site organization within 10 working days of registration.
- 6.3 The new additional site shall have received an internal audit to the RFM Chain of Custody Standard and there shall be no outstanding non-conformances before the site is added to the member site register.
- 6.4 The Certification Body shall be formally notified of the removal of any site from the member site register within 10 working days of withdrawal.
- there shall be a documented procedure for the removal of any site that includes removal of any claims to the scope of certification such as activities, materials, products and/or use of the ecolabel or trademarks.

7.0 Central office control and responsibilities

- 7.1 The central office shall demonstrate its ability to collect and analyse data from all member sites including itself. There shall be a documented annual management review meeting covering:
- system documentation and system changes.
 - the management reviews.
 - complaints.
 - evaluation of non-conformities and corrective actions.
 - internal audit planning and evaluation of the results; and
 - different legal requirements.
- 7.2 The central office shall have a system for ensuring that all market claims and trademark use by all participating sites meet the RFM Chain of Custody Standard requirements prior to publication:

- a valid permit for use of RFM Chain of Custody trademarks must be held by the organization; and
 - any representation of certified status of sites and their products shall be made in reference to the certified organization.
- 7.3 The Applicant shall have a documented procedure for handling non-conformities to this standard. Records of non-conformances shall include:
- clearly documented details of the non-conformity.
 - identification of the responsible person assessing non-conformity.
 - root cause analysis.
 - clearly documented corrective action plans and timescale; and
 - documented verification that the corrective action has been implemented and the non-conformity closed.
- 7.4 Corrective action plans shall be accurately documented; identifying authorized responsible personnel and with specified time limits to complete the plan.
- 7.5 There shall be an internal audit plan, checklist, and schedule available to cover the central office and member sites.
- 7.6 Internal audits of the member site and central office shall be carried out at least annually and prior to application for Multi-site certification.
- the central office shall have a clear system for reporting on these inspections to the site managers.
- 7.7 Internal auditors shall be suitably trained and independent of the area being audited.
- 7.8 All records of the internal audit plan, audit findings and follow up of corrective actions resulting from an internal audit shall be maintained and available to the Certification Body on request.
- 7.9 There shall be a documented procedure for the identification of certified products to enable traceability of all certified product to the applicable sites.
- 7.10 There shall be evidence that central office tests the traceability system across the Multi-site Organization for the range of RFM Chain of Custody certified products to ensure traceability can be determined from incoming product to finished product and vice versa. This shall:
- be carried out at least annually.
 - include a quantity check/mass balance.
 - traceability challenge (backwards and forwards); and
 - be documented and the results shall be retained for inspection.
- 7.11 All traceability records shall be kept for a reasonable period to correspond with the shelf life of the product or for a minimum of 3 years. Traceability records shall be accurate, legible and unadulterated.