

	Standard Operating Procedure	SOP Number E-704	Revision 3
	AQL Statistical Sampling Plan	Effective Date 05/10/24	Page Page 1 of 7
Written by/ Date H. Bunn 03/23/24	Reviewed by/ Date SS 03/25/24	Approved by/ Date [Signature] 05-25-24	
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1.0 Purpose

The purpose of this procedure is to define and describe the sampling plan when statistical sampling is required.

2.0 Scope

This procedure applies to all sampling processes where statistical sampling is required at Ion Nutritional Labs.

3.0 Responsibility

- 3.1 It is the responsibility of Quality Management to implement and maintain this procedure.
- 3.2 It is the responsibility of all personnel involved in any sampling process that required statistical sampling to strictly follow this procedure.

4.0 Definitions

- 4.1 **AQL** – Acceptance Quality Limit; Maximum number of defective units, beyond which a batch is rejected
- 4.2 **Inspection** – Evaluation for qualitative characteristics only, i.e. cleanliness and component integrity
- 4.3 **Examination** – Evaluation for quantitative characteristics, i.e. length and width

5.0 References

- 5.1 ANSI/ ASQ Z1.4, American National Standard, Sampling Procedures and Tables for Inspection by Attributes
- 5.2 E-701, SOP, Packaging Component Sampling Procedure

5.3 E-702, SOP, Finished Product Sampling Procedure

5.4 E-703, SOP, Raw Material Sampling Procedure

6.0 General Requirements

6.1 For packaging components such as bottles, caps, desiccants, etc., a statistical sampling plan is utilized to determine the required sample size for inspection.

6.2 For raw material sampling, the sample size determined is to be taken from the $\sqrt{N + 1} = n$ formula, where N is the number of containers received.

6.3 For QC in-process inspection, sampling is typically defined in the batch record.

6.4 Finished Product sampling is defined in SOP E-702 Finished Product Sampling Procedure.

7.0 Procedure for Statistical Sampling - Inspection

7.1 For statistical sampling, the ANSI Sampling Plan (ANSI/ ASQ Z1.4) is to be used. Refer to Attachment 1 Sample Size Code Letters and Attachment 2 Single Sampling Plans for Normal Inspection.

7.2 The general inspection level II will be used for each type of in-process to be sampled, inspected, and recorded on the specification sheet or the batch record.

7.3 The general inspection level I will be used for each type of packaging component to be sampled, inspected, and recorded on the specification sheet.

Defect Category	AQL	Defect Description	Defect Examples
Critical	0.10	Potential impact to consumer safety	Broken, contents exposed (desiccant), contaminated with unknown foreign material, incorrect source material
Major	0.65	Visual or physical defect that is generally not acceptable to customer does not affect safety of the product; could affect normal use of product	Shape distortion, incorrect source material, incorrect size, shape or color
Minor	2.5	Visual defect that may go unnoticed by the customer does not affect normal use or safety of product	Slight color distortion, dusty, minor cosmetic issues

7.4 Unless otherwise specified on the specification sheet or batch record, the levels reflected in the above table are the default AQL levels.

7.5 During inspection/ examination of each component, any defects observed will be classified as one of the above categories. A reject disposition may be selected even if component meets AQL as defined above.

7.6 Table I: Sample size code letters

7.6.1 In determining the required sample size, the lot or batch size is used to determine the sample size code letter.

7.6.2 The lot or batch size is listed in the first column of the table. This represents the total population size of the material to be sampled.

7.6.3 The code letters for each inspection level are recorded in the columns to the right of the lot or batch size and are arranged by inspection level for each lot or batch size listed.

Example: To determine the code letter for a population of 25,000 units using General Inspection Level II, the lot or batch size line to use is the 10,001 - 35,000 line. Under the General Inspection II column the code letter required is "M".

7.7 Table II-A: Single Sampling Plans for Normal Inspection

7.7.1 To determine the sample size, using the code letter determined in 7.5.3, the sample size is stated in the second column

Example: If "M" is the code letter determined, 315 units are to be sampled.

7.8 Acceptance Quality Limits (AQLs) Using Attachment II

7.8.1 The Acceptable Quality Level (AQL) values are listed at the top of the table and range from 0.010 to 1000.

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7.8.2 The acceptance and rejection values are listed in columns underneath the corresponding AQL values.

7.8.3 In some columns either upward arrows or downward arrows are shown; these arrows direct the viewer to use the sample size, acceptance and rejection values listed either above or below the arrow.

Example: For code letter M and a sample size of 315, the specification sheet lists a parameter to be inspected with an AQL of 2.5. From viewing the chart, the value listed for acceptance is 14 and the value listed for rejection is 15. This means that from the inspection of the 315 units, if 14 do not meet the stated specification the batch or lot is still acceptable, but if 15 do not meet the stated specification the batch or lot is rejected.

7.8.4 If the batch/lot needs to be rejected, the component should be immediately quarantined until a disposition decision has been made.

8.0 Procedure for Component Sampling – Examination

8.1 Examination of components will be conducted so that at least one component from each container received will be evaluated for quantitative features defined on component specification.

8.2 The number of components examined will be at least 3 but no more than 10 per lot.

8.2.1 For example, if two containers of one lot are received, one component from each container will be examined per specification and a third component will be randomly chosen for examination from either container.

8.2.2 For example, if 20 containers are received of one lot, 10 random components from individual containers will be examined per component specification.

8.2.3 The results of the examination along with details regarding container source will be captured on the packaging component inspection forms

8.3 If the batch/lot needs to be rejected, the component should be immediately quarantined until a disposition decision has been made.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	02/25/14	New	14-0174	V. Iltcheva
1	08/19/16	Updated definitions and AQL settings	16-0765	E. Hasanbasic
2	10/16/19	Revised to be in line with current practice. Clarified AQL Details and added "inspection" to SOP	19-0756	J. Sassman
3	03/08/24	Corrected references to other procedures. Removed obsolete information. Updated format and logo. Changed responsibilities section.	CC-24-0110	K. Burris

10.0 Attachments

10.1 Attachment 1 – Sample Size Code Letters

10.2 Attachment 2 – Single Sampling Plans for Normal Inspection

Attachment 1 – Sample Size Code Letters

Lot or Batch Size	Special Inspection Levels				General Inspection Levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1,200	C	C	E	F	G	J	K
1,201 to 3,200	C	D	E	G	H	K	L
3,201 to 10,000	C	D	F	G	J	L	M
10,001 to 35,000	C	D	F	H	K	M	N
35,001 to 150,000	D	E	G	J	L	N	P
150,001 to 500,000	D	E	G	J	M	P	Q
500,001 and over	D	E	H	K	N	Q	R

Attachment 2 – Single Sampling Plans for Normal Inspection

Sample size code letter	Sample size	Acceptance Quality Limits, <i>AQLs</i> , in Percent Nonconforming Items and Nonconformities per 100 Items (Normal Inspection)																									
		0.010	0.015	0.025	0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25	40	65	100	150	250	400	650	1000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
B	3	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
C	5	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
D	8	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
E	13	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
F	20	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
G	32	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
H	50	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
J	80	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
K	125	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
L	200	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
M	315	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
N	500	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
P	800	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Q	1250	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
R	2000	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑

↓ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 percent inspection.
 ↑ = Use the first sampling plan above the arrow.
 Ac = Acceptance number.
 Re = Rejection number.