



Monday March 27, 2006

Proj-739

U.S. Nuclear Regulatory Commission
Washington D.C.
20555-0001

Attention: Document Control Desk

Subject: Summary Table of Proposed Changes to Draft Safety Evaluation For Topical Report (TR) MURUBLU05NP, "Topical Report For Delta Protection Mururoa BLU Suit Systems" (TAC No. MC8994).

The following changes to the draft SE will clarify and finalize the report in a precise manner. They are as follows.

- 1) Page 3, second paragraph: Please replace "INPS" by "BIA". This is the notified body for the BLU system.
- 2) Page 4, paragraph 3: QA first line. "In accordance with IPSN requirements" should be replaced by, "In accordance with CE PPE directive 89/686/EEC dated 08 10 1996, and the European Notified Body requirement.
- 3) Page 4 paragraph 3, line 4: replace "IPSN" by the "Notified Body"
- 4) Page 2, under 2.0 Regulatory Evaluation 4th line: Please change "NISOH" to "NIOSH".
- 5) Chapter 4.1 line 2: The blower reference should be "C500-012EK-AB60" instead of C500-012ER-AB60.
- 6) Page 5 under Conclusion 5.0: The 2nd line "ethylfuge" should read "Ethyfuge"

We trust the above changes can be implemented as quickly as possible. We look forward to your final safety evaluation (SE).

Sincerely,



Gary Zimmermann
Delta Protection/Bacou-Dalloz

BACOU-DALLOZ PROTECTIVE APPAREL LTD: 4200 St. Laurent Blvd, 6th floor, Montreal, Quebec, Canada H2W 2R2
Tel.: +1 514-282-0503 Fax: +1 514-282-8871 - www.bacou-dalloz.com

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SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

MURUBLU05NP, "TOPICAL REPORT FOR DELTA

PROTECTION MURUROA BLU SUIT SYSTEMS"

DELTA PROTECTION/BACOU DALLOZ

PROJECT NO. 739

1.0 INTRODUCTION AND BACKGROUND

By letter dated October 27, 2005 (Ref. 1), as supplemented by letter dated January 26, 2006 (Ref. 2), Delta Protection, a member of the Bacou Dalloz group of personal safety equipment manufacture and supply companies, submitted a topical report (TR) concerning the BLU models of their Mururoa respiratory protection suits for Nuclear Regulatory Commission (NRC) review and approval. The TR covers two suit systems, the Mururoa BLU Ethyfuge, and the Mururoa BLU PVC. These suits differ only in the composition of the material with which the suit enclosures are made. The BLU model suits combine the powered air filtration feature of a powered-air-purifying respirator (PAPR) with the suit enclosure design of the Delta Protection Mururoa V4, supplied air suit systems. The air purifying feature of the BLU models eliminates the need for a breathable air distribution system (external manifold, regulator, air line hose, etc.) associated with a supplied air suit system.

Bacou Dalloz is a multi-national group of companies with extensive experience in the production and supply of occupational personal protective equipment. They have over 20 years of successful use with Mururoa style (and similar models) suits in European power plants. Their products must be certified to European Committee (EC) Standards, as established by the Institute for Nuclear Protection and Security (INPS), the European certifying agency comparable to National Institute for Safety and Health (NIOSH).

The Delta Protection Mururoa BLU suits have a hybrid design for a respiratory protection device. The BLU design combines the powered air filtration of a PAPR with the suit enclosure design of the Delta Protection Mururoa V4 models of air supplied suits. The Mururoa BLU has an advantage over air supplied suits since wearers' movements are not restricted by an air line hose. Also, eliminating the need to set up an air distribution system at the work site saves time and overall radiation exposure. However, since the suit supplies filtered ambient air to the wearer, they are only effective against particulate airborne contamination. In addition, the suits are designed to be used only in atmospheres containing specific contaminants in concentrations that are not immediately dangerous to life or health (IDLH) and have an oxygen content of at least 19.5 percent by volume.

In June of 2003, the NRC granted the Duke Power Company approval to use the F1 and MTH2

(supplied air) models of the Delta Protection Mururoa V4 suits (Ref. 3). Subsequently, the NRC has, on a case-by-case basis, reviewed and granted more than 40 approvals for use of the MTH2 and F1 models of the Mururoa suits. The purpose of this TR review is to increase the efficiency of NRC reviews by providing a single technical basis and approval that can be referenced by licensees in future approval requests under Section 20.1703(b) of the *Code of Federal Regulations*.

2.0 REGULATORY EVALUATION

Part 20, "Standards for Protection Against Radiation," Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," provides for the use of respiratory protection equipment (respirators) for protection against airborne radioactive materials.

Section 20.1703(a) requires respiratory equipment be certified by the National Institute for Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA) when used to limit the worker intakes of radioactive materials. Currently, there is no NIOSH certification schedule for full body encapsulating suits, such as the Delta Protection Mururoa models.

Section 20.1703(b) permits licensees to apply to the Commission for authorization to use respiratory equipment that has not been tested and certified by NIOSH. This regulation requires the licensee to demonstrate by appropriate testing that a respirator is capable of safely providing the necessary level of user protection under the anticipated conditions of use. As noted above, the NRC has approved, on a case-by-case basis, several licensee requests to use the Delta Protection air supplied models of the Mururoa suits. These approvals were based on the technical testing and certification by the applicable European certifying authorities.

European Standards EN 1073-1:1998, "Protective clothing against radioactive contamination," and EN 12941:1998, "Respiratory protective devices - Powered filtering devices incorporating a helmet or a hood - Requirements, testing, marking," is used as the technical basis for European certification of the Mururoa BLU suits.

Criteria and background information used for the NRC staff's evaluation include 10 CFR Part 20, Subpart H; Regulatory Guide 8.15, Revision 1, "Acceptable Programs for Respiratory Protection"; NUREG/CR-0041, Revision 1, "Manual of Respiratory Protection Against Airborne Radioactive Materials"; 30 CFR Part 11, NIOSH testing and certification regulations; LA-10156-MS, "Acceptance-Testing Procedures for Air-Line Supplied-Air Suits," June 1984; NIOSH DRAFT for COMMENT, "Concept for Industrial Powered, Air-purifying Respirator Standard," May 30, 2005; and ANSI Z88.2-1992, "American National Standard Practices for Respiratory Protection."

NRC guidance provided in NUREG/CR-0041 encourages the use of suits, noting that, in certain work environments, air-supplied suits may be the best respiratory application when factoring in heat stress, minimizing skin contamination, and maintaining worker doses as low as reasonably achievable (ALARA).

3.0 TECHNICAL EVALUATION

As part of the technical basis to support NRC approval, Delta Protection provided the European safety certifications of the Mururoa BLU suits. EC Type Examination Certificates, were issued

by the German certifying body, BIA, for the Mururoa BLU PVC model (Attachment 6.6.1 to Ref. 1) and the Mururoa BLU Ethyfuge model (Attachment 6.6.2 to Ref. 1), dated October 10, 2004. Since there is currently no single performance standard applicable to powered-air-purifying, fully encapsulating suit devices, BIA certified the Mururoa BLU suits against the applicable criteria in EC Standards EN 1073-1:1998, "Protective clothing against radioactive contamination," and EN 12941:1998, "Respiratory protective devices - Powered filtering devices incorporating a helmet or a hood - Requirements, testing, marking," (Attachments 6.6.8 and 6.6.9 to Reference 1, respectively).

The EC Standards, used to certify the Mururoa BLU models, are generally consistent with the pertinent acceptance criteria provided in the Los Alamos National Laboratory Report used to test and authorize the use of air-supplied suits at U.S. Department of Energy sites (Ref. 4) and the proposed revised NIOSH standards for industrial PAPRs (Ref. 5). The INPS certification testing regime was broadly based and included a range of various functional areas, including suit material strength/tear and puncture resistance, material flammability, wearer comfort, noise level, wearer visibility, air flow, carbon dioxide concentrations, and degree of contaminate in-leakage during a series of varied simulated work practices/exercises. Both models passed all required tests and both provided a measured average protection level (fit factor) of at least 20,000. Measured in a simulated work environment, a fit factor is the ratio of contaminate concentration outside the suit, to the contaminate concentration inside the suit. Given an overall measured fit factor of 20,000 (averaged over all exercise activities), allowing an Assigned Protection Factor (APF) of 2,000 provides a conservative safety factor for estimating the actual protection provided to the user by the suit in the actual working environment. Generally, APF's are lower than fit factors for all types of respirators, as workplace demands are typically greater (higher heat and humidity, longer work durations, greater worker fatigue, etc.) on the respirator user than simulated work activities in a laboratory setting.

The Mururoa BLU suits are constructed with the following design features common with other Mururoa models: (1) Dual zippers (metal zipper inside and plastic zipper outside), (2) welded sleeve to insert communication cable, (3) a removable strip near the mouth that could be used for emergency breathing in case of loss of supplied air, (4) an egress strip stretching from left arm, over the head, to the right arm that is used for undressing and for self-rescue in an emergency, such as loss of supplied air, (5) dual magnetic exhaust valves that provide ventilation, and relief of excess pressure in case the suit is squeezed/pinched unexpectedly, (6) air flow to hands, feet, face, and chest, (7) low noise levels (less than 75 dB at maximum rated blower speed), and (8) reinforced elbows, knees, and crotch areas.

In addition, the Mururoa BLU suits are fitted with a battery powered Micronel Powered Air Purifying blower unit to provide air flow (optional rated settings of 600 l/min (20 cfm) or 400 l/min (14 cfm)) to the suit. A pocket, internal to the suit, holds the blower with attached battery pack in the small of the wearer's back to minimize interference with suit movement. This design minimizes contamination of the blowing unit and battery pack. Ambient air is drawn in and filtered through four external high-efficiency filters and distributed throughout the suit during use. The blower has an internal electronic controller to maintain the selected rated flow output. In the event of a defective controller, the blower unit fails safe to its maximum speed. Two warning alarms are also associated with the blower units that signal the wearer to leave the work area and discontinue use of suit. A continuous tone, clearly audible to the wearer, is sounded within the suit on a low battery voltage condition. The unit is designed to alarm when

there are 15 minutes of use remaining. An intermittent tone is sounded if the air flow rate drops below the rated setting. In the event of loss of air flow to the suit, the dual magnetic ventilation valves shut, keeping the suit inflated and providing breathable air to the wearer for several minutes. In addition, the wearer can easily extricate himself/herself by pulling off the mouth strip and then opening the hood, or pulling the egress strip from either forearm over the head toward the other forearm.

Based on these designed safety features, the NRC staff finds that the suit design provides for easy and effective self-rescue, thus avoiding asphyxiation if the air flow is interrupted or lost. As a result of external radiation levels present in typical job sites, suit users are typically provided with radiological protection (RP) coverage (closed-circuit television or on scene RP coverage, and continuous audio communication). This communication/coverage adds to the assistance available to the suit wearer, if needed. Due to these design features of the suit, coupled with required training of all suit users on escape methods, and limiting the use of the suits to non-IDLH atmospheres, the requirement for standby rescue persons in Section 20.1703(f) is not applicable.

Quality Assurance (QA) of the suits is in accordance with IPSN requirements. Delta Protection is ISO 9001 registered. In addition to their internal QA program, an independent review by an outside organization (ASQUAL) is conducted annually to assure that the manufactured suits are consistent with IPSN certification. As part of the required QA program, Delta Protection maintains a vendor-user alert system to provide timely reports to the end users if any deviations, or deficiencies, should any arise.

Based on the testing data provided, these suits will provide the suit wearer with an adequate level of protection, and with an adequate margin of safety and conservatism, while working in airborne radioactivity areas. Both models are approved as a respiratory protection device with an APF of 2000, against airborne particulate contamination, when used in accordance the following configuration and conditions of use, relative to their form, fit, and function.

4.0 APPROVED DEVICE CONFIGURATION AND CONDITIONS OF USE

1. Mururoa BLU one-piece encapsulating suit (of either PVC or Ethyfuge construction), fitted with 1) a Micronel C500X-012ER-A B60 blower with a C501A-012AK-A battery (consistent with the parts list in Section 7 of Attachment 6.6.6 to Ref. 1) and 2) four Scott PF 10 P3, or four Delta Protection P3, high efficiency particulate filter cartridges. All four filter cartridges must be matching and replaced as a set.
2. Procedures for use of the suit systems are integrated into the respiratory programs required by Subpart H of 10 CFR Part 20. Fit testing of user is not applicable to fully encapsulating suits. Prior to use, wearers are trained on these conditions of use as well as the emergency escape features of the suits.
3. Suits are used in accordance with recommendations in Attachments 6.6.4, 6.6.5, and 6.6.6 of Reference 1.

4. Suit enclosures are single use only, and are discarded after use. Unused suit enclosures are stored in their original manufacturer's packing (in an environment not colder than 32 deg. F, nor hotter than 140 deg. F), with a maximum storage shelf-life of 3 years. Suits are not to come in contact with anything colder than 41 deg. F, nor hotter than 140 deg. F, during use.
5. Suits are donned with a fully charged battery pack installed on the blower. The maximum period of use (timed from a fully charged battery), is 4 hours with the blower set at 600 l/min, and 7 hours with the blower at the 400 l/min setting.
6. Suits are used only in atmospheres containing specific contaminants in concentrations that are not IDLH, as given in Reference 5, and have an oxygen content of at least 19.5 percent by volume.
7. Communication channels are established with the Delta Protection to report any defects experienced with the device, and ensure that any manufacturer's notifications concerning the suit systems are received in a timely manner.

5.0 CONCLUSION

Based on the NRC staff's review of the referenced TR, the NRC staff concludes that the use of the Mururoa BLU (PVC or Ethylfuge) protective suit systems, consistent with the configuration and conditions of use noted above, is in accordance with the requirements of 10 CFR Part 20. Granting an approval for the use of these suits with an APF of 2000, against airborne particulate contamination, will improve overall worker safety while working in high surface contaminated areas, and in high and potentially high airborne radioactivity areas, satisfies the 10 CFR Part 20 ALARA requirements, and is, therefore, acceptable.

6.0 REFERENCES

1. Bacou Dalloz/Delta Protection MURUBLU05NP, "Topical Report Submittal of Delta Protection Mururoa Blu Single Use Encapsulating Suits," October 27, 2005 (ADAMS Accession No. ML053060280).
2. Letter from Gary Zimmerman, Business Development Manager, Delta Protection/Bacou Dalloz, "Response to RAI for Topical Report # MURUBLU05NP Mururoa BLU Self Fed Encapsulation Suits," January 26, 2006 (ADAMS Accession No. ML060310265).
3. NRC Safety Evaluation, "Use of French Designed Respiratory Protection Equipment - Duke Energy Corporation," June 30, 2003 (ADAMS Accession No. ML031810133).
4. Los Alamos LA-10156-MS, "Acceptance-Testing Procedures for Air-Line Supplied-Air Suits," June 1984. Available through NTIS, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.
5. NIOSH "Concept for Industrial Power, Air-purifying Respiratory Standard," Draft for Comment, May 30, 2005 (<http://www.cdc.gov/niosh/npptl/standardsdev.html>).

6. NIOSH Publication No. PB-94-195047, "Documentation for Immediately Dangerous to Life or Health Concentrations (IDLH)," May 1994 (<http://www.cdc.gov/niosh/idlh/intridi4.html>).

Principal Contributor: R. Pedersen

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