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TO SEI NOCSAE PARTICIPANTS:

SEI Certification Bulletin #22
Standards Update/Certification Implementation Dates /Quality Audits

This bulletin will serve to provide SEI NOCSAE certification program updates, such as NOCSAE standard revisions, governing body certification implementation dates, and various other SEI related certification topics.

NOCSAE STANDARDS ACTIVITY

SEI staff was in attendance at the NOCSAE Summer Standards Committee meeting held in Boston, MA on July 26, 2019. As a result, we have provided below SEI's summary of the standards development activity taken during the meeting.

Revised NOCSAE Standards

NOCSAE proposed the following standard revisions since the Winter 2019 Standards Committee meeting. Revisions are typically substantive changes to the performance requirements or test methods that could potentially affect initial or annual certifications.

ND200-19 *Standard Test Method and Performance Specification Used in Evaluating The Performance of Protectors for Commotio Cordis (Proposed Revision)*

- Added requirement to place logo on the primary protective component
- Added a definition of Primary Protective Component
- Changed "chest protector" to "protector"

ND049-19 *Standard for Newly Manufactured Lacrosse Balls*

- Added Section 6.1.2 to specify requirements for balls with a textured surface

Modified NOCSAE Standards

NOCSAE acknowledged the following standard modifications. Modifications are non-substantive edits that are provided for clarification only, do not alter the substantive content of the standards, and will not affect initial or annual certifications.

ND021-18m19a *Standard Projectile Impact Test Method and Equipment Used in Evaluating the Performance Characteristics of Protective Headgear, Faceguards, or Projectiles-Modification*

- Removed requirement that packaging must have the month and year (can now be on ball, packaging or both).



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UPCOMING CERTIFICATION DATES REMINDER

Polo Helmets

The US Polo Association issued a mandate stating that all players at United States Polo Association (USPA) events will be required to wear helmets certified to the National Operating Committee on Standards for Athletic Equipment (NOCSAE) polo helmet Standard. This mandate takes effect **June 1, 2020**. The SEI NOCSAE certification program includes polo helmets to be certified to NOCSAE ND050-11: *Standard Performance Specification for Newly Manufactured Polo Helmets*. SEI also offers certification of polo eyewear to NOCSAE ND055-11: *Standard Performance Specification for Helmet Mounted Polo Eye Protection*.

Baseballs

The NFHS has modified their rules language to state that baseballs shall meet the NOCSAE performance standard effective **January 1, 2020**. The SEI NOCSAE certification program includes baseballs to be certified to NOCSAE ND027: *Standard Performance Specification for Newly Manufactured Baseballs*.

Lacrosse Protectors for Commotio Cordis

Beginning in **January 2021**, US Lacrosse boys' and girls' youth field lacrosse rules will require that protectors for Commotio Cordis worn by goalies must meet NOCSAE ND200: *Standard Test Method and Performance Specification Used in Evaluating the Performance Characteristics of Chest Protectors for Commotio Cordis* to be deemed legal for play. In addition, **beginning in 2022**, all field players in boys' lacrosse must wear protection for commotio cordis that also meets the same NOCSAE performance standard.

Baseball Protectors for Commotio Cordis

Per the NFHS rule change, catchers' protectors for Commotio Cordis shall meet the NOCSAE ND200: *Standard Test Method and Performance Specification Used in Evaluating the Performance Characteristics of Protectors for Commotio Cordis* effective **January 1, 2020**.

SEI CERTIFICATION TOPICS

Baseball Testing Sample Requirements (**CORRECTION** from SEI Bulletin #21)

Unfortunately, we have determined that a correction is needed with regard to information provided previously in SEI Bulletin #21, as noted below:

At least ~~six (6)~~ **twelve (12)** samples of each ball model should be submitted for testing. NOCSAE ND 127-18 *Laboratory Procedural Guide for Certifying Newly Manufactured Baseballs*, section 6.3 states that all of the submitted balls shall be measured for mass and circumference. No less than 6 samples of submitted balls will be measured for either C-D or COR. None of the submitted balls shall be tested for both C-D and COR.

NOCSAE QC/QA Program Requirements

As part of the SEI NOCSAE audit process, SEI auditors are reviewing the required NOCSAE QC/QA plans during the headquarters audit and verifying its execution at the supplier location audit(s). This has resulted in SEI fielding questions regarding the NOCSAE QC/QA requirements such as:

- 1.) Which entity (in the case where there are multiple locations) is in control of the quality plan?
- 2.) Which entity is executing the quality plan?
- 3.) Are product model quantities large enough to represent the product lots/batches to meet the NOCSAE QC/QA requirements?

In an effort to further educate/train SEI's staff and auditors, earlier this year, NOCSAE held an auditor training session. During the training session, NOCSAE reviewed the NOCSAE QC/QA requirements and the quality plans described in NOCSAE ND011-13 *Manufacturers Procedural Guide for The Control of Quality and Sample Selection for Testing to NOCSAE Standards* including the Statistical Process Control (SPC) and Acceptable Quality Level (AQL) approaches to quality plans. The SPC approach requires a participant to understand their product and the raw materials to a high degree and plot data on critical components to demonstrate compliance. While more work up front, the SPC approach results in smaller numbers of final product testing. The AQL approach results in larger numbers of final product being tested, however, with this approach, there is potentially little need for understanding of product and raw materials. With NOCSAE's permission, we are sharing their PowerPoint presentation as a part of this Bulletin.

Please direct any questions regarding SEI's quality audit process to SEI's Manager of Quality Audits, Kate McDonald (kmcdonald@seinet.org).

Legacy Product Listing

As noted in Bulletin #21, SEI has created a "Legacy Product Listing" to include products which are no longer in production but may still be in use. The Legacy Product Listing is separate from the SEI Certified Product List and is located on the SEI Website on the SEI/NOCSAE page which can be found through the "Quick Links" (https://www.seinet.org/bulletin_in_nocsae.htm).

We hope you have found this bulletin to be helpful. Do not hesitate to call a member of the SEI staff with questions on the information contained within this bulletin.

Sincerely,



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cc: SEI Staff
SEI Quality Auditors
SEI Approved Laboratories
NOCSAE
SFIA

SEI/NOCSAE Certification

March 20 2019

SEI certification to NOCSAE

- This arrangement should lead to a very high level of assurance that products marked with the SEI/NOCSAE logo meet the standard.
- NOCSAE Document 001 requires very high QC demands for most products. These demands require compliance to 3 sigma, or greater than a 99% compliance with the standard.
- The SEI auditor program is the gate keeper for this program.
- The program in some areas is not working.

Baseball Batting Helmet Example

- Not brand specific
- Batters helmet require random impact test locations.
- While there is a limited number of impacts there is a theoretical infinite number depending on where you start.
 - * NOCSAE is evaluating changes to limit the random possibilities similar to the football approach
- Helmets certified and tested at independent labs on year one, have been retested. The same model helmets have been retested in subsequent years, by the same labs. The labs have correctly tested a different random location and have recorded failures.
- Such a failure must be the result of only two possibilities.

Two reasons for a failure

Assuming the lab has done its job correctly. Good equipment, methods and a legal random impact selection

- Lab error for the independent labs has been ruled out.
- Remaining causes are:
 - A) The tested helmet is the one in about a thousand that might be a failure in spite of meeting the QC requirements.
 - B) The QC requirements have not been met, thus many more helmets might also fail in the tested location. The certification is not valid.
- Investigation has demonstrated that B is the correct answer. Both the manufacturer and the SEI audit and certification compliance system has failed.
- **THIS IS UNACCEPTABLE**

Causes and solutions. Auditor Insights

- Demonstration of compliance to the standard is not limited to repeated NOCSAE testing.
- NOCSAE testing is perhaps the least effective way of demonstrating compliance.
- In the case of using a sampling plan NOCSAE testing is about the only option. This would include a sampling plan testing for functionally all of the almost infinite number of random locations.
- This approach is not cost effective and if this approach is employed you should ask to review the testing data. The data should match the stated sampling plan to the AQL level of at least 0.65

SAMPLING PLAN APPROACH

- For example if between 501 and 1200 helmets are from the same batch then depending on how much is known about the operation a sample plan of either Normal, or more likely Tightened is needed.
- This demands that 50 sets of three helmets be tested (150). In theory each of the helmets that receive a random impact should receive the same random impact (150). However, if you were persuaded to allow each of the sets to receive a different Random that “might” be acceptable (lots of backup data). If so you would have 50 of the potentially infinite random locations accounted for (the other locations addressed in some way).
- Depending on how the data looks when the stats are done, you might be convinced that the lot passes. If only one sample were to “frankly” fail the test, then the lot would be rejected. If the stats showed less than 3sigma compliance the lot fails. The variation of random locations may force that issue.

SAMPLING PLAN APPROACH

- To be convinced that this sampling plan was demonstrative of compliance, you should have confidence that the random locations represent most of the area around the helmet that are likely to be subjected to direct impact. CG of ball through CG of helmet, and each set of two impacts is similar to all the others. This should not be yours to decipher but rather the test lab/manufacturer should offer up this explanation for your review.
- Such a sampling plan requires lots of testing, lots of explanation and lots of your time to drill down into the data to be sure of your confidence level that the lot passes. This approach is a warning sign of a less than controlled operation thus extra diligence is required.

The Statistical Process Control (SPC) approach

- This is the most cost effective way and also the most reliable way to determine compliance. It requires control and oversight.
- Givens:
 - The NOCSAE test protocol is the standard
 - The NOCSAE tests in general are a Biofedlic approach with lots of moving parts. The variation of a Biofedlic test system like NOCSAE testing is greater than testing that could be applied to the components that lead to compliant production units.
 - This takes a greater understanding and control of the component parts and the assembly to be successful.

SPC

- This method still requires early NOCSAE testing that is used to determine compliant components, as well as limited NOCSAE testing of batches.
- A real life example of this approach.
 - Batters Helmet shell is made from a specific polymer make up from a known entity. A certificate for each batch of the raw plastic is provided with key test results such as melt flow, notched impact and modulus. Random samples may be taken to determine the provided data is accurate. As time passes with no noted deviations the sampling become much less. Any change in the supplier or material ID requires a complete reboot of data development.

SPC

- There are various molding machines and post molding operations like, drilling, painting, etc.
- These operations should be closely monitored for things like screw speed, barrel temperatures, cycle times, drying of the polymer, open time of the tool, tool temperature profiles, start up shots needed to stabilize the operation after any shut down, and any other parameters.
- If post molding operations are undertaken there will be charts of times and temperatures of the shell when these are completed. Suspected good shells are then randomly selected and subjected to impact testing such as a cold crack test. This is a simple go/no-go test.

SPC

- The same detailed approach is undertaken for the impact liner.
- Data such as minimum thickness, minimum compression deflection, density as well as other parameters are specified. Note: Durometer is not effective in most cases.
- Incoming raw materials are tested to determine the properties specified are met within determined ranges that are known to produce passing test scores.
- These data points are tracked and process control charts for all parameters of each component are collected and only product with “in control” specs are used in the assembly.

SPC

- The components are assembled in a specific order with specific inspections along the process to insure the materials are affixed with specified methods and outcomes.
- A very small sampling of the final product is subjected to NOCSAE testing. Sample size of 3 per thousand units produced is not uncommon.
- Stats are developed for this small number of testing which over time will also demonstrate compliance.
- Actual test data from the NOCASE test will yield a one sided curve that is supported by the data.

SPC

- The selection of these parameters, mentioned earlier, is key.
- For example, lets look at one simple but critical foam component.
- Testing has demonstrated that a minimum thickness of $\frac{1}{2}$ inch of 6lb per cubic foot density foam with a 25% Compression Displacement of 18 psi and a resilience or COR of 30% will meet the NOCSAE standard.
- However the supplier of the material explains they can only provide a tolerance of $\frac{1}{8}$ " on thickness, 2lbs plus or minus on density, which directly effect the CD number, resilience is not critical but is another check.
- So what to do?

SPC

- It has been determined $\frac{1}{2}$ " works but the spec is limited to plus or minus $\frac{1}{8}$ " and $\frac{3}{8}$ " does not work. You set the spec to $\frac{5}{8}$ "
- The density of 6lbs works but 5 may not, 7 works better. So you set the spec to 8lbs because of the 2lbs tolerance
- No matter what you want a minimum of 18psi on CD but also no higher COR than 30% so far your changed specs do that
- Some material arrives that is $\frac{1}{2}$ inch thick, 6 lbs density, has at least 18psi CD and is 30% or less COR No problem you know it works

SPC

- However, you know some material will arrive at $\frac{3}{4}$ " thick 9lbs density and having tested that you know that helmet fit is slightly compromised, but the non critical fit foam (another less studied component still works) and the NOCSAE numbers are lower for the max spec $\frac{3}{4}$ " 9lb foam which has a compression of 22lbs, what does that mean?
- It means you know there may be some snugness of fit on some heads but that the test numbers will be lower. It is not your ideal because of fit and weight but the risk of test failure is zero. However:

SPC

- When you run the stats the SD is pretty high because that thicker denser piece tests better than the ideal mix of performance and fit, but given the limits of the specs you take that. Why?
- Because you can prove that there will never be a failure if the specs are met, and even though the SD might be high it is always skewed towards the lower number, thus there is no need to add the SD to highest number or even the average. The instructions on fit talk about finding that helmet that fits you best. Some of those higher density thicker helmets will fit someone just right.

SPC WORKS

- This approach, which requires considerable up front engineering and establishment of specs for all critical parameters is the best assurance of performance.
- These established specs however must be closely monitored with in house simple testing done to be sure what is specified is what is used.
- As no company is perfect there will be records of batches of materials that did not measure up, and thus were rejected.
- As you review these records the effectiveness of the original specs, the level of commitment to meeting them and the random but small number of NOCSAE test data will support the program.

The Audit

- You do not need to be a sampling , stats or specs expert to audit this kind of operation.
- If the approach is a sampling plan, demand to see the plan. There are almost no, non-published plans that work. In other words a recognized approach such as Mil std 105 latest, or a published ASQ guide is what should be presented as a sampling plan
- EXAMPLE: Mil Std 105e does a good job of explaining sampling plans as does NOCSAE doc 011. You should become familiar with both. Some other sampling plan may be presented but will be similar enough for you to understand the concepts.

The Audit Attributes Approach

- Based on the following example plan.
- We will be using Normal to Tightened sampling. Unless there is compelling up front data similar but more limited than the SPC data we discussed a Tightened plan is called for. Because there is little to no proof of historic performance.
- Sampling level II is called for because of the Critical outcome of failure.
- AQL of 0.65 yields the following chart.

MIL STD 105E legible copy.pdf

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The Audit Attributes Approach

- So based on the plan you should see how you got to the numbers presented in the first few slides. 150 helmets arguably or at least 50 if you can be convinced that they know the product enough to make that claim.
- How do you know? Well you are going to ask exactly that. Your key question which you will ask likely hundreds of times will be HOW DO YOU KNOW?
- Back to our example: the company puts forward a batch control sampling plan not SPC and they agree to test 150 plus samples to account for randomness, you as HOW DO YOU KNOW that is OK?

The AUDIT Attributes Approach

- The response should be to show you the plan, show you the data points. There should be no “frank failures”. If there is you are done they fail.
- If no frank failures, for the attributes of SI you must then ask HOW DO YOU KNOW there are no statically discovered failures?
- They should produce the data likely in a spread sheet, with stated Standard deviation which when multiplied by three and added to the average yields a number of less than 1200. If so you are satisfied. If not you fail the batch.

The Audit Attributes Approach

- Still on batch testing but this time they tell you they only tested 50 helmets, all the same random position.
- You ask How do you know that is enough? How do you know no other random will fail? You hear crickets, you fail them.
- But, if they say we did testing of lots of helmets and we picked the most likely to fail random. You ask How do you know? They should show you that data and you ask about another dozen How do you know questions, and only if the logic and method put forth makes plenty of sense do you say OK. It is unlikely you will get there but it is possible.

The Audit SPC

- This will also be filled with HOW DO YOU KNOW questions but the chances are this will be much smoother because users of this approach they have to have a great understanding of thier operation.
- You can ask about any part of the product they are tracking and ask How DO You Know that is a critical component? How do you know these values are the right ones?
- Inversely some component or operation that is not being tracked should trigger How do you know that part is not worth tracking? Unless the answer makes sense you fail them. Unlikely because they should lay this out in a way that just makes sense and feels real.

Questions?

- I suggest you all think this through in association with audits you have done and we schedule another session to respond to specific items.