Dragon, Karen E. (CDC/NIOSH/EID)

From: Robert.Sell@Draeger.com
Sent: Wednesday, May 02, 2007 11:37 AM
To: NIOSH Docket Office (CDC)
Subject: Long-Term Field Evaluation (LTFE) NIOSH Docket Number (NIOSH - 101)
Attachments: DSTN 5932 - English.doc; LTFE Concept Comments - NIOSH Docket No 101- May 2007.doc

Hello:

Attached please find additional comments to the docket on the LTFE Program.

Regards

Bob Sell

Sr. Project Engineer - Protection

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May 1, 2007

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Reference: DOCKET NUMBER NIOSH - 101
Long Term Field Evaluation Program Concept

Dear Sir / Madam:

Draeger Safety manufactures respirators for various markets and applications therefore we are providing additional comments in response to the NIOSH Long Term Field Evaluation Program Concept posted February 2007 and the extension of the comment period to May 1, 2007.

The following Draeger Safety comments are being submitted for consideration:

Sampling Plan and Statistical Considerations for the LTFE Program:

- We would propose that alternate sampling plans be considered for the SCSRs which look at the methods of how they are deployed. For SCSRs that are cached the sampling plan could require fewer units and SCSRs that are machine carried or man carried could be focused on more. Even the method of deployment (man or machine) may reveal different results.

- In addition, we would like to see this information on the manner of deployment be identified and analyzed in the report that would be published.

- There are other statistical methods that can be used and we would suggest that one of the methods that Draeger Safety (DSTN 5932 – Guidance for the Determination of Process Capability Investigations) uses be evaluated to determine if it could be applicable for the intended purpose that NIOSH is looking for. A translated copy of the document is being provided for review. In the event that the full German text is desired for review, please contact me and it will be provided.

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Draeger Safety thanks NIOSH for the opportunity to provide these additional comments. Please consider our comments concerning the ongoing changes to the proposed Long term field Evaluation Program.

If there should be any questions concerning this matter, please do not hesitate to contact me at 412-788-5685 or via e-mail at Robert.Sell@Draeger.com.

Respectfully,

Robert Sell

Robert Sell
Sr. Project Engineer

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DSTN 5932 Supplement 1 **Issued January 2000**

Guidance for the Determination of Process Capability Investigations

1 Statistical Basis

1.1 Average value <X>

$<X> = \Sigma (x_i) / n$

x_i : Measured values
n: Number of measurements

The average value is formed, as the measured values are summed and the sum is divided by the number of the measurements.

1.2 Dispersions σ

$\sigma^2 = [\Sigma (x_i - <X>)^2] / (n-1)$

The dispersion can be determined either according to above formula or by evaluation of the developing frequency distribution of the measured values, which are registered in a histogram. If the distribution corresponds to a Gaussian distribution (bath tub curve), the dispersion leaves itself σ determine then in good approximation by measuring the width of the distribution with 61% of the maximum height. In such a way determined value is finally still halved.

1.3 C_p- and C_{Pk}- Index

With C_p- and C_{Pk}- Indices the ability of a process is described to manufacture the demanded quality criteria.

BELL CURVE DIAGRAM

C_p- Index

C_p- Index considers only the dispersion of a process and is calculated as follows:

$C_p = (OG - UG) / (6 \cdot \sigma)$

OG: Upper tolerance limit
UG: Lower tolerance limit

C_{Pk}- Index

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C_{Pk} - Index considers the situation of the average value of the frequency distribution apart from the dispersion of the process also to the specification borders. It is therefore particularly meaningful.
$C_{Pk} = (\Delta krit)/(3 \cdot \sigma)$

$\Delta krit$: Critical distance to the specification border

$\Delta krit = <X> - UG$
and/or.
$\Delta krit = OG - < X>$

Remark: It is in each case the smaller $\Delta krit$ to the computation of C_{Pk} - To use index.

A process can be judged as able, if

$C_p > 1.33$
and
$C_{Pk} > 1.33$

are fulfilled .

Processes, to which applies

$1.33 > C_{Pk} > 1.00$,

are only conditionally capable of and require an appropriate monitoring of the average value situation. In relation to C_p - Index of smaller C_{Pk} - Means index that the average value of the distribution lies outside of the tolerance center.

1.4 Attributive of characteristics

For the determination of the abilities by processes, manufactured with those attributive characteristics who that, is it meaningfully, only C_{Pk} - To determine index.
First the number of defective parts of C of a manufacturing lot is determined.
With several equivalent large examined lots this number is averaged.

$<C> = [\Sigma (C_i)] / n$
<C> : Middle number of errors of a manufacturing lot
C_i : Number of errors of a lot

The dispersion σ is calculated out
$\sigma = (<C>)^{1/2}$ (Root from <C>).

With C_{max} (Maximum permissible number of incorrect units per lot) is calculated

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$\Delta krit = C_{max} - \langle C \rangle$

$\Delta krit$: Critical distance to the specification border

and

$C_{Pk} = \Delta krit/(3 \cdot \sigma)$.

As is the case for quantitative characteristics the process applies as able, if

$C_{Pk} > 1.33$

can be fulfilled.

2 Planning of a Process Capability Investigation

Before administering the process capability investigation the following points are to be clarified and documented in a process study plan:

2.1 Which process does it concern?
Necessary:
a short description of the process,
the used machines and devices of the necessary auxiliary materials,
in and outgoing products,
Listing of the designs concerned,
Listing of the FKVs (procedures) concerned.

2.2 Is the process accomplished as described?

2.3 Which process parameters are examined?

2.4 Which product characteristics are examined?

2.5 Are the examined product characteristics meaningful concerning the process characteristics which can be examined?

2.6 Which number of measurements is planned?

2.7 Who is responsible for execution?

2.8 When is the investigation to begin?

2.9 When is the investigation to be final?

3 Execution

The process ability investigation is accomplished in accordance with the provided process study plan. The determined measured values are to be logged and be

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documented with the evaluation. Deviations from the process study plan are to be justified.

In order to be able to meet apart from the statement about the process capability also statements about the control of the process, the data acquisition must be repeated at least 3 times. It is to be made certain that all process parameters are again stopped before beginning of the data acquisition (as if the process would have been again started). This includes scaffolding the process which can be examined also.

4 Evaluation

4.1 Ability of processes

For the evaluation of the process capability are those

- -Average values
- -Dispersions
- -C_p - Indices
- -C_{PC} - Indices

to determine from the available measuring data.

The process classified as

- able, if $C_{Pk} > 1.33$
- causes able, if $1,33 > C_{Pk} > 1.00$
- not able, if $1.00 > C_{Pk}$.

4.2 Control of processes

For the determination of the control of the process it is examined whether itself the average values that seized parameters substantially changed.
A process is called controlled, if the maximum differences of the average values

$\Delta_{max} = < X >_{max} - <X>_{min}$

smaller than the process dispersions σ are.

A process classified as

- controls, if $\Delta_{max} < \sigma$
- does not control , if $\Delta_{max} > \sigma$

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5 Measures

Process-improving measures can be necessary, if the process
- not able
or
- is controlled.

Whether such measures can be accomplished, depends on the respective risk, which is connected with the regarded characteristic.
Characteristic deviations, which arise very frequently, which cannot be recognized surely or a great importance for the function of the product to have, are usually not acceptable and must by effective corrective measures are prevented.

With not capable processes usually the selection of another, more capable process is necessary.
With controlled processes must be examined, by which coincidental or systematic influences the process result (average value) is changed or be changed can. These influences are to be eliminated then in an improvement program.
Also the production of instructions for process, which a once found optimal parameter attitude fixes, can contribute in many cases crucially to the process control and to the removal of coincidental measured variables.

If no measures in principle improving the process can be found, then also connecting of a sort process at the outlet side is conceivable as part of the manufacturing process and permissible as improvement measure, if this sort process is not part of a quality inspection (release).

After execution by improvement measures the process ability investigation to examination of the effectiveness of the measures is to be repeated.

6 Documentation

The entire documents of the process ability investigation including the recordings over accomplished improvement measures are to be kept in the manufacturing book.

The individual documents are with indication of the name of the creator for marking its department/cost centre and the date of the production in order to make later further inquiries possible.

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