

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

From: Robert.Sell@Draeger.com
Sent: Monday, April 09, 2007 12:41 PM
To: NIOSH Docket Office (CDC)
Subject: Long-Term Field Evaluation (LTFE) NIOSH Docket Number (NIOSH - 101)
Attachments: LTFE Concept Comments - NIOSH Docket No 101- April 2007.doc

To whom it may concern:

Attached please find Draeger Safety's comments for the referenced NIOSH Docket No.

Regards

Bob Sell

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April 4, 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 offer the following comments in response to the NIOSH Long Term Field Evaluation Program Concept posted February 2007.

The following Draeger Safety comments are being submitted for consideration and we will comment step-by-step through the documents that were posted:

LTFE Program Concept:

- Page 3: SCSR Collection Procedure – From the Public Meeting it was noted that the mine operators did not have to participate in the LTFE program and that it has been a strictly volunteer program. We feel that this should not be permitted to continue and all mines are be subjected to the LTFE program just as they are required to adhere to and comply with the current Miner's Act. This section references 42 CFR, 85a (Occupational Safety and Health Investigations of Places of Employment) and we believe that Section 85a.3 of this document does provide the right to NIOSH to mandate the retrieval of SCSRs for the LTFE Program. We suggest that you review this section and consult with MSHA to determine if this provides sufficient authority to obtain SCSRs from those who do not want to participate in the program.
- Page 3: SCSR Evaluation Procedure – Also pointed out at the Public Meeting, it is understood that Man Test #1 from 42 CFR, Part 84 is being used for human subject tests. We suggest that Man Test #1 be identified in this section as the test being used.
- Page 6: LTFE Reporting – In addition to the mine operator we also suggest that the initial report and the interim report also be provided to the SCSR manufacturer for their equipment. If properly used, the mine operator has the potential to contact the manufacturer to further information (or other questions

concerning the SCSR as an output of these reports) that the manufacturer would be unaware of if not copied on these reports. this information would also be valuable to the manufacturer as data for product improvements, changes to the users instructions, training and future developments.

Data Analysis:

- There is no mention of the interim report in this document. We suggest that the information is added.
- In addition to the mine operator we also suggest that the initial report and the interim report also be provided to the SCSR manufacturer for their equipment. If properly used, the mine operator has the potential to contact the manufacturer to further information (or other questions concerning the SCSR as an output of these reports) that the manufacturer would be unaware of if not copied on these reports. this information would also be valuable to the manufacturer as data for product improvements, changes to the users instructions, training and future developments.
- Page 2, First Paragraph: We suggest that the beginning statement be changed from "All data each approval...." be amended to read "All data for each approval..."
- Page 2, First Paragraph: The statement concerns a five year running analysis and the reliability of the approval type projected based on the five year sampling. What would be the output of this data? We suggest that a report also be published, but not included in the annual LTFE Report. Also, if the data does not predict a suitable reliability, what actions will NIOSH take for the existing product in the field? Some possible scenarios may include: 1) Review / Reduction in the service life plan for the product, 2) A mandatory service life of the product in which the SCSRs would need to be replaced, and 3) Evaluation of the certification process to determine if additional testing should be included. We would like some clarification on this statement.

Reporting Form:

- Page 1, Last Paragraph: The statement / personal comment does not feel that belt worn devices should not be reported to the mine operator or to the regulatory authorities. We suggest that this be removed and that the information is to be relayed to both the mine operator and the regulatory authorities. The wearer may be the problem in that the unit is not inspected in accordance with the manufacturer's instructions and they may need additional training in this area.

Sampling Plan and Statistical Considerations for the LTFE Program:

- After reviewing this document, we find it to be clear and concise and it looks to be a good analysis method.

In general, we find this to be a good program concept and it provides the details that previously were not known on the LTFE Program.

Draeger Safety thanks NIOSH for the opportunity to provide comments. Please consider our comments concerning the ongoing changes to the standard.

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