MANUFACTURERS PROCEDURAL GUIDE FOR THE CONTROL OF QUALITY AND SAMPLE SELECTION FOR TESTING TO NOCSAE STANDARDS

NOCSAE DOC (ND) 011-13m16

Prepared By

NOCSAE

NATIONAL OPERATING COMMITTEE
ON STANDARDS FOR ATHLETIC EQUIPMENT

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1. Scope

1.1 This procedural guide establishes some basic principles and benchmarks that can be used to evaluate QA/QC practices for sampling and product assessment for the purpose of determining compliance to NOCSAE standards.

1.2 All requirements of this procedural guide must be in accordance with NOCSAE DOC (ND) 001.

1.3 These guidelines do not purport to address all of the safety problems, if any, associated with their use. It is the user's responsibility to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1.4 These guidelines do not advocate any preferred methods for managing, controlling, or improving the quality of manufactured products. The user is liable for developing and maintaining systems that will ensure that all products bearing the NOCSAE logo and SEI certification seal, whether tested or not, will fully comply with the applicable NOCSAE performance standards.

2. Referenced Documents

2.1 NOCSAE DOC (ND) 001 Standard Test Method and Equipment Used in Evaluating the Performance Characteristics of Headgear/Equipment.

2.2 Aikens, C. Harold, *Quality Inspired Management – The Key to Sustainability*, Prentice-Hall, 2011, ISBN 978-0-13-119756-3.

2.3 Military Standard 105-E, *Sampling Procedures and Tables for Inspection by Attributes*.

2.4 Military Standard 414, *Sampling Procedures and Tables for Inspection by Variables for Percent Defective*, 1957,

2.5 ISO 2859-1:1999, *Sampling Procedures for Inspection by Attributes – Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection*.

2.6 ISO 3951-1:2013, *Sampling Procedures for Inspection by Variables – Part 1: Specification for Single Sampling Plans Indexed by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection for a Single Quality Characteristic and a Single AQL*.

2.7 ANSI/ASQ Z1.4: *Sampling Procedures and Tables for Inspection By Attributes.*

2.8 ANSI/ASQ Z1.9: *Sampling Procedures and Tables for Inspection By Variables for Percent Nonconforming.*

2.9 ASTM E2234-09 (2013): *Standard Practice for Sampling a Stream of Product by Attributes Indexed by AQL.*

2.10 ASTM E2762-10 (2014): *Standard Practice for Sampling a Stream of Product by Variables Indexed by AQL.*

3. Terminology

3.1 Inspection Lot: For the purpose of lot acceptance it is important that representative samples be drawn from a rational inspection lot. The inspection lot should correspond to a homogeneous batch or production lot, as defined by Section 3.41 of NOCSAE DOC (ND) 001. A rational inspection lot will contain units that were produced during a period when there was no significant change in parts/materials, suppliers of parts/materials, or production methods. For example the lot could comprise all the units produced during a single production run if the units in the run were produced continuously with a single set-up, and with no change in raw materials. Under certain circumstances multiple runs can be combined into a single inspection lot provided set-ups and/or material changes are judged to have minor impacts on the variability of product quality. The fundamental idea is that all components that make up the final product and all units within the inspection lot will have been produced essentially under the same conditions. A new inspection lot should be created whenever a change occurs such that future production (after the change), when compared with past production (before the change), would create differences in the ability to comply with NOCSAE standards.

3.2 Acceptance Sampling: Acceptance sampling is a method that uses statistical probabilities, a set of decision rules, and a relatively small proportion (drawn as a sample) of an inspection lot, to determine whether the entire inspection lot is in compliance with NOCSAE requirements. The sample test results are used to estimate the overall inspection lot quality and form the basis for either accepting or rejecting the lot. Once the decision is made the inspection lot is either stored, shipped, scrapped, or re-cycled according to a set of distribution/disposition instructions predetermined by the user.

3.3 Acceptable Quality Level (AQL): Acceptance sampling plans are typically designed around an AQL, which is the worst tolerable fraction defective of an inspection lot that is acceptable to the producer. Such plans have a high probability that lots with fraction defectives equal to or better than the AQL will be accepted.

3.4 Rejectable Quality Level (RQL): In an acceptance sampling plan the RQL, also called the lot tolerance percent defective (LTPD) or limiting quality (LQ), is the worst tolerable fraction defective of an inspection lot that is acceptable to the consumer. Sampling plans that are designed around a stated AQL have a low probability (typically 10%) that lots with fraction defective equal to the RQL will be accepted.

3.5 Risk: In the absence of 100% error-free inspection it is not possible to know for certain that a sample drawn from an inspection lot is representative of the entire lot. Since large samples are neither practicable nor economically feasible there is always some level of risk that the test results could lead to the wrong decision (that is, rejecting good lots or accepting poor ones). There are two types of risk. One is the α or Type I error (called the producer's or seller's risk), which is expressed as the probability that a lot that is equal to or better than the AQL will be rejected. The other type is the β or Type II error (referred to as the consumer's or buyer's risk), which is the probability that a lot as bad as some specified RQL will be accepted.

3.6 Confidence Level: Confidence is a measure of how certain one is that some hypothesis or prediction is correct, or that a chosen course of action is the best. Confidence levels for acceptance sampling plans shall be based on the producer's risk α (nominally in the vicinity of 5%) and consumer's risk β (typically set at 10%).

Confidence levels are expressed in terms of these two stated risks.

3.6.1 Example. An acceptance sampling plan that has been designed with an α of 5% and a β of 10%, provides a 95% chance that a good lot (i.e. one equal to or better than the stipulated AQL) will be accepted, and a 5% (100% - 95%) chance that a good lot will be rejected. In the consumer's interest the RQL represents a *worst quality limit* where the probability of acceptance is β (10% in this example).

3.6.2 Confidence Statement. One can never *prove* that a lot is *good* and accepting a lot does not mean that the entire lot is compliant. However, the converse is true since rejecting a lot is more definitive. If a lot is rejected, one can state with $(1 - \alpha)$% confidence (95% confidence in this example) that the lot quality is worse than the AQL. If the lot is accepted one can conclude with $(1 - \beta)$ % confidence (90% confidence in this example) that the lot quality is superior to the RQL. Passing the lot only proves that the lot is superior to the RQL, not the AQL. An unfortunate downside of acceptance sampling is that statistical sampling plans will accept some lots with quality levels inferior to the AQL should such lots be produced.

3.6.3 Typical Plans. Inspection plans prescribed by MIL-STD-105 and MIL-STD-414, and other similar sampling standards, have α values that range from around 91% for small lots to 99% for large ones. The level of protection increases with increasing lot size in recognition of the comparatively high cost of rejecting large versus small inspection lots. The corollary to this is that over time α percentage of good lots will be rejected and erroneously scrapped or subjected to needless rework costs. One can also expect that lots with quality levels between the AQL and RQL will be accepted on a regular basis.

3.7 Random Sample: A sample that contains a **representation of all** manufactured units within an inspection lot is considered to be random. Samples are generally limited to a single model and size. Different models and sizes can only be included in the same sample in the rare cases where there are no differences in design geometries (e.g. helmet shell or padding) or characteristics of testing paraphernalia (e.g. headforms). Where different models and sizes can be included in the same sample, the sample must include a proportional representation of all models and sizes in the inspection lot to be tested. In all samples, mixed or otherwise, individual units should be randomly selected so that all production time intervals and variability of raw materials and components are represented within the sample, with the exception that in the case of SPC sampling the sampling scheme should be designed so that variability due to different production time intervals should show up between, rather than within, samples.

3.7.1 Ensuring Randomness. The specific methodology employed to ensure randomness is at the discretion of the manufacturer or re-certifier, and should be fully supported by documentation that accompanies QA/QC protocols submitted to SEI and NOCSAE. This element is of critical importance in any QA/QC protocol because randomness is essential to the statistical efficacy of any acceptance sampling plan.

3.7.2 Non-random Practices to Avoid. Examples of practices that would not be random are, 1) "salting" a sample with products known to be of superior quality, or 2) taking a "convenience" sample – for example those most easily

accessed, taking as a group consecutive units from the production line, or selecting full boxes off the top layer of the nearest pallet.

3.8 Reasonable Testing Program: A reasonable testing program includes any tests which are identical or equivalent to, or more stringent than, the tests defined in the appropriate specification and which are performed on each unit in a random sample selected from the inspection lot, as described in Section 4.

3.9 Failures: If the reasonable testing program shows that an inspection lot may contain headgear/equipment units that fail the acceptance criteria, as specified in the applicable QA/QC protocols, no unit in the inspection lot can be certified pending the completion of those remedial actions specified by the applicable protocol. If rectification sampling[1] is possible and can identify all noncomplying units in the lot, then such noncomplying units must be destroyed or altered by repair, redesign (a new model name may be necessary if the redesign is significant), or use of a different material or component, to the extent necessary to make them conform to the standard. Where rectification sampling is not possible the entire inspection lot must be scrapped or re-worked. In the case of rework, the entire lot must be resubmitted for testing as required by the applicable QA/QC protocols.

3.10 Statistical Process Control (SPC): SPC is a system that uses in-process quality controls and statistical tools to monitor and control materials and production processes with the aim of creating quality at the source of manufacture. The philosophy behind SPC recognizes that all processes exhibit intrinsic variation. If the variation becomes excessive, undesirable or unpredictable outcomes can result. The application of SPC has as its goals, 1) to provide knowledge of process behavior and outputs, 2) to influence process behavior in order to achieve targeted outputs, and 3) to identify and eliminate, or reduce the effects of, major sources of variability so as to improve process performance.

3.11 Quality Culture. An organization's culture is the collection of behaviors, beliefs, and values that are inculcated through communications, strategy, relationships, priorities, measurements, rewards, operating conditions, and management style. The quality culture defines the relative importance of quality and customer satisfaction in the organizational culture and value system.

3.12 Superior Quality Culture. A superior quality culture exists in an organization when, 1) the responsibility for quality is shared by all employees top to bottom, and all employees actively participate in creating and improving quality; 2) formal procedures exist to measure quality, identify and resolve problems, and to continuously improve; 3) quality is an integral component in employee training, evaluation, and rewards; 4) data collection and information systems are used to support and document fact-based decision making; and 5) quality is a priority in the management of internal operations and in managing external relations up and down the supply chain.

3.13 Common Cause Variation. Common cause variation, also called noise or inherent variation, is the consistent and predictable fluctuation of some variable around its average. This type of variation is repeatable and occurs as a result of how a system is designed and operated. Variation due to common causes is unavoidable and represents a limit of the system's true capability, that can only be improved through a systems improvement or redesign. With a properly designed sampling plan common cause variability will typically be captured within the sample group.

[1] Rectification inspection is a strategy whereby Inspection lots that have been rejected under attributes inspection are

3.14 Special Cause Variation. Special cause variation, also called exceptional or assignable cause variation, is due to non-repeatable, unpredictable factors that create non-random patterns of data output. Special cause variation reduces process capability below its true potential and, due to its unpredictability; its presence prevents one from predicting quality of output with any statistical accuracy. When all special causes have been identified and removed a process is said to be in a state of statistical control.

4. Sample Determination

4.1 Random Sampling: Groups of headgear and other equipment units selected for testing must constitute random samples as defined by Section 3.7. How this is done is at the discretion of the manufacturer; however, the requirement that a sample be random means that the individual units selected for testing should be chosen in a manner that ensures the capture of all anticipated sources of variation that can, and likely did, occur during the entire duration of the applicable production run(s) (e.g. variation in raw materials, machine differences, the influence of different workers, impact of time of day, shift differentials, etc.). The selection of individual units for testing should be conducted such that each unit of product in an inspection lot has the same probability of being chosen.

4.2 Sample Size: The word *sample* is defined differently depending on whether the sample is for the purpose of acceptance sampling (final testing) or to support SPC on the factory floor, as described in Sections 5 and 6. In the former case a sample is a collection of units selected randomly in accordance with Section 4.1. There will typically be one large test sample for each inspection lot. If attributes (pass/fail) and variables (measurements) criteria are both employed, more than one sample per lot may be appropriate. In the case of SPC a sample is a small number of units drawn at random intervals during a production run. In this case there will be numerous small samples per lot. The sample size to be tested is to be determined by the manufacturer's QA/QC protocol and must be statistically sound. For acceptance sampling the sample size is as defined by published MIL-STD, ISO, ANSI or ASQ standards.[2] In the case of in-process SPC testing, the sample size will normally be not less than three or more than five, and the sampling frequency should be selected in a manner that will most likely detect any changes in process behavior.

4.3 Level of Sampling Discrimination. For testing under acceptance sampling, unless otherwise justified under Section 6, sampling plans should be based on **Normal inspection** and **Inspection level II** (MIL-STD-105) and **Inspection level IV** (MIL-STD-414)[3], or equivalent. Single sampling will normally be employed; however, where practical and justified by the manufacturer's QA/QC protocols, double or multiple sampling plans may also be used.

4.4 AQL As A Sampling Plan Design Parameter. In selecting acceptance sampling

[2] For guidance on what is an acceptable sample size refer to Military Standard Series (MIL-STD-105, MIL-STD- 414), ANSI/ASQ Standard Series (ANSI/ASQ Z1.4 and Z1.9), ISO Standard Series (ISO2859-1 and ISO3951), or ASTM Standard Series (E2234 and E2762).

[3] It is anticipated that when applying MIL-STD-414 or ANSI/ASQ Z1.9 the "variability unknown" method will be used with the "standard deviation" or "range" method, at the discretion of the user. The "variability known" method, when used, must be justified by documentation in the manufacturer's QA/QC protocols with a copy supplied to NOCSAE and SEI.

plans, manufacturers and re-certifiers are to select plans that produce an acceptable quality level (AQL) as specified in Section 6.3 of NOCSAE DOC (ND) 001. The exception to this is the one-sided upper specification limit on SI less than 1200 (for example where SI < 300) when specified for equipment classified Level 3 as defined in Section 3.29 of NOCSAE DOC (ND) 001, in which case an AQL of 2.5% is to be used. NOCSAE considers any lot that passes acceptance testing under approved QA/QC protocols, and designed for such AQL thresholds, to be in full compliance with the applicable NOCSAE standards.

4.5 RQL and OC Curve Considerations. While NOCSAE DOC (ND) 001 does not specify a maximum RQL, QA/QC protocols should strive to achieve minimum consumer risks while satisfying the producer's risk as required by Section 4.4. Acceptance sampling plans should include a combination of sample sizes and acceptance criteria that result in OC curves with the steepest slopes practicable. Such plans should generally maintain RQL's of less than 7%.

4.6 Switching Rules. Some sampling standards include a provision for switching from Normal to Reduced inspection.[4] Reduced inspection as defined in such standards is not recommended unless statistical control of the relevant key manufacturing processes can be established and documented. If statistical control of the key manufacturing processes can be achieved and sustained, and is supported by a quality culture as described in Section 6.3, then some form of reduced sampling may be invoked as long as the total sampling effort is no less rigid than that required by the relevant sampling standard. ***Reducing the level of sample discrimination from General Level II or General Level I to any of the Special inspection levels (S-1, S-2, S-3, or S-4) is not justified under any circumstance.***

5. Assessing Compliance

5.1 At the discretion of the manufacturer, QA/QC protocols may be based on variables (measurement) criteria designed to monitor the degree of conformance to relevant specifications (e.g. 'SI (protective headgear); 'SCOF' (hand protection); 'resultant peak g' and/or 'displacement' (shin guards); 'weight', 'circumference', 'C/D', and/or 'COR' (balls)), or alternatively protocols may be based simply on attributes criteria (pass/fail). Variables measurement, whenever possible, provides more information and requires smaller sample sizes. The following are examples of ways to apply these testing approaches for a newly manufactured football helmet model.

5.1.1 Example: If an attributes criterion is selected, each helmet in the sample will be impacted in accordance with the relevant test table and the failure of any of the prescribed impacts will be reported as a failure of the relevant helmet tested. Only one report is to be generated for the test results per helmet. (Refer to Section 19 of NOCSAE DOC (ND) 001 for impact locations).

5.1.2 Example: If a variables criterion is selected, samples must be tested independently by drop location and temperature conditions. Each helmet selected for the sample is to be impacted in accordance with the relevant test table, by model and size and all results individually reported.

5.2 At the manufacturer's discretion, SPC methods may either be substituted for or

[4] For example, Section 9 of ISO2859-1, Section 4.7 of MIL-STD-105E, Section 5 of ISO 3951, and Section B14 of MIL-STD-414

supplemental to acceptance sampling. SPC may be used in lieu of acceptance sampling if all of the following conditions are met.

5.2.1 A detailed description of SPC procedures has been fully documented in QA/QC protocols and a copy provided to NOCSAE and SEI.

5.2.2 Test data is tracked on a continuous basis, using a target variable(s) (e.g. 'SI' (protective headgear); 'SCOF' (hand protection); 'resultant peak g' and/or 'displacement' (shin guards); 'weight', 'circumference', 'C/D', and/or 'COR' (balls)) appropriate to product performance.

5.2.3 Relevant process variables, as defined in Section 6.3.2.2, are tracked on a continuous basis, against specifications thought to be important to achieving compliance with all final product performance specifications. This may also include tracking key variables of purchased materials and components.

5.2.4 Appropriate SPC tools (e.g. control charts, capability analyses, etc.) should be applied, maintained, and analyzed using sampling plans designed to capture active sources of variability that are systemic (i.e. common cause as defined in Section 3.13), and have the additional ability to detect the presence of sources that are non-recurrent (i.e. special or assignable cause as defined in Section 3.14). Models, sizes, colors, impact locations, and temperatures should be tracked and charted independently. In the case of protective headgear each of the relevant specified (including the random impacts) impact locations/conditions should be tracked and charted independently. Different models should not be mixed on the same chart. However different sizes and/or colors may be combined on the same chart provided the manufacturer can demonstrate that there is no statistical evidence of size-to-size and/or between colors variation. Otherwise, each size and/or color should be plotted on separate charts. Statistical control (or lack thereof) must be demonstrated for process mean (with respect to the specified nominal target variable) and variability (sample range or standard deviation).

5.3 If manufacturers are to rely solely on SPC, then for each drop location and temperature (in the case of impact tests), and for each model and each size, manufacturers must demonstrate the capability to meet performance specifications on a continuing basis. For random locations the demonstration of capability may be based on corollaries developed through comparing test results of random locations to standard locations. The requirements differ depending on whether statistical control has been demonstrated and secondly, whether the product tested is headgear/equipment that has been classified as level 3 or levels other than 3, as defined respectively in Sections 3.29, 3.30, and 3.31 in NOCSAE DOC (ND) 001.

5.4 When SPC is applied to certain key production processes, manufacturer's may at their discretion elect to use acceptance sampling to determine the compliance of production lots of final product. In this case it may be appropriate to use a form of reduced sampling as described in Section 4.6.

5.5 When SPC is applied to final product, or to process variables, the procedures used to conduct capability analyses (and thereby document compliance to specifications) depend on whether or not statistical control can be established.

5.5.1 Processes in Statistical Control. For processes that have demonstrated

statistical control (i.e. long-term stability and repeatability, and the elimination of special cause variation as defined in Section 3.14) estimates of process or inspection lot means and standard deviations can be estimated using control chart information. To apply this method to process variables it is important that small samples be collected at random from the production line in time-ordered sequence throughout the production time interval. When applied to inspection lots, SPC is more a measure of inspection lot homogeneity than process stability, so it is important that samples be representative of the entire applicable production run(s). Refer to Sections 3.7, 4.1, and 4.2. If control charts of these samples are in statistical control, the control chart parameters can be used to compute a capability index C_{pk} as follows.

$$C_{pk} = \text{minimum}\left\{C_{pl}, C_{pu}\right\}$$

where

$$C_{pu} = \frac{USL - \overline{\overline{X}}}{3s_{process}} \; and \; C_{pl} = \frac{\overline{\overline{X}} - LSL}{3s_{process}}$$

$\overline{\overline{X}}$ = the centerline on an $\overline{X}$ chart of the variable of interest

$s_{process}$ = the process standard deviation as estimated from variability sources captured within samples. This is typically the common cause variation as defined in Section 3.13

$s_{process}$ is estimated from $\frac{\overline{R}}{d_2}$ or $\frac{\bar{s}}{c_4}$

$\overline{R}$ or $\bar{s}$ is the centerline of a control chart of ranges or standard deviations, respectively, of samples tested

d_2 and c_4 are control chart constants that depend on sample size

For example, for $n = 5$, $d_2 = 2.326$ and $c_4 = 0.94$

Note: For a one-sided specification the C_{pk} calculation uses only the C_{pu} or C_{pl} as appropriate. For example, in the case of headgear where SI is the tracking variable:

$$C_{pk} = \frac{1200 - \overline{\overline{SI}}}{3s_{process}}$$

where,

$\overline{\overline{SI}}$ is the centerline on an $\overline{X}$ chart of the SI variable

$\overline{R}$ or $\bar{s}$ is the centerline of a control chart of SI ranges or standard deviations

5.5.1.1 Level 3 Equipment/Gear: The requirements in Section 6.3.1.1 in NOCSAE DOC (ND) 001 must be met. A 3σ capability translates to $C_{pk} \geq 1$.

5.5.1.2 Levels other than 3 Equipment/Gear: The requirements in Section 6.3.1.2 in NOCSAE DOC (ND) 001 must be met. A 1.5σ capability translates to $C_{pk} > 0.5$.

5.5.2 Processes Where Statistical Control Cannot Be Established or Demonstrated: When statistical control cannot be established there is more uncertainty in process capability since unidentified special causes of variation, as defined in Section 3.14, are present. In these cases the mean and standard deviation of processes or inspection lots must be estimated from process or final test data. As in Section 5.5.1 it is important that the data include numerous small samples that have been collected from the production line, in time-ordered sequence, throughout the production time interval, or randomly across the entire inspection lot. Refer to Sections 3.7, 4.1, and 4.2. If control charts of these samples are not in statistical control, the raw data collected can be used to compute a capability index P_{pk} as follows.

$$P_{pk} = \text{minimum}\left\{P_{pl}, P_{pu}\right\}$$

where

$$P_{pu} = \frac{\left|USL - m_{observed}\right|}{3s_{observed}} \text{ and } P_{pl} = \frac{\left|LSL - m_{observed}\right|}{3s_{observed}}$$

$$s_{observed} = \sqrt{\frac{\sum_{j=1}^{kn} x_j}{kn}} = \text{standard deviation of entire data set}$$

$s_{observed}$ captures both common cause and special cause variation (See Sections 3.13 and 3.14)

$$m_{observed} = \frac{\sum_{j=1}^{kn} x_j}{kn} = \text{average of entire data set}$$

n = sample size

k = number of samples taken

5.5.2.1 Level 3 Equipment/Gear: The requirements in Section 6.3.1.1 in NOCSAE DOC (ND) 001 must be met. A 4σ capability translates to $P_{pk} \geq 1.33$

5.5.2.2 Levels other than 3 Equipment/Gear: The requirements in Section 6.3.1.2 in NOCSAE DOC (ND) 001 must be met. A 2σ capability translates to $P_{pk} > 0.67$.

5.5.3 As long as a continuously monitored process remains in statistical control with respect to all identified major sources of variability (refer Section 5.2.4), and control charts maintained on a continuous basis on product test data are in accordance with Section 5.5.1, the relevant manufacturer or certifying body may certify full NOCSAE compliance for all models, sizes, and colors of products so produced, and those products may bear the NOCSAE seals and other approved compliant language, and be approved for shipment to their respective market. For headgear compliance control must exist at all impact locations and at ambient and high temperatures. (Refer to Section 19 of NOCSAE DOC (ND) 001 for impact locations).

5.5.4 In the event that a manufacturer cannot implement effective in-process controls and/or does not have the ability to sample in the manner described in Section 3.7 and 4, the manufacturer will activate a statistically sound acceptance sampling plan in accordance with MIL-STD, ISO, ANSI, ASQ or a similar standard. Inspection lots must be segregated by model, size and color, and each inspection lot accepted under the plan employed before lots

bearing NOCSAE seals and compliant language can be released for shipment.

5.6 Each manufacturer has a great deal of latitude in the application of these methodologies and is free to employ other methods to fully comply with NOCSAE DOC (ND) 001. The criteria listed in Section 6 can be used to evaluate the acceptability of any QA/QC system. To prevent the acceptance of non-compliant products such approaches may include the normalization of data in projectile impacts to capture the potential variations intrinsic to the testing, or normalizing the standard deviation, based on anticipated variations in materials.

6 QA/QC Benchmarks

6.1 QA/QC Effectiveness. Section 6.2 of NOCSAE DOC (ND) 001 requires that manufacturers of certified products operate effective QA/QC protocols. The effectiveness of any specific quality control system, in assuring that products subjected to testing under that system are NOCSAE compliant, depends on the set of quality control tools used and the quality culture of the organization concerned. The four-generation taxonomy shown below may be helpful in determining how close an organization is in achieving a superior quality culture as defined in Section 3.12. ***This taxonomy and the benchmarks listed under Section 6.2 are only provided as a guide to the organization, systems, and behaviors that should characterize effective QA/QC protocols as specified in the NOCSAE standard.***

6.1.1 First Generation: Pre-deployment. During pre-deployment the organization is at a basic level of quality control. One could expect to find a high dependence on the measurement of outcomes, little if any interest in process or materials controls, minimal quality training, an autocratic management style, low level of employee empowerment, and little or no formal procedures for identifying and solving problems. Evidence that an organization is on the threshold of advancing to the Second Generation is the genuine recognition of the need for change, and initiatives to broaden training, increase employee participation, and emulate best practices.

6.1.2 Second Generation: Internalization. In the second generation the focus is on internal affairs and includes programs that foster company-wide employee participation, the beginnings of structured problem-solving techniques, some interest in measurement and data analysis, and some enforcement of quality standards on suppliers.

6.1.3 Third Generation: Systemization. As the emphasis changes from individual processes to a broader systems view, the organization can be said to have evolved to the third generation. At this level one can expect fundamental systems improvements, such as the implementation of cellular manufacturing, pull scheduling (Kanban), self-managed work teams, and an expanded use of analytical tools.

6.1.4 Fourth Generation: Stakeholder Focus. When QA/QC has been internalized as evidenced by mission, strategy, and operations; and when stakeholders have been identified and emphasized in all business decisions, an organization can be considered to have reached the pinnacle and fourth generation. At this level quality systems employ internal tools routinely to monitor and improve all primary value-producing operations, and are even typically applied to support functions. Quality is seen to be an essential

driver in the development of corporate strategy; in all operational decisions; in human resource management including training, performance evaluation, and rewards; and in the development of data collection, analysis, and feedback mechanisms.

6.2 Benchmarks That May Typify a Superior Quality Culture. To develop and nurture a superior quality culture an organization should be at least at the third generation level of development. Specific benchmarks in management systems, process controls and improvement mechanisms, and the approach to problem solving, as listed below, can be indicators of the strength of the underlying workplace culture.

6.2.1 Management Systems

6.2.1.1 ISO 9001, QS 9000, AS9100 Certification, or equivalent.

6.2.1.2 Company has applied for the Malcolm Baldrige National Quality Award, the European Foundation for Quality Management Excellence Award, the Deming Prize, the Shingo Prize, one of the U.S. state quality awards,[5] or a similar national award in a foreign country.[6]

6.2.1.3 The application of Quality Function Deployment (QFD) or similar methodology that emphasizes customer satisfaction, and creates operational definitions for translating customer requirements into quantifiable performance metrics.

6.2.1.4 Company Tag lines, mission statement, annual report, or other public documents portray a commitment to quality principles and/or stakeholder interests.

6.2.1.5 There is evidence that management at all levels (starting at the top) actively participates in continual delivery and improvement of quality. Evidence could include the use of such tools as the balanced scorecard,[7] the seven new tools of management,[8] management participation as champions of six-sigma problem solving teams,[9] etc.

6.2.1.6 Human resource management integrates quality factors into hiring, compensation, recognition and rewards, and promotion decisions. Responsibilities and accountabilities for meeting quality standards are clearly stated in job descriptions.

6.2.2 Factory Controls and Quality Improvement

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[5] Quality awards are available in Alabama, Alaska, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin

[6] Among those countries with a national quality award are Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Columbia, France, Germany, India, Indonesia, Iran, Italy, Japan, Luxemburg, Malaysia, Mexico, Netherlands, Philippines, Poland, Russia, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Thailand, Turkey, and United Kingdom

[7] Aikens, C. Harold, *Quality Inspired Management: The Key to Sustainability*, pages 40-42

[8] Ibid, pages 210-218

[9] Ibid, pages 533-541

6.2.2.1 Statistical Process Control (SPC). Appropriate control charts are maintained for all key processes, together with the use of supportive software (such as Minitab) and a procedure of review and prescribed corrective actions.

6.2.2.2 The workplace culture embraces the 5S discipline.[10]

6.2.2.3 The workforce practices kaizen or kaizen-blitz[11] on a regular basis as a part of continuous improvement efforts.

6.2.2.4 Application of quality initiatives in maintenance, such as Total Productive Maintenance, Predictive or Proactive maintenance practices, or another quality-centered maintenance program.[12]

6.2.2.5 Flow-oriented factory design, pull-scheduling (Kanban), and/or cellular manufacturing.[13]

6.2.2.6 Routine measurement studies and performance of gauge R and R (repeatability and reproducibility) studies.[14]

6.2.3 Problem-solving Methodologies. Evidence exists to suggest that the organization is committed to identifying and solving problems and employs formal and structured methods to stimulate creativity, facilitate planning, generate reliable information, and produce workable solutions.

6.2.3.1 Evidence that the company is a High Performance Work Organization and/or employs High Performing Work Practices and empowers its personnel through Self-directed or Self-managed Work Teams.[15]

6.2.3.2 Evidence that the seven “old” tools of quality are widely applied for the purpose of collecting reliable information from daily operations and using that information to identify and solve problems.[16]

6.2.3.3 Application of Failure Mode Effects Analysis (FMEA) to proactively identify and correct problems before they have a chance to occur or the Global 8D problem solving methodology.[17]

6.2.3.4 Use of analysis of variance (ANOVA), correlation analysis, and/or design of experiments (DOE) to improve processes.[18]

6.3 Criteria for Evaluating QA/QC Protocols. Effective quality control protocols involve some combination of controls on materials, manufacturing processes, and final inspection.

6.3.1 When the organization is First or Second Generation. If an organization is

[10] Ibid, pages 171-173
[11] Ibid, pages 174, 443-445
[12] Ibid, pages 159-161
[13] Ibid, pages 417-423
[14] Ibid, pages 292-309
[15] Ibid, pages 60-76
[16] Ibid, pages 194-210
[17] Ibid, pages 176-182
[18] Ibid, pages 484-519

judged to be First or Second Generation, as defined in Sections 6.1.1 and 6.1.2, then it can be assumed that little or no reliable information exists on how well the process has performed (i.e. in meeting specified requirements) at each stage of the manufacturing cycle. In this case the test results obtained from final inspection represent the ***only*** information available. The manner in which the individual test units are selected, the number selected for testing, and the acceptance criteria employed are critically important. Under this scenario, the recommended guidelines of Section 4.3 should be followed.

6.3.2 When the Quality Culture is Third or Fourth Generation. If verifiable and sustainable process knowledge is available from reliable data collection mechanisms, then conclusions on NOCSAE compliance can and should weigh more heavily on the information generated by these systems than on final product testing. This is more likely to be the case if a superior quality culture, as defined in Section 3.12, exists.

6.3.2.1 Key to Success. The key is in knowing within a defined level of statistical confidence how well any manufacturing process has performed (with respect to the specified requirements) at every major step of the manufacturing cycle. The idea is that if the quality at each stage of the building process is exceptional, starting with the raw materials and purchased components, there is less need for scrutiny of the finished product – when it is too late to intervene and correct any problems. The reward for achieving verifiable and sustainable process knowledge is the need to test fewer units to confirm compliance.

6.3.2.2 Relevant Process Variables. The variables/attributes that should be measured, tracked, and reported are obviously not the same as the product performance variables/attributes. For example the *SI* of helmets or the *COR* of lacrosse balls are performance variables that are applicable to the final product. Process variables might be such things as shell thickness or hardness, material density, pressure, cycle time, temperature, flow rate, foam thickness, or chemical composition. The challenge is to determine how targets and tolerances of the key process variables translate to compliance with respect to final product performance.

6.3.2.3 Achieving Statistical Control. Statistical control on all key process variables is important. **Variables** measurements (in preference to attributes) should be used whenever practicable with appropriate control charts for both average and standard deviation.

6.3.2.4 Measurements and Analysis. It is an expectation that organizations that have achieved a superior quality culture, or have made significant progress toward that goal, will have formal and structured systems of measurement and analysis. This would include such methods as regularly conducted capability studies, the performance of histogram analyses, and the routine performance of gauge repeatability and reproducibility (R and R) or other measurement studies.

6.3.2.5 Final Inspection and Testing. When reliable process information is

available that provides evidence of process capability and/or stability of the key variables that effect the safety performance of final products, there is justification for a reduction in the number of units drawn (as compared to the quantities required under Section 4.3) from an inspection lot and submitted for final testing.

6.3.2.5.1 Processes Are In Statistical Control (i.e. **both** average and standard deviation or range) and all $C_{pk} \geq 1$. In this case consideration can be given to changing the requirements of Section 4.3 to ***Normal Inspection Level I***.

6.3.2.5.2 Some Processes are Not in Statistical Control (i.e. with respect to both average and standard deviation or range). If, for those processes where statistical control has not been established, the computed P_{pk}'s ≥ 1.33 and for all processes where control has been established the computed C_{pk}'s > 1, consideration can be given to changing the requirement of Section 4.3 to ***Normal Inspection Level I***.

6.3.2.5.3 Further Reduction in Test Quantities. If control charts of final test results indicate statistical control for **both** average and standard deviation or range for a minimum of 25 tests, and further the test C_{pk}'s ≥ 1 for all tests, consideration can be given to further reducing the sampling effort to ***Reduced Inspection Level II***. The sample size may be maintained at this level as long as the tests continue to be in control and the C_{pk}'s ≥ 1. When either of these conditions fail to apply, sampling should be increased to ***Normal Inspection Level II***.

APRIL 2014 Modifications

- Extensive modifications to clarify quality control systems

MAY 2014 Modifications

- Added in section 5.3 wording for handling random location corollaries

AUGUST 2014 Modifications

- Removed word “Test” from definition for Failures section 3.3
- Changed word ‘Catastrophic” to Level 3 throughout document
- Changed word ‘Non-catastrophic” to Levels other than 3 throughout document

OCTOBER 2014 Modifications

- Added language to section 4.4 for clarity
- Corrected references to sections of ND001 in section 5.3

DECEMBER 2014 Modifications

- Corrected misidentified section numbers

MAY 2016 Modifications

- Changed document title
- Expanded the Table of Contents
- Expanded the scope to include QA/QC benchmark assessment guidelines.
- Added Section 1.4 disclaimer
- Expanded references with Sections 2.2 – 2.10
- Renamed “Production Lot” as “Inspection Lot” and moved from Section 3.4 to 3.1.
- Expanded definitions of “Inspection Lot” (3.1) and “Acceptance Sampling” (3.2) to add clarity
- Added definitions to Section 3 for “AQL” (3.3), “RQL” (3.4), “Quality Culture” (3.11), “Superior Quality Culture” (3.12), “Common Cause Variation” (3.13), and “Special Cause Variation” (3.14)
- Renumbered Sections 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, and 3.8 to 3.2, 3.6, 3.9, 3.7, 3.8, 3.5, & 3.10 respectively
- Expanded the definition of “Confidence Level” (3.6) and added subsections for clarity
- Expanded the definition of “Random Sample” (3.7) and added subsections for clarity
- Expanded the definition of “SPC” (3.10) for added clarity
- Expanded language in Sections 4.3 and 4.4 for added clarity
- Added Sections 4.5 and 4.6 to provide information on RQL and switching rules
- Added Section 5.2.3 to require SPC tracking of process variables
- Moved old Section 5.2.3 to 5.2.4
- Added Section 5.4 to provide an exception to Normal sampling
- Added Section 5.5 and moved Sections 5.3.1 and 5.3.2 to 5.5.1 and 5.5.2 respectively
- Moved Section 5.4 to Section 5.6 and expanded
- Added Section 6 to include benchmarks against which QA/QC systems can be evaluated