GSA Policy on Supplemental Audits of Facilities

Issue 5.2

04-June-2024

A. Overview

The GSA standards and associated certification process are based on ISO17065, which necessitates full compliance with the requirements of the Standards in order to achieve certification. This is accomplished through audits by third party certification bodies (CBs) to ensure that facilities are in compliance with all criteria of the applicable Standard. Facilities must undertake corrective actions (CAs) to mitigate the root cause of all non-conformities (NCs) identified during certification audits. Additionally, CBs may have to evaluate potential NCs arising from situations such as failed product testing and complaints from customers, Standard Program Owner, or the CB themselves. This policy document addresses the framework of NCs, their severity, and other conditions that may warrant a supplemental audit (i.e., in addition to a normal certification audit) as necessitated by the CB and/or GSA for verification purposes. Supplemental audit procedures for CBs and facilities are described herein. These rules are applicable against the full range of GSA standards.

Additionally, there are situations where supplemental audits are necessary, e.g. extension of scope of certification, program integrity concerns, etc. This policy describes the procedures for such supplemental audits.

Note: The CB shall NOT schedule or conduct a supplemental audit until they receive authorization from GSA

B. Categories of Supplemental Audits

Supplemental audits are divided into the following categories:

1. Limited Scope Follow-up Audit
2. Re-Audit
3. Extension of Scope Audit
4. Program Integrity Audit
5. Targeted Audit (e.g., Food Safety Residue Testing Failures)

C Description of Supplemental Audits – Reason, Duration, Scope, Process

1. Limited Scope Follow-up Audit

1.1 Reason: A limited scope follow-up audit is necessary in specific situations noted below:

a. Where non-conformity (NC) thresholds (severity and/or number) stated in Appendix 1 have been exceeded during the recent certification audit.

1.2 Audit Duration:

a. The duration for an onsite limited scope follow-up audit is 0.5-1.0 audit days depending on the number and severity of NCs and shall not exceed 1.0 audit day. If the CB determines that the auditor needs more than 1.0 audit day for the onsite verification, then prior approval from GSA shall be obtained.

1.3 Scope and Process:

a. The scope of the limited scope follow-up audit is for the auditor to verify the proper implementation of the CAs established by the facility to correct all nonconformities issued during the recent audit, including their root causes. The purpose of this audit is to confirm with an onsite visit, through observation of facility operations and objective evidence, that all of the corrective actions have been effectively implemented and were verified by the auditor as being in full compliance to the applicable Standard.

b. The CB must obtain the objective evidence of CAs implemented to address the NCs and their root cause prior to scheduling the onsite limited scope follow-up audit.

c. The auditor shall review all CA evidence submitted by the facility prior to scheduling the limited scope follow-up audit. This is necessary so the auditor can ensure the evidence is satisfactory to close the NCs during the onsite visit.

d. In general, the CB should consider assigning the auditor who performed the recent certification audit leading to the limited scope follow-up audit. In the event a new auditor is assigned, he or she shall be provided details of the NCs and CA evidence prior to conducting the limited scope follow-up audit.

e. Timeframes

    1. New facilities: CBs shall make every effort to complete a limited scope follow-up audit and subsequent certification decision within KPIs stated in the GSA CB Requirements Document[1] from the date of the initial onsite audit. In situations where this cannot be achieved, then upon GSA discretion, new facilities shall be allowed up to 120 calendar days from the date of the initial certification audit to complete the entire certification process. In the event that the limited scope follow-up audit and subsequent certification decision does not occur within 120 calendar days from the date of the initial certification audit, new facilities must reapply to BAP and complete an audit against the full scope of the applicable Standard.

    2. Recertifying facilities: the limited scope follow-up audit and subsequent certification decision shall occur between the facility's recertification audit date (date the recent audit conducted) and their certificate validity date. In the event the limited scope follow-up audit and subsequent certification decision is not fully completed prior to the certificate expiry date, recertifying facilities must re-apply to BAP and complete an audit against the full scope of the applicable Standard. Only under extenuating circumstances an extension to this timeline may be granted to recertifying facilities at the discretion of GSA.

f. In the event that the limited scope follow-up audit establishes that requirements remain inadequate, and the auditor was unable to close out the NCs, such facilities must re-apply to BAP and complete an audit against the full scope of the applicable Standard.

g. If the facility declines to have a limited scope follow-up audit necessitated by the CB to close out open NCs then the facility must re-apply to BAP and complete an audit against the full scope of the applicable Standard.

[1] Requirements for Certification Bodies Offering Certification Against the Criteria of the Global Aquaculture Alliance Best Aquaculture Practices

h. In the event that additional NCs are observed other than those that the auditor set out to verify during the limited scope follow-up audit, the CB shall evaluate the situation and make a decision on either suspension or withdrawal of the certification of already certified facilities. Accordingly, the CB shall decide on the continued certification status of the facility, or if the facility must re-apply to BAP and complete an audit against the full scope of the applicable Standard. If this occurs at a new facility the CB must stop the certification process and such a facility must re-apply to BAP and complete an audit against the full scope of the applicable Standard.

2. Re-Audit

2.1 Reason: A re-audit to the full scope of an applicable Standard is necessary in specific situations as noted:

a. The number and severity of NCs are high enough (see Appendix 1) that both the CB and GSA feel the facility clearly lacks an understanding and implementation of the Standard requirements, compliance with laws, and/or has insufficient systems in place to demonstrate full compliance.

2.2 Audit Duration:

a. The duration for the re-audit is the same as that of a certification audit per GSABAP CB Requirements Document[2] since these audits are against the full scope of an applicable GSA Standard.

2.3 Scope and Process:

a. The scope of the re-audit is same as that of a certification audit based on the applicable Standard and requires verification of compliance to all requirements of the applicable Standard. Corrective action evidence from the previous audit shall be reviewed by the auditor prior to the re-audit.

b. If NCs are identified during re-audits, they are handled per normal process according to the Program rules and applicable Standards and governed by the NC thresholds (severity and/or number) stated in Appendix 1.

3. Extension of Scope Audit

3.1 Reason: An extension of scope audit is necessary in specific situations as noted:

a. Where the seafood processing facility is certified to one species category and intends to add on a new species category.

Examples include processing facility certified to farm raised only would like to add wild caught species or vice versa.

b. Where a processing facility intends to expand its current processes and product forms into additional processes and product forms that could impose changes to the scope of the Standard.

Examples:

[2] Requirements for Certification Bodies Offering Certification Against the Criteria of the Global Aquaculture Alliance Best Aquaculture Practices

i) A facility producing raw product forms would like to add breaded, RTE cooked, and/or low acid canned foods, etc. ii) Adding a scombroid species to the processing lines which would introduce a significant hazard - Scombrotoxin. In general, if the facility is adding any new hazards and food safety risks that were not part of the initial audit that led to certification, they need an extension of scope audit.

c. Where a seafood processing/reprocessing/CoC certified facility intends to add a BAP star status product.

Examples:

i) A BAP certified processing/reprocessing/CoC certified facility that is processing only 1-star status product wants to add 2, 3, and/or 4-star status products from certified facilities.

d. Where a farm and/or hatchery facility is certified to one category/species/ production method and intends to add a new category/species/production method. *Examples:*

i) A land-based farm with ponds that intends to add production cages in streams/rivers.

ii) A certified farm or hatchery producing salmon intends to add a new nonsalmonid species. Note: a salmon farm or hatchery adding trout may not require an onsite extension of scope audit if they can show the production system, methods and feed is similar for both species.

e. Where a seafood processing or reprocessing certified facility intends to add enhanced social. Examples:

i) After being certified, a seafood processing facility wants to add enhanced social.

ii) At the time of application the seafood processing facility opted into the enhanced social , but scheduling prevented the SPS auditor and the enhanced social auditor from auditing the facility at the same time.

3.2 Audit Duration:

a. The duration for an onsite extension of scope audit shall not take more than:

1. Farms/hatcheries – one-half audit day
2. Seafood processing plants –one audit day depending on the complexity of processes and number of species and number of hazards.
3. Enhanced Social – 1.5 days

b. If the CB determines that the auditor needs more time for the onsite extension of scope audit, then prior approval from GSA shall be sought.

3.3 Scope and Process:

a. The purpose of the extension of scope audit is to verify that the additional categories, risk factors, processes and species are compliant to the applicable Standard.

b. In situations where an extension of scope audit is considered for scheduling just prior to a re-certification audit, then the full scope re-certification audit can replace the need for an extension of scope audit.

c. The extension of scope audit follows the same audit guidelines as that of an initial certification audit to include all assessment elements – opening meeting, facility site audit (including only the additional products, processes and species being included), collection of product samples (if required), review of management systems, records and procedures pertaining to those additional aspects being included into certification, closing meeting – includes provision of nonconformance (if any) summary report.

d. If the extension of scope audit demonstrates compliance, the certificate shall be updated with the new scope. The updated certificate shall retain the same certificate expiry date as the certificate currently in place.

e. If NCs are identified during extension of scope audits they are handled per normal process and timelines according to the Program rules and applicable Standards and governed by the NC thresholds (severity and/or number) in Appendix 1. If thresholds warrant a limited scope follow-up audit or a re-audit, the CB shall evaluate the situation and make a decision on either suspension or withdrawal of the existing certification. Accordingly, the CB shall decide on the continued certification status of the facility, or if the facility must re-apply and complete an audit against the full scope of the applicable Standard.

f. If NCs identified are out of the scope of the "extension of scope audit" these shall be brought to the attention of the CB and BAP immediately and depending on the severity and number of NCs, the CB shall evaluate the situation and make a decision on either suspension or withdrawal of the existing certification. Accordingly, the CB shall decide on the continued certification status of the facility, or if the facility must re-apply and complete an audit against the full scope of the applicable Standard.

g. An extension of scope audit could require additional finished product testing due to addition of species or product forms. In this instance the CB auditor shall oversee product sampling per Annex 4 of the SPS.

h. If an extension of scope audit at farms, hatcheries and processing plants requires effluent samples, the CB auditor shall oversee effluent sampling per applicable Standard.

i. For extension of scope audits that do not require an onsite visit refer to 6.2a below.

4. Program Integrity Audit

4.1 Reason: A Program Integrity (PI) audit may be necessary in specific situations as noted:

a. Where the facilities have violated the Program rules, requirements and/or the contractual agreements, and deviations to Standard compliance are considered by GSA as a threat to the Program. Such deviations could be of any category and might affect any or all pillars (social, environmental, animal welfare, food safety also including traceability and legality) of the Program.

b. These audits may be conducted regularly based on a risk analysis but not limited to facility performance patterns (history of audit outcomes), customer complaints, incidents, Program integrity violations, media criticisms, high detention rate by regulatory authorities,

history of consistent problems, traceability and mass balance issues and government sanctions.

4.2 Audit Duration:

a. The duration for an onsite PI audit is governed by observed/reported violations and could take a minimum of one-half audit day, and up to three audit days or more for an in-depth investigation of the problem at hand.

4.3 Scope and Process:

a. The purpose of the PI audit is to ascertain that the Program rules are being implemented as agreed upon and compliance verified to the applicable contractual agreement and/or Standard.

b. PI audits are generally at the discretion of GSA. The PI audits may also be conducted randomly as a result of a risk analysis conducted by GSA.

c. PI audits are generally conducted by PI team members. Upon specific request from GSA these audits may be conducted by CB auditors.

d. In the event that additional non-conformities are observed other than those that the auditor set out to investigate during the PI audit, the CB that issued the current certification would be informed of the situation (if the auditor is not from the CB personnel). The CB that granted the certification must then make a decision on either suspension or withdrawal of certification. Accordingly, the CB that granted the certification shall decide on the continued certification status of the facility, or if the facility must re-apply and complete an audit against the full scope of the applicable Standard.

5. Targeted Audit (e.g. Food Safety Residue Testing Failures)

5.1 Reason: A targeted audit is necessary in specific situations as noted:

a. Audits similar in nature to PI audits conducted by the CB for specific observed/reported potential NCs (e.g., regulatory detentions like FDA Red List).

b. Facilities that fail Standard drug or microbiological parameter testing requirements during Finished Product Testing and Food Safety and Residue Testing (FSRT).

5.2 Audit Duration:

a. The duration for a targeted audit is governed by observed/reported violations and could take a few hours to one audit day depending on the complexity of the investigation.

b. If the CB determines that the auditor needs more time for the targeted audit, then prior approval from GSA shall be sought.

5.3 Scope and Process:

a. The purpose of the targeted audit may be due to concerns over the facility's inability to meet the requirements of FSRT program or a specific deviation from the requirements of the applicable Standard.

b. The process would be similar to that of the limited scope follow-up audit to verify the CAs implemented by the facility.

c. Generally, the CB that issued the current certification would undertake such targeted audits at the discretion of GSA.

d. In situations where the targeted audit does not require an onsite visit, then a desktop review of the deviation/violation is conducted to assess the situation.

e. The facility must submit objective evidence of CAs implemented to address the deviation and its root cause to the CB prior to the scheduling the targeted audit.

f. The auditor shall review all CA evidence submitted by the facility prior to scheduling the targeted audit. This is necessary so the auditor can ensure the evidence is satisfactory to mitigate the deviation identified.

g. In the event that the targeted audit establishes that compliance with the requirements of the applicable GSA standard remain inadequate, a complete audit against the full scope of the applicable Standard may be required at the discretion of GSA.

h. In the event that additional non-conformities are observed other than those that the auditor set out to verify during the targeted audit, the CB shall evaluate the situation, make a decision on either suspension or withdrawal of the certification of already certified facilities. Accordingly, the CB shall decide on the continued certification status of the facility, or if the facility must re-apply and complete an audit against the full scope of the applicable Standard.

6. CB Procedures for Conducting Supplemental Audits

6.1 For Limited Scope Follow up Audits and Re-Audits:

a. Auditors conducting new certification/recertification audits are required to submit NC summary reports to the CB office, and the CB ascertains as part of the technical review, whether or not the NCs issued (number and severity) are appropriate.

b. Once the technical review is complete, the CB may consider that a limited scope follow-up or a re-audit is deemed appropriate based on the NC thresholds in Appendix 1.

c. If a supplemental audit (either a limited scope follow up or re-audit) is deemed appropriate, the CB shall send the NC summary to GSA

(programintegrity@globalseafood.org) and state clearly in the subject line, or first line of the email: **"NOTE – Supplemental Audit Request (state type of audit either limited scope follow-up audit or re-audit)".**

6.2 Extension of scope and targeted audits:

a. The necessity for onsite or administrative extension of scope or targeted audits will be reviewed by GSA based on requests received directly from the facilities or through their CBs.

b. For extension of scope audit requests that the CB receives directly from the facilities, all necessary information received from the facility shall be forwarded to GSA.

c. Requests for extension of scope or targeted audits shall be submitted to GSABAP (programintegrity@bapcertification.org) stating clearly in the subject line, or first line of the email: **"NOTE – Supplemental Audit Request (state type of audit either extension of scope or targeted audit)".**

6.3 All supplemental Audits:

a. The necessity for supplemental audits will be reviewed by GSA based on requests received directly from the facilities or through their CBs.

b. As noted earlier the CB shall NOT schedule or conduct a supplemental audit until they receive authorization from GSA.

c. Based on information received from the CB and/or facilities, GSA will either:

i) confirm to proceed with the supplemental audit.
ii) request additional information and clarification, or.
iii) reject the request for a supplemental audit with an explanation.

d. The duration of the supplemental audit must be formally agreed between the CB and GSA.

e. The CB shall notify the facility, with a copy to GSA (cbdept@globalseafood.org), that a supplemental audit must be scheduled, the type of supplemental audit required, and an explanation as to why the supplemental audit is required.

f. The CB shall notify GSA (cbdept@globalseafood.org) that audit has been agreed to along with the scheduled audit date.

g. The CB shall meet time frames stated above and in the GSA CB Requirements Document[3].

h. The CB is responsible for determining relevant requirements to be audited from applicable Standards per supplemental audit type.

7. Audit Report Structure

7.1 Audit Reports Shall Meet the Following Criteria:

a. Limited scope follow-up audits: As these audits are a continuation of the certification audit a separate report is not necessary. The audit report shall state that a limited scope follow-up audit was initiated for on-site verification and closure of the NCs. Evidence for either closing the NCs or keeping the NCs open shall be provided with justification citing the objective evidence.

b. Re-audits: As these audits are to the full scope of the Standards, auditors shall use the same report format as that used for a full initial certification or re-certification audit in the BAP Portal system.

c. Extension of scope, program integrity, and targeted audits: These audits shall be reported in a manner so as to address the specific situation for which the audit was

[3] Requirements for Certification Bodies Offering Certification Against the Criteria of the Global Aquaculture Alliance Best Aquaculture Practices

required. The format shall either be stipulated by GSA, and/or a format determined by the CB as being the most appropriate.

d. In all circumstances, the audit reports must include the following.

   i. A reference on the first page as to what type of supplemental audit the report pertains to.

   ii. The dates of the original audit and the dates of supplemental audit. iii. The scope of the supplemental audit. iv. The name(s) of the auditor(s) that conducted both the original audit and the supplemental audit.

   iii. A clear distinction between any new NCs arising from the supplemental audit and those from the original audit stated clearly.

e. For reports utilizing the GSA Portal system, the auditor can use the full BAP audit checklist and cite "N/A" for clauses outside the scope of the supplemental audit.

f. For reports utilizing formats other than the GSA Portal system, the auditor can use either the full BAP audit checklist and cite "N/A" for clauses outside the scope of the supplemental audit, or can delete all N/A portions of the checklist, provided that the proper clause numbers and subject headings are preserved.

g. All details shall be clear, unambiguous and the Standard requirements properly referenced.

h. All supplemental audit reports must be sent to GSA after a thorough technical review and subsequent approval by the CB.

APPENDIX 1

Non-Conformance (NC) Number and Severity Thresholds

NC numbers and severity			Supplemental audit type
Critical	Major	Minor	
≥1	0	0	Re-audit
0	≥7	0	Re-audit
0	0	≥35	Re-audit
0	6	≥15	Re-audit
0	6	<15	Limited scope follow-up audit
0	5	15-34	Limited scope follow-up audit
0	4	20-34	Limited scope follow-up audit
0	3	25-34	Limited scope follow-up audit

Note: NC numbers and severity are inclusive.

Examples:

1. *Facility with 6 Majors and 15 Minors necessitates a re-audit*
2. *Facility with 6 Majors and 14 Minors necessitates a limited scope follow-up audit*
3. *Facility with 4 Majors and 20 Minors necessitates a limited scope follow-up audit*
4. *Facility with 4 Majors and 19 Minors – no supplemental audit required*
5. *Facility with 2 Majors and 34 Minors – no supplemental audit required*