

SEAFOOD INDUSTRY GUIDE

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1. A formal quantity control function is in place with someone in authority to review production processes and records, investigate possible errors, and approve, control, or reject lots.

- Do you have a formal program in place? Is it documented?
- Is there training for packaging staff and is the training readily available and updated?
- Who is responsible for ensuring net quantity compliance? Are they empowered to stop production and/or shipment of goods to make corrections, and held accountable when they fail to take appropriate actions?
- Do they have the support and tools (laboratory facility, proper test and measurement equipment, support to test, audit, and implementation of checks and balances) to do the job?
- Do they have the backing of headquarters to reject lots or take other action?
- What audit trails are in place?
- Are results reviewed? By who? How often?
- Are internal inspections and audits being performed or is a third party being used to ensure that the quantity inside the package meets the labeled net content?
- How is follow through on problems handled and is it documented so you can show a regulatory official that the system is working?
- Supervision - How do you ensure people are doing their job and how are they held accountable?
- Who is analyzing the data and reports?
- Do you have a program or system in place to inspect, validate, certify and ensure that your suppliers have good quantity control procedures at the source of packing and at the point of receiving?
- Do you have a program to routinely inspect product that is received?
- Do you live and breathe quantity and quality control every day? Is it part of the culture?

2. Adequate facilities (e.g., equipment, standards and work areas) for conducting quantity control functions are provided and maintained.

- “Adequate Facilities” refers to such things as labs, dedicated testing rooms or work area, proper equipment such as sieves, sinks, freezers, scales....
- Do they have the tools (sieves, lab, and accurately maintained scales) to succeed?

3. A quantity control program (e.g., a system of statistical process control) is in place and maintained.

- Consider using a spreadsheet, database, statistical process control software, or paper based system. Look for anomalies, patterns, systematic errors.
- Are the variations within the controls you set?
- Plot deviations. MAV’s can point to such things as surges, vibration and other factors.
- Many books exist on this subject. They will provide good ideas on forms and reports to use, as well as data tracking, graphing, including defining upper and lower limits.
- Consult with your quality control people to help with statistical control. These individual are usually well versed and well trained in this area.
- What are the controls in place?

4. Sampling is conducted at a frequency appropriate to the product process to ensure that the data obtained is representative of the production lot.

- If sampling is done off line or off site, use HB133 Table 2-1 sampling plans.
- If sampling directly from the line, it is recommended that a minimum of 30 out of every 1000 be sampled. Do a quick analysis of gross weight (net + glaze + tare). This is usually enough to know the system is under control.
- Verify the percentage (%) of ice glaze frequently.
- Biggest mistake is to check only the beginning of the run and not sampling throughout (i.e., doing the first 30 items then stopping). Be random and thorough. Sampling needs to provide constant and immediate feedback.
- Automatic checkweighers can produce automated reports, and even sound an alarm when MAV’s are exceeded. Make sure automated systems cannot be disabled without the approval or without a record of the action and justification being created.

5. Production records are maintained to provide a history of the filling and net content labeling of the product.

- Purpose to provide traceability and audit trail.
- Can demonstrate to regulators, internal auditors, and customers’ good practices.
- Someone should be responsible for reviewing and maintaining.
- Need documented procedures on record and document controls.
- Good data helps you isolate problems to plant or supply chain.

- 6. Each “production lot” contains on the average the labeled quantity and the number of packages exceeding the specified Maximum Allowable Variation (MAV) value in the inspection sample shall be no more than permitted in Tables 2-1 and 2-2 in NIST Handbook 133.**
- Does it meet the Average and MAV requirement?
 - Are procedures in place to ensure the average requirement is being met and that MAV’s are identified in real time and corrected?
 - Table 2.1 tells you how many MAV’s are allowed based on lot size, while Table 2-5 will tell you what the MAV is.
 - MAV limits are extremes (negative errors). Set to lower limits and avoid MAV’s altogether (i.e., set up a control chart one with a line at MAV level, the other at ½ the MAV or less.)
- 7. Packaging practices are appropriate for specific products and measurement procedures (e.g., quantity sampling, density and tare determinations) and guidelines for recording and maintaining test results are documented.**
- Scallops, shrimp, and crab legs for example, are all different. Fill level determination, package tare used, percentage tare used may all vary.
 - Are procedures understood by those involved? Are they documented?
 - How well are the distribution process (moisture content, shelf life distribution, environmental handling) understood and the impact it could have on various type commodities in ensuring the integrity of net weight?
- 8. Personnel responsible for quantity control follow written work instructions and are competent to perform their duties (e.g., background, education, experience and training). Training is conducted at sufficient intervals to ensure good practices.**
- Is the person in this position qualified?
 - Is training formalized?
 - Are there checks and balances in place to re-enforce on a day to day basis?
 - What accountability exists?
 - The person responsible will ultimately set the standard for integrity and quality.
 - Are HB133 test procedures understood for ice glazed and block product?

9. Recognized procedures are used for the selection, maintenance, adjustment, and testing of filling equipment to insure proper fill control.

- Consider as part of your service contract that your device will be tested in accordance with HB44 and that complete and thorough tests will be done within “acceptance” tolerance. Request reports documenting errors “as found” and “how left”.
- Buy your own certified, calibrated weights (i.e., 5lb and 10lb) and do your own audit testing. Check all scales daily or even on a more frequent basis.
- Evaluate buying more accurate scales that have a smaller resolution such as 0.005 lb.
- Consider a checkweighing system. This system could automatically track records.
- How often is the equipment tested, inspected, and adjusted? Know your equipment.
- Are operators properly trained on how to use, maintain and adjust filling equipment, and how to test for accuracy?
- Is a maintenance program in place to ensure the weighing accuracy of devices being used? How often? Do they adhere to HB44 requirements? What records are kept and by whom?
 - Is the device National Type Evaluation Program (NTEP) approved and does it conform to HB44 requirements?
 - Is the device suitable (capacity and scale division) for your operation?
 - Is the device secure on a stationary platform?
 - Is the environmental impact (e.g., airflow, wash down, cleaning, usage) on the operation and performance of your scales understood?
 - Are the weights used by the technician who performs maintenance and testing on the scales traceable and certifiable to a national standard?

10. Weighing and measuring devices are suitable for their intended purpose, and measurement standards are suitable and traceable to national standards (test weights). This includes a system of equipment maintenance and calibration to include recordkeeping procedures.

- Are your devices suitable for your environment and product? Check with your scale company.
- Do you understand the technical operations, specifications, and use of the equipment?
- NIST HB112 is an EPO on “how to” test scales device (does not cover in motion weighing devices). Become familiar with this document. <http://www.nist.gov/pml/wmd/pubs/handbooks.cfm>

11. Controls over automated data systems and software used in quantity control ensure that information is accessible, but changeable only by authorized personnel.

- Safeguards and controls should be put in place to prevent data from being changed or falsified. Are these controls documented?
- Identify what can be changed and identify authorized personnel (e.g., supervisor). Are there controls in place such as password protection?
- What audit trails and reports exist to capture system changes and overrides?
- Does automatic maintenance (i.e., nightly data maintenance) exist that could cause the change to revert back? Know your system.

12. Tare materials are monitored for variation. Label changes are controlled to ensure net quantity matches labeled declaration.

- Know when tare and packaging materials change as well as when a supplier changes.
- Periodically weight (e.g., minimum average of 10 samples) and test for tare weights....don't assume. Are package tare understood and multiple samples taken regularly to verify accuracy?
- Know that changes to labeling (i.e., special stickers) could affect tare weight.
- Monitor and verify percentage glaze frequently.
- How is tare verified real time?
- What is the percentage of ice glaze being used? Does it vary by product? Is the tare weight of the package and ice glaze tare correctly being deducted from net weight? How is this verified? How accurate is it? Is there a process in place to communicate this to customers? What is the best process for determining net weight before ice glaze is applied?