50-344

JAN 07 1993

MEMORANDUM FOR: Richard W. Cooper, Director, DRSS, Region I
J. Philip Stohr, Director, DRSS, Region II
Charles E. Norelius, Director, DRSS, Region III
L. Joseph Callan, Director, DRSS, Region IV
Ross A. Scarano, Director, DRSS, Region V

FROM: LeMoine J. Cunningham, Chief
Radiation Protection Branch
Division of Radiation Safety
and Safeguards
Office of the Nuclear Reactor Regulation

SUBJECT: FOLLOW-UP ON A REPORT OF RESPIRATOR DEFECT

Trojan Nuclear Power Plant staff submitted information to us concerning quality control concerns with Mine Safety Appliances Co. (MSA) full face negative pressure respirators (Ultra View and Ultra Twin) with potential 10 CFR Part 21 implications. We have contacted the National Institute of Occupational Safety and Health (NIOSH) and MSA concerning this matter and are providing the following for your information. This is not an official radiation protection branch (PRPB) Part 21 closeout, as the consequences of the respirator defects do not meet the threshold requirements of Part 21 (they do not create a potential safety hazard).

PRPB contacted NIOSH informing them of Trojan's report of defects (see enclosure 1). NIOSH then contacted MSA and followed up on the vendor response (see enclosures 2 & 3). MSA responded to NIOSH (see enclosure 4) by characterizing the problem as an isolated incident unique to their special order process and not a generic issue. NIOSH concluded that MSA had made satisfactory progress toward the resolution of this problem (enclosure 5).

PRPB wanted to pursue the special order issue further and after conferring with NIOSH contacted MSA directly to ask what actions were taken to prevent any reoccurrence with other special orders. MSA responded (enclosure 6) that it has reviewed its inspection procedures with its production personnel and have taken steps necessary to prevent occurrences of this type in the future.

Since the vendor's corrective actions appear to be appropriate, PRPB plans no further action in this matter. If you have any questions contact Dan Carter at (301)504-1848.

Original signed by LeMoine J. Cunningham

LeMoine J. Cunningham, Chief
Radiation Protection Branch
Division of Radiation Safety
and Safeguards
Office of Nuclear Reactor Regulations

Enclosures: As stated
DISTRIBUTION: See next page

OFC	PRPB:DRSS	RPB:DRSS:SC	RPB:DRSS:BC	
NAME	DCARTER:JL	JWIGGINTON	LCUNNINGHAM	
DATE	01/7/93	01/7/93	01/7/93	

Official Record Copy Document Name: msa21

D103

DISTRIBUTION:
B. Murray, RIV
F. Congel
E. Butcher
L. Cunningham
Central File, P1 37
F. Combs, 6H3
J. Wigginton
PRPB R/F
R. Anderson, TTC
T. Essig
PDR, LL6
L. Norrholm, 9D4
J. Joyner, RI
W. Cline, RII
C. Pederson, RIII
J. Reese, RIV
J. Cutshall, MSA
R. Metzler, NIOSH
G. Huey, Trojan
L. Kokajko, 13E16

Enclosure 1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

AUG 12 1992

Mr. Richard W. Metzler, Chief
Certification and Quality Control Branch
National Institute of Occupational Safety
and Health
Division of Safety Research
Room S-105
944 Chestnut Ridge Road
Morgantown, West Virginia 26505-2888

SUBJECT: PROBLEMS WITH MSA RESPIRATORS

Dear Mr. Metzler:

This letter is to bring to your attention an issue identified to us by one of our power reactor licensees. This issue (see enclosure) focuses on quality control concerns with Mine Safety Associates (MSA) full face negative pressure respirators (Ultra View and Ultra Twin). These concerns range from respirator microphones being installed upside down, filter gaskets installed upside down, a missing inhalation valve disc and improperly installed lens rings causing distortion of rubber around the lens covers. These deficiencies were identified by the licensee as part of their incoming quality control (QC) checks on all new respirators prior to field use.

The licensee notified MSA of these problems and a vendor representative was sent to the reactor site to investigate the matter. The MSA representative inspected 20 respirators identified as having problems and confirmed that 11 had rubber distortion of some matter in the face piece area; the remaining 9 were able to be repaired on site. The 11 respirators with distorted rubber were returned to MSA for evaluation. Two of the 11 respirators returned failed the vendor DOP testing criteria.

MSA claimed that they did not know how these problems occurred and said that their QC was "as good as always." MSA representatives informed our licensee that they did not feel it was necessary to alert other MSA customers of these problems unless other customers expressed similar problems. If MSA is waiting for feedback from their customers, then we should point out that not many of the thousands of NRC licensees (aside from the 100 or so power reactor licensees) have comprehensive, sophisticated incoming QA/QC programs which test 100 percent of the negative pressure respirators prior to use. We suspect that the vast number of respiratory protection programs across the country for not have formal aggressive incoming QC programs.

I would like to talk with you about MSA's apparent lack of willingness to inform their customers of possible generic problems with their products. While this is not a serious worker safety issue at nuclear power reactor facilities, because there respirators are used only in areas of relatively low concentrations of radioactive materials, we are considering issuing an

information notice to the nuclear industry. The purpose of this industry notice would be to inform our licensees of this issue so that they might consider expanding the scope of their own QC programs. Please contact me at (301) 504-1067 or Jim Wigginton at (301) 504-1059.

Sincerely,

Original signed by LeMoine J. Cunningham

LeMoine J. Cunningham, Chief
Radiation Protection Branch
Division of Radiation Protection
and Emergency Preparedness
Office of Nuclear Reactor Regulation

Enclosure: As stated

Distribution:
FCongel
EButcher
LJCunningham
JWigginton
TEssig
DCarter
FCombs, 6 H3
DCool, NLS 139
Regional BC's
RPB R/F
Central Files

OFC	RPB:DREP:NRR	RPB:DREP:NRR	C:RPB:DREP:NRR		
NAME	DRCarter:mgc	JEWigginton	LJCunningham		
DATE	08//2/92	08/12/92	08/12/92		

OFFICIAL RECORD COPY
DISK\DOCUMENT NAME: A:\MSA

Enclosure

RECORD COPY

QA RECORD WHEN COMPLETED PAGE A1 of A_

CORRECTIVE ACTION REQUEST (CAR)

INITIATION

PART A

CAR Number C-92-0L95 [13]
Date: 4/14/92 Severity Level II [14]

INITIATOR SECTION [1] Audit/Surveillance No. _____

SYSTEM NUMBER[2] N/A TROJAN COMPONENT ID NUMBER[2] N/A

DATE OF DISCOVERY[3] 4/14/92 TIME OF DISCOVERY[3] 2200 PLANT MODE[3] 1

METHOD OF DISCOVERY[4] Material Inspection Prior To placing Respirators in use

PROBLEM DESCRIPTION[5] Upon receipt of new Respirators from MSA corporation it was discovered that the Quality of Workmanship was not up to standards and questions arose as to the Integrity of the Respirators. (See attached). A meeting was conducted with MSA Representatives on 4-14-92 to discuss these issues and was informed that 2 of the 11 Respirators returned to MSA Failed DOP Testing. Questions still Remain as to whether this is Reportable under 10 CFR Part 21

CLOSED

Attachments[6] Yes ✓ No ___

REQUIREMENT[7] Possible 10 CFR Part 21 Reportability

Attachments[8] Yes ___ No ___

[9] INITIATOR [signature] /PRINT Michael Monroe DEPT. R&P PHONE 7682 DATE 4/14/92

[10] SUPERVISOR [signature] /PRINT G R Hazy TIME 1700 PHONE 7871 DATE 4/14/92

[11][12] COMPLIANCE IDENTIFIED POTENTIAL NOV YES ___ NO ___ SUPERVISOR COMMENTS

PA A. NUMBER ALL ATTACHED PAGES SEQUENTIALLY A2, A3 ETC.

EMP/M.S
File # QA-15
Attachment 1
Page 1 of 2

C92-C195

H-2

April 13, 1992
MM-008-92

MEMORANDUM

TO: G. R. Huey

FROM: M. Murdock MM

SUBJECT: Poor Quality Respirators Received From MSA

The following event scenario is being documented to identify the poor quality of respirators that were recently received from MSA. The scenario also details those corrective actions that have been taken, and a some questions that are still remaining.

December, 1991

During the last week of December 1991, the new small and large respirators were received at Trojan. Utility workers purchased the respirators from the warehouse and were preparing them for use. This included sanitizing and complete inspection. The Utility Workers, Joan Thackery and Margaret Brady, noticed that the microphones were installed by the manufacturer upside down.

A complete inspection of all newly purchased respirators, along with all respirators containing microphones, was performed. Those found to be incorrect were corrected. MSA was notified, and their response was that the microphones would still work and that it would not result in the respirator's integrity.

March 11, 1992

Training was being given to all Rad Waste Handlers and Utility Workers on the maintenance, inspection, cleaning, and repair of respirators as part of their first quarter training by MSA representative Bob Rucinski. During this training, Dennis Cross noticed that one of the new respirators -- indicated by the gold lens ring as being a large -- was in fact, a medium respirator.

The respirator was corrected and computer checks showed that the respirator had never been issued. Again, all respirators recently purchased along with all the new small and large ones already in service were inspected. No others were found to have this problem.

March 30, 1992

A new shipment of small and large respirators were received at the plant and purchased by Joan and Margaret from the warehouse (10 large, 10 small). While preparing these respirators for use, they noticed the first respirator to have its microphone upside down and repaired it. Further inspection showed that all 10 of the large and 7 of the small respirators had problems. The following is a list of the indications.

- Upside down microphones.
- Improperly installed lens rings. Some were pinching the rubber between the mating portions which caused the rubber to bulge out. One had the lens not even seated in the rubber portion at the bottom of the face piece holder. Some rings were not lined up with the center lines indicated at the top and bottom of the respirator.
- Microphones found installed at the 5 and 8 o'clock positions which were pressing into the rubber.
- Upside down filter gaskets.
- Missing inhalation valve disc.
- Gap between the speaker assemblies and the rubber.
- O rings on the speaker assemblies rotated to the wrong position.

Joan and Margaret called Dallas Somerville to inform him of these problems. Dallas asked that they bring the respirators from the assembly room to the conference room and he would call MSA. Bob Rucinski of MSA was notified and arrived at the plant at 1200. He inspected all of the 20 respirators and confirmed that all 10 large and 1 small had the rubber distorted in some manner in the face piece area. The remaining 9 small respirators were able to be repaired.

C92-0195 A-8

A complete inspection of all respirators in stock at the warehouse was performed with Bob Rucinski. No problems were found. A detailed inspection of all respirators purchased since December of 1991 and already in service in cabinets and emergency lockers was also performed, and no problems identified.

NOTE: 1. Problems with microphones being installed upside down was in both ultra twin and ultra view respirators.
2. Rubber distortion and missing pieces were isolated to ultra twins only.

Another meeting will be conducted with representatives from MSA along with Dallas Somerville, Joan Thackery, Margaret Brady, Spike Ford of the compliance group, and myself at the plant on April 14, 1992. Items to be discussed will be the lack of quality workmanship recently indicated with the MSA respirators, what MSA's results of investigating the problems were, and potential reporting issues.

MM:bjp

c; T. Meek
D. Somerville
S. Ford
J. Thackery
M. Brady

NOTES FROM MTG WITH MSA - BOB RUCINSKI
DAVID TAYLOR

1. MSA CLAIMS THAT ALL RESP WERE DOP TESTED PRIOR TO LEAVING THEIR FACILITY.

THE RESPIRATORS ... RECEIVED AT TROJAN WERE MODIFIED WITH THE MICROPHONES FROM STOCK ONES

2 OF THE 11 THAT WERE RETURNED TO MSA FAILED DOP TESTING

ONE FAILED DUE TO DISTORTED RUBBER AROUND THE LENS COVER

THE OTHER FAILED DUE TO IMPROPER PLACEMENT OF THE MICROPHONE - INTERFERED WITH THE EXHALATION VALVE

MSA HAS MODIFIED DRAWINGS FOR THEIR PEOPLE ON PROPER PLACEMENT OF THE MICROPHONE

MSA REPS. DID NOT FEEL IT WORTHY OF ALERTING OTHER CUSTOMERS UNLESS OTHER SIMILAR CONCERNS WERE BROUGHT TO THEIR ATTENTION BY OTHER CUSTOMERS.

MSA CLAIMED THEY COULD NOT DETERMINE HOW THIS OCCURRED. SAID THEIR QUALITY CONTROL WAS AS GOOD AS BEFORE.

Enclosure 2

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

NIOSH Reference: TN-06205

Centers for Disease Control
National Institute for Occupational
Safety and Health – ALOSH
944 Chestnut Ridge Road
Morgantown, WV 26505-2888

August 20, 1992

Mr. LeMoine J. Cunningham
United States Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Cunningham:

The National Institute for Occupational Safety and Health (NIOSH) has received your letter of August 12, 1992, concerning nonconformances with Mine Safety Appliances Company (MSA) Ultraview and Ultratwin negative-pressure facepieces.

The investigation of these reported nonconformances has been assigned NIOSH Task Number TN-06205. Mr. Jeffrey L. Gutshall of MSA has been contacted, and NIOSH awaits the manufacturer's report of investigation concerning this matter. You will be kept informed of the developments concerning this investigation.

If NIOSH can be of further assistance, feel free to contact this office.

Sincerely yours,

Don Campbell for

Richard W. Metzler, Chief
Certification and Quality
Assurance Branch
Division of Safety Research

Enclosure 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Reference: TN-06205

Centers for Disease Control
National Institute for Occupational
Safety and Health – ALOSH
944 Chestnut Ridge Road
Morgantown, WV 26505-2888

August 31, 1992

Mr. Jeffrey L. Gutshall
Mine Safety Appliances Company
P.O. Box 439
Pittsburgh, Pennsylvania 15230

Dear Mr. Gutshall:

The National Institute for Occupational Safety and Health (NIOSH) has received a report of nonconformances with the MSA Ultraview and Ultratwin negative-pressure facepieces. These nonconformances reportedly involve microphones and filter gaskets being installed upside down, a missing inhalation valve disc, and improperly installed lens rings.

These nonconformances have been reported to NIOSH by Mr. LeMoine J. Cunningham of the U.S. Nuclear Regulatory Commission. A copy of the letter initiating this investigation is enclosed.

The investigation and ultimate resolution of this nonconformance investigation have been assigned NIOSH Task Number TN-06205. The MSA report of investigation and proposed corrective action, if any, should be submitted by September 18, 1992. Special consideration should be given to Mr. Cunningham's concern about notifying other users of the need to closely inspect their own respirators for similar nonconformances.

Please provide this office with a list of all model and certification numbers involved in this investigation.

Sincerely yours,

John M. Dower for

Richard W. Metzler, Chief
Certification and Quality
Assurance Branch
Division of Safety Research

Enclosure

cc:
L. Cunningham (NRC)

Enclosure 4

Mine Safety Appliances Company • Safety Products Engineering • P.O. Box 439 • Pittsburgh, PA 15230

Telephone: (412) 776-7700

WRITER'S DIRECT DIAL NO.

(412) 776-7740

September 17, 1992

Mr. Richard Metzler
Certification Branch
NIOSH
944 Chestnut Ridge Road
Morgantown, WV 26505

RE: Reported MSA Facepiece Problems TN-06205
MSA REF: NP92-48

Dear Mr. Metzler:

This is in response to your letter dated August 31, 1992.

MSA was made aware of this problem through our field representative. A subsequent investigation confirmed that these respirators were not representative of the quality our customers have come to expect from MSA. The subject respirators were repaired and returned to the customer.

These respirators are not stocked equipped with a communications package. This is usually added by the user through the use of a kit. In this instance, a number of respirators were supplied so equipped through a special order.

The positioning of the microphone can be changed by the user to suit preference. If, however, the microphone is in the lower quadrant of the facepiece, it can interfere with our DOP test fixturing. This is why it is shown in the 12:00 position on the drawing. Any other position is user determined and is cosmetic.

Our information confirms this problem is isolated to this special order. It is conceivable that some of these escaped normal Q.C. inspection.

The lens ring assembly procedures, as well as the valve, gasketing and other installations are monitored by each worker in the work cell. Furthermore, each facepiece is normally 100% DOP inspected and random post production samples are removed and inspected. Q.C. has been alerted to this problem and has reviewed the inspection procedures with production personnel.

MSA sold over 50,000 Ultra-Twin respirators in 1991. Thousands have been sold to commercial nuclear users. A greater number were purchased by the D.O.E. No other problems have been reported. This confirms the finding at Trojan that a 100% inspection of their stock found no other defective respirators.

MSA is convinced that this is not a generic problem with our products. Our internal review, the customer review, as well as a review of field experience confirm this as an isolated incident.

If you have any questions, please contact me.

Sincerely,

Jeffrey L. Gutshall
Design Engineer,
Government Relations
Safety Products Division

JLG:lb