



March 26, 2015

Mr. Thomas Herrera  
United States Nuclear Regulatory System  
Materials Safety & Inspection Branch  
Division of Industrial and Medical Nuclear Safety  
Two White Flint North  
11545 Rockville Pike  
North Bethesda, MD 20852-2738

RE: REQUEST FOR ADDITIONAL INFORMATION, METSO AUTOMATION USA, INC., AMENDMENT  
REQUEST DATED JANUARY 15, 2015

Dear Mr. Herrera,

This letter is in response to your request for additional information dated March 3, 2015. If you need additional information, please let me know.

Sincerely,

A handwritten signature in black ink that reads "Jack Ramsey".  
Jack Ramsey  
Radiation Safety Officer



General

1. The following Sealed Source and Device Certificates should remain active:
  - NR-0596-D-110-G      BG-V or BG-V air
  - NR-0596-D-113-G      PaperIQ Series
  - NR-0596-D-114-G      PaperLab Filler Module
2. The manufacturer is the same for all three device registration certificates, however, the PaperLab Filler Module is manufactured in a different facility than the PaperIQ Series and the BG-V gauges.

NR-0596-D-110-G  
NR-0596-D-113-G  
Metso Automation, OY  
Lentokentankatu 11  
SF-33101 Tampere  
Finland

NR-0596-D-114-G  
Metso Automation, OY  
Kehraamontie 3  
87400 Kajaani  
Finland

The distributor will be the same for all 3 device certificates  
Metso Process Automation USA, LLC  
2425 Commerce Ave., Suite 100  
Duluth, GA 30096-8913

3. Here are the most recently distributed device serial numbers that were not mentioned in the original application.

NR-0596-D-110-G

<u>Model</u>	<u>Serial#</u>	<u>Date Distributed</u>
BG V	UM196	11/05/13

NR-0596-D-113-G

<u>Model</u>	<u>Serial#</u>	<u>Date Distributed</u>
BWM	14652820	04/04/11
BWM-H	21823323	10/23/11
BWM-L		None Ever Distributed
BWM2-T		None Ever Distributed
ASM2		None Ever Distributed

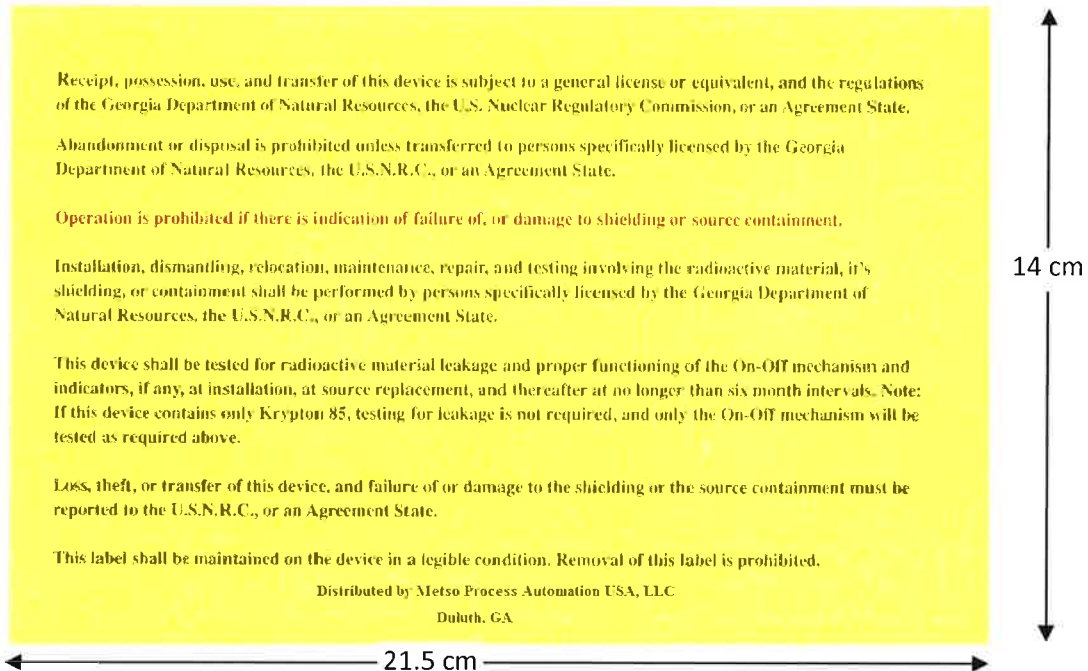
Note: The following device was distributed since the original amendment was submitted  
BWM2-H    80042535    03/05/15

NR-0596-D-114-G

<u>Model</u>	<u>Serial#</u>	<u>Date Distributed</u>
PaperLab Filler Module		None Ever Distributed

Labeling

4. The GL Rules and Regulations Label will identify the distributor and location as follows:



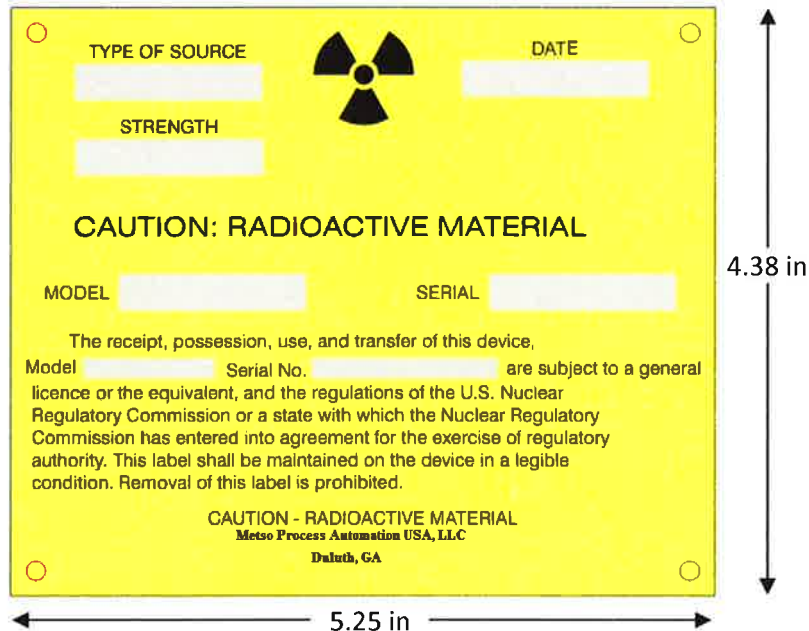
5. The Label will be of a tough, industrial vinyl glued to the outside of the sensor as shown in the schematic below. The label is approximately 14 cm x 21.5 cm.



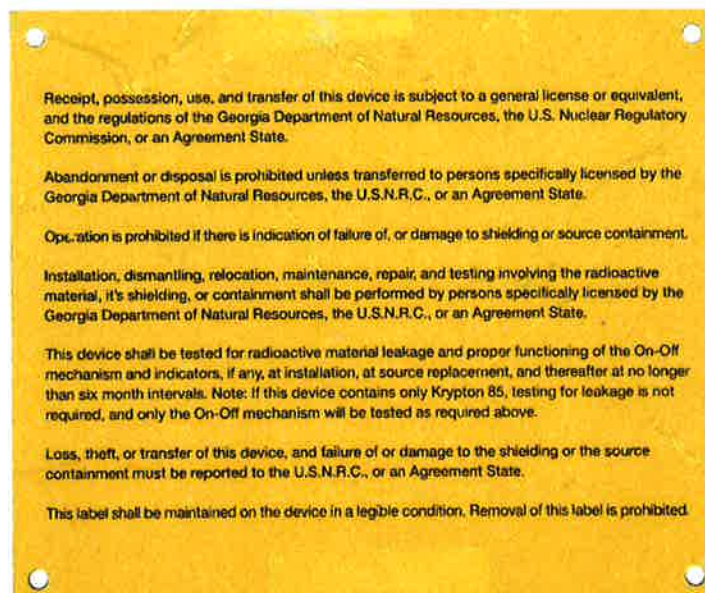
6. Example of labels for NR-0596-D-110-G and NR-0596-D-114-G

a. NR-0596-D-110-G: BG-V or BG-V with Air

Both labels are made of aluminum or steel, and are attached using rivets, epoxy, or other long lasting, durable adhesive. Dimensions of both labels are the same.

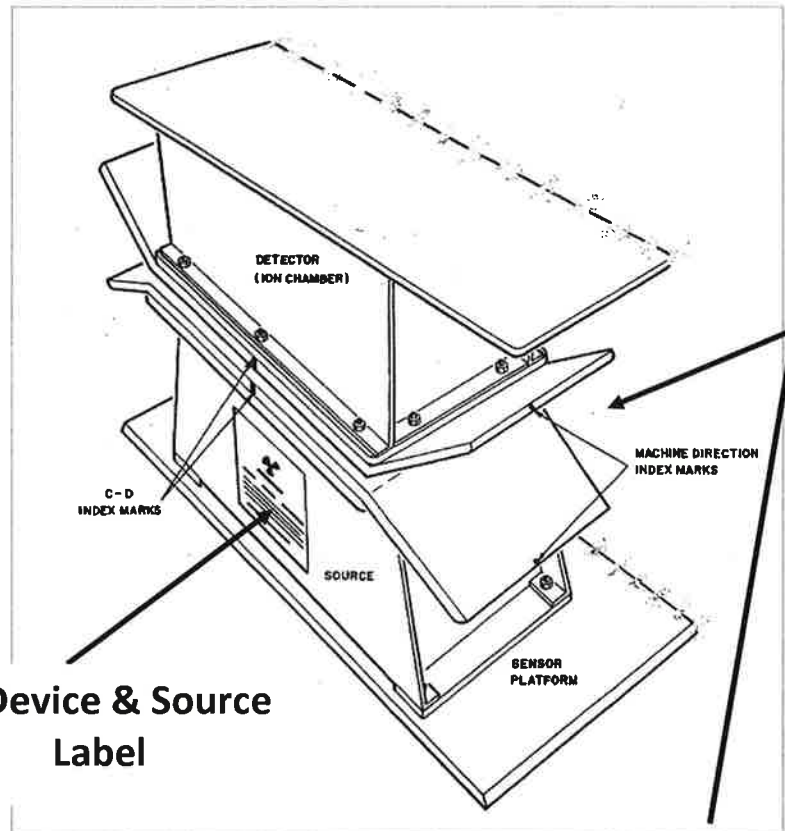


**GL Device & Source Label**



**GL Regulations Label**

The labels will be attached on each side of the sensor as shown below.

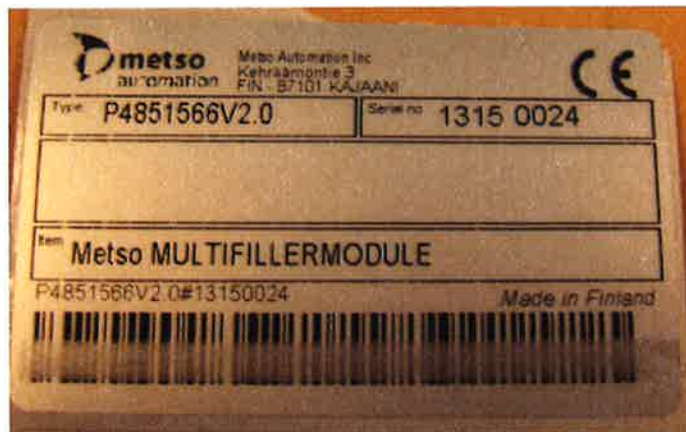
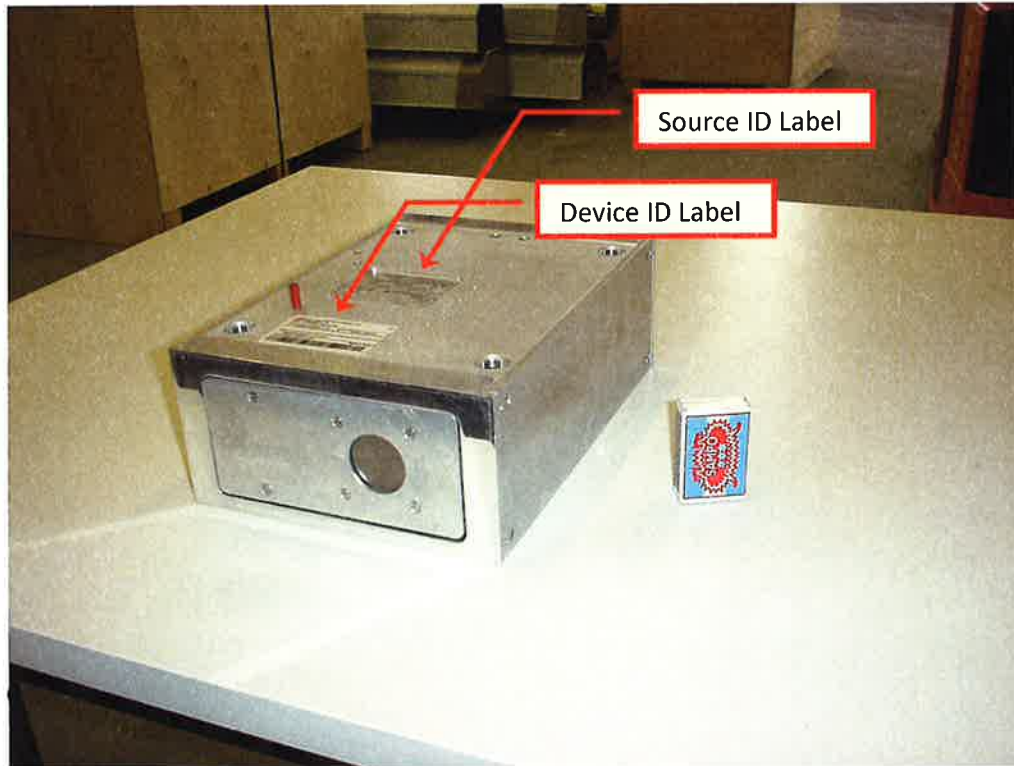


**GL Device & Source  
Label**

**GL Regulations  
Label**

b. NR-0596-D-114-G: PaperLab Filler Module

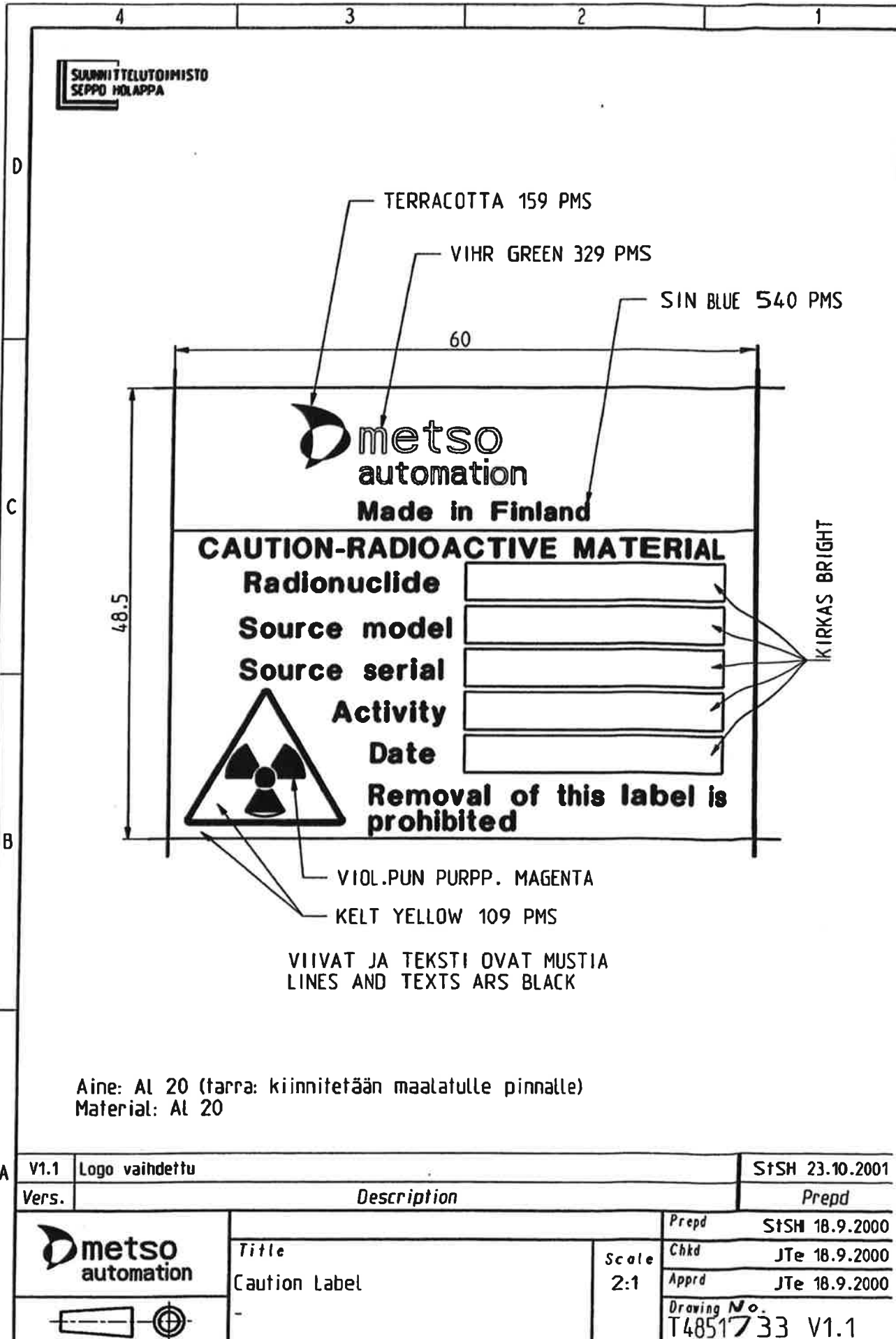
The Source ID Label has the same general design as the PaperIQ Source ID Labels in Certificate NR-0596-D-113-G and can be manufactured in either aluminum or stainless steel. The Device ID label is made of a durable fiber or vinyl and is attached to the device on the same side as the Source ID label. The location of the Source and Device Labels are shown below.



**Device ID Label**

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(c) Metso Automation 2001

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(c) Metso Automation 2001

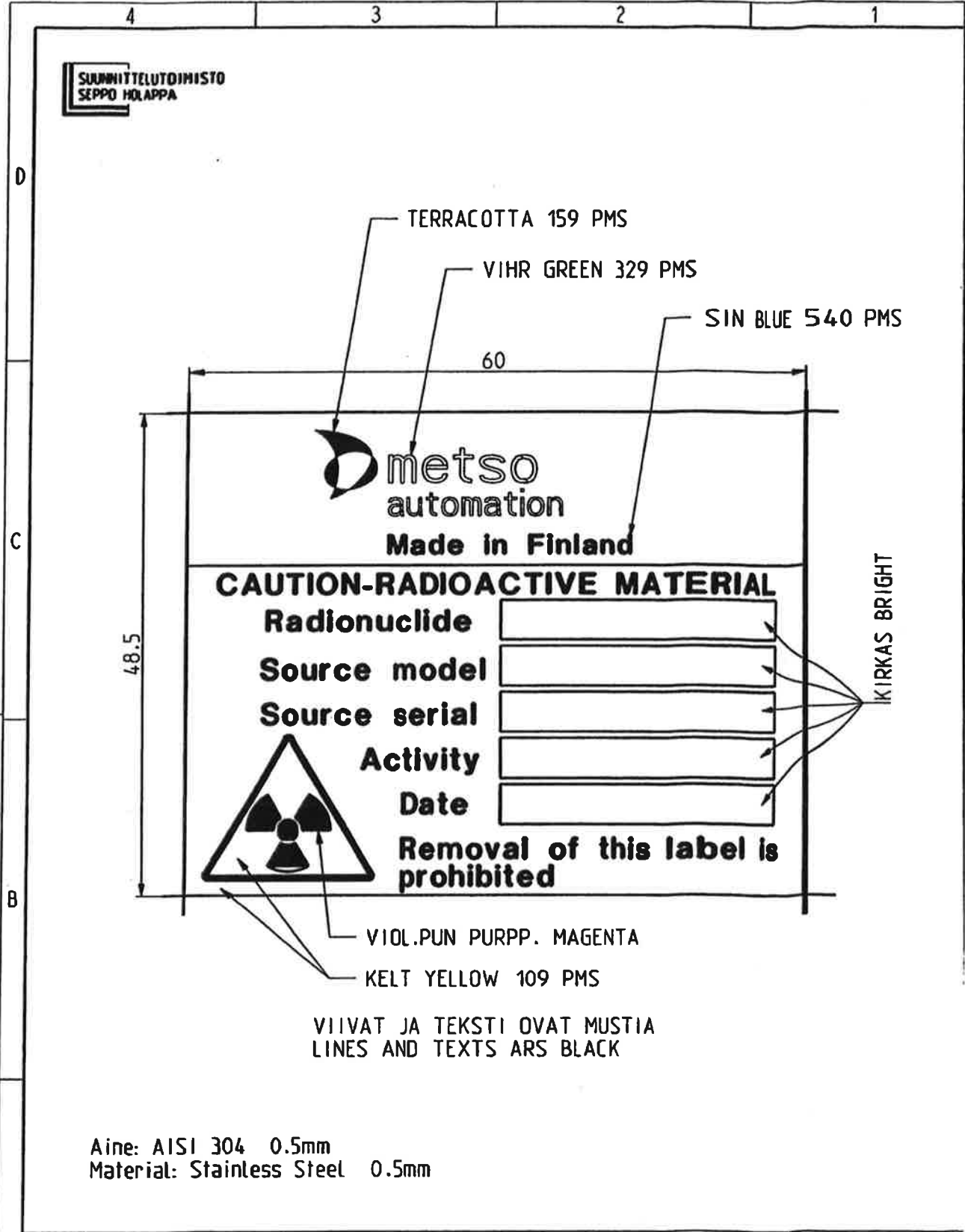


Aine: Al 20 (tarra: kiinnitetään maalatulle pinnalle)  
Material: Al 20



V1.1	Logo vaihdettu	StSH 23.10.2001
Vers.	Description	Prepd
	Title Caution Label	Prepd StSH 18.9.2000
		Chkd JTe 18.9.2000
	Scale 2:1	Apprd JTe 18.9.2000
		Drawing No. T4851733 V1.1

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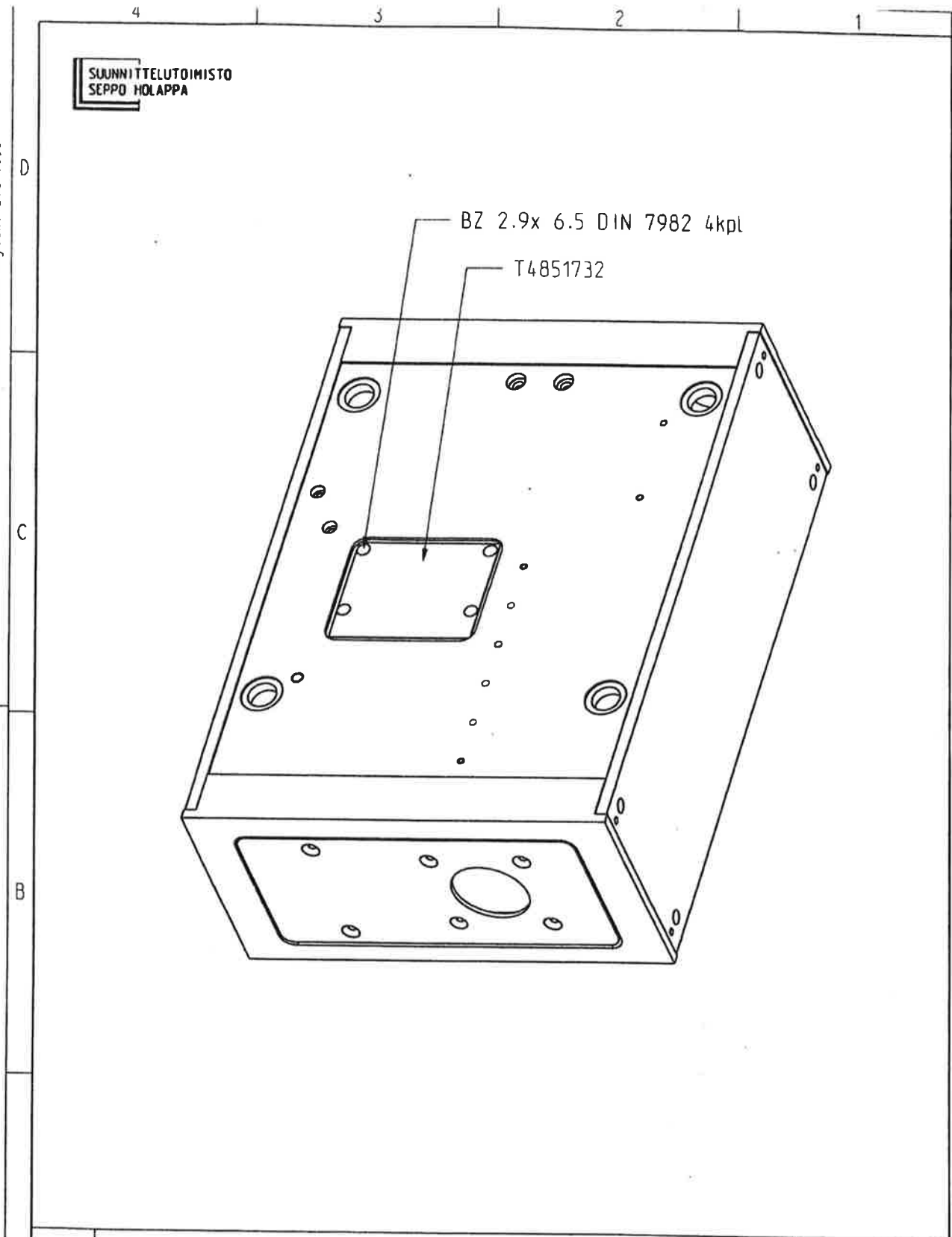
A	V1.1	Logo vaihdettu	StSH 23.10.2001
	Vers.	Description	Prepd
			StSH 18.9.2000
			JTe 18.9.2000
			JTe 18.9.2000
			Drawing No.
			T48517 32 V1.1



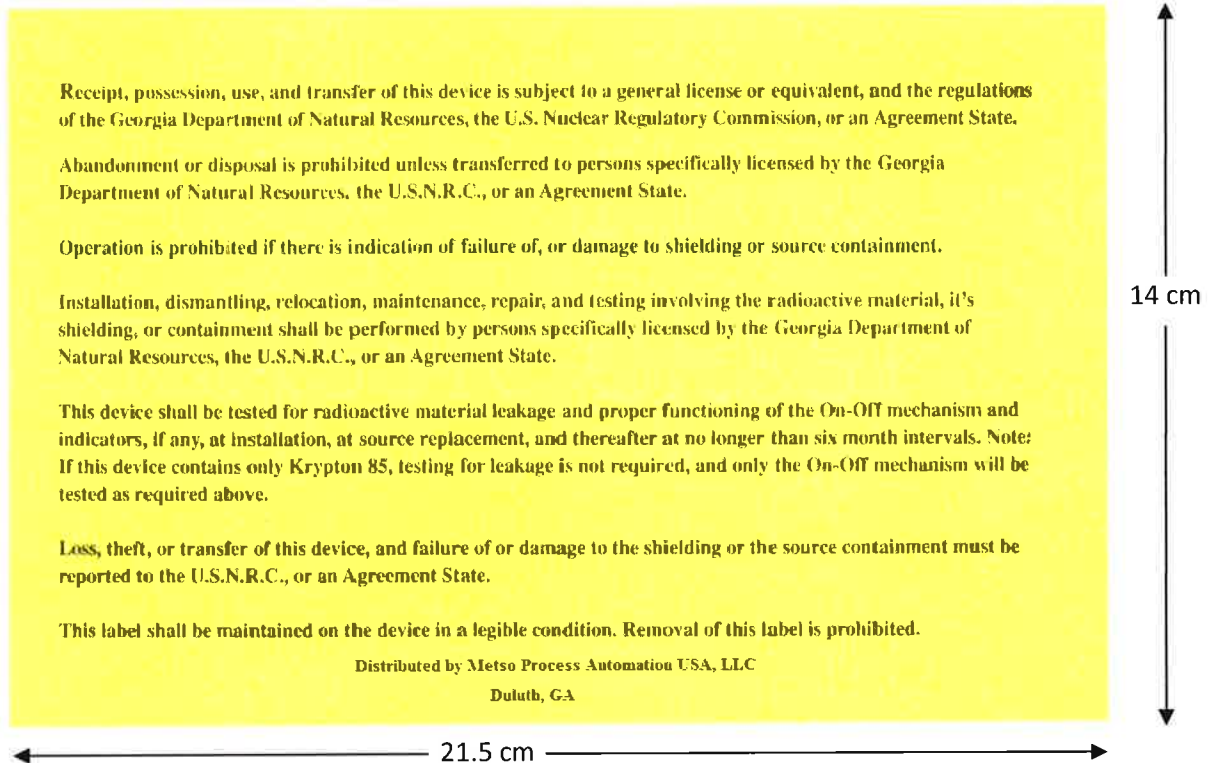
This document must not be copied without our written permission, and the contents thereof must not be imparted to a third party or be used for any unauthorized purpose (c) Valmet Automation Kajaani Ltd 1996

Tämä asiakirja ei saa ilman meidän lupaamme jäljennä. Siinä ei myöskään saa esittää toiselle tai muutoin asiattomasti käyttöä. (c) Valmet Automation Kajaani Oy 1996

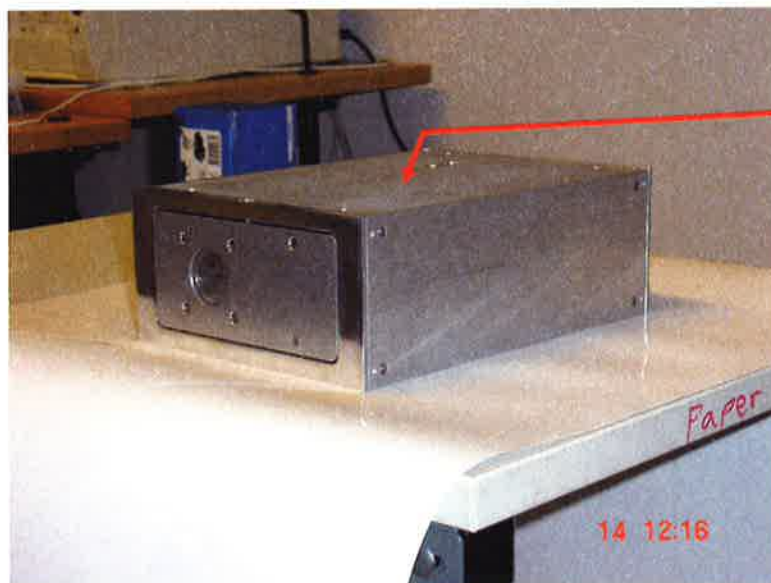


Vers.		Description		Prepd	
		Caution Label Placing		SISH 18.9.2000	
			Title		
			Scale 1:2		
			Prepd		
			Chkd		
			Apprd		
			Drawing No. 20.9.2000		
			K4851730 V1.0		

The GL Rules and Regulations Label is attached to the device on the opposite side of the device from the Source and Device ID Labels. The following is an example of the label with the name and location of the distributor identified.



The Label will be located on the sensor as shown, opposite the Source and Device ID Labels.



GL Rules & Regs Label



### Quality Assurance

7. Metso Automation Oy is an ISO 9001:2008 certified manufacturing company. Each of their manufacturing facilities in Tampere and Kajanni are covered under this QA Program. The facilities are certified and audited by Det Norske Veritas (DNV GL), a global Quality Assurance Corporation. Through their Quality Assurance Program, we are ensured of receiving equipment whose materials, construction, and final assembly are inspected, tested, and meet the design specifications.
  - a. Once the equipment is received and installed at the customer site, Metso Automation USA, Inc. installs the sealed sources and ensures that the final radiological tests and inspections are performed successfully prior to turning the equipment over to the customer:
    - i. A final visual inspection is performed of all components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions.
    - ii. An inspection is performed to ensure proper labeling is affixed to the equipment as required
    - iii. The final product is leak tested to 185 Bq (0.005  $\mu$ Ci)
    - iv. A radiation profile is performed to assure radiation levels do not exceed the maximum values stated in the application.
    - v. A final test is performed, including the shutter test to ensure all safety systems work as intended
  - b. Metso Automation USA, Inc. will maintain records in the U.S. as required by the provisions set forth in 10CFR 110.53(b), for future regulatory review.
  - c. In accordance with the guidance in NUREG-1556, Volume 3, Revision 1, Section 10.7, "Quality Assurance and Quality Control", Metso automation USA, Inc. will evaluate Metso Automation's Quality Assurance program in Finland, and will perform periodic audits of the facility in Finland.



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# DNV BUSINESS ASSURANCE

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# MANAGEMENT SYSTEM CERTIFICATE

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Certificate No. 76162-2010-AQ-FIN-FINAS

*This is to certify that*

## **METSO AUTOMATION OY PROCESS AUTOMATION SYSTEMS**

**Lentokentänkatu 11, 33900 Tampere; Finland**

*has been found to conform to the Management System Standard:*

**ISO 9001:2008**

*This Certificate is valid for the following product or service ranges:*

**Sales, development, project execution, manufacturing and customer service of process automation systems.**

*Initial Certification date:*  
02 December 1992 – 03 June 2014

*This Certificate is valid until:*  
31 December 2017

*The audit has been performed under the supervision of*

**Mariusz Pisera**  
*Lead Auditor*



*Place and date:*  
Espoo, 29 December 2014

*for the Accredited Unit:*  
DNV GL BUSINESS ASSURANCE  
FINLAND OY AB

**Kimmo Haarala**  
*Management Representative*

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

DNV GL BUSINESS ASSURANCE FINLAND OY AB – KEILASATAMA 5, 02150 ESPOO, FINLAND - +358 10 292 4200 - WWW.DNVBA.FI



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# DNV BUSINESS ASSURANCE

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## APPENDIX TO CERTIFICATE

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This Appendix refers to Certificate No. 76162-2010-AQ-FIN-FINAS

### **METSO AUTOMATION OY PROCESS AUTOMATION SYSTEMS**

locations included in the certification are as follows:

Metso Automation Gmbh, Franzosengraben 12,1030 Vienna; Austria  
Metso Process Automation Canada Ltd., 8161 Keele Street, Unit 1, L4k 1z3 Vaughan; Canada  
Metso Automation S.R.O., Zeleny Pruh 95/97, 140 00 Prague 4; Czech Republic  
Metso Automation Oy, F. O. Virtasenkatu 6, 55100 Imatra; Finland  
Metso Automation Oy, Kehräämöntie 3, 87100 Kajaani; Finland  
Metso Automation Oy, Elektroniikkatie 9, 90570 Oulu; Finland  
Metso Automation S.A., Pas Division 84 Rue De Venteille, 33187 Le Haillan Cedex; France  
Metso Process Automation Deutschland Gmbh, Max-Delbrück-Str. 3, 51377 Leverkusen; Germany  
Metso Process Automation Deutschland Gmbh, Raiffeisenallee 5, 82041 Oberhaching; Germany  
Metso Automation As, Teglverksveien 7, 3400 Lier; Norway  
Metso Automation Polska Sp. Z O.O., Ul. Kosciuszki 1c, 44-100 Gliwice; Poland  
Metso Industrial Control System (Shanghai) Co., Ltd., 261 Meiyue Rd, 200131 Shanghai; China  
Metso Automation Ltd., 2 Lindenwood, Crockford Lane, Rg24 8qy, Basingstoke, Hampshire; United Kingdom  
Metso Process Automation USA LLC., 2750 Morris Road, 19446 Lansdale; USA  
Metso Process Automation USA LLC., 2425 Commerce Avenue, Suite 100, 30096 Duluth; USA  
Metso Processos de Automacao do Brasil Ltda., Do Brasil Ltda., Avenida Independência, 2500 Bairro Ipora, 18087-101 Sorocaba; Brazil

*Initial Certification date:*

02 December 1992 – 03 June 2014

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*This Certificate is valid until:*

31 December 2017

---

*The audit has been performed under the supervision of*

---

**Mariusz Pisera**  
*Lead Auditor*



*Place and date:*

Espoo, 29 December 2014

---

*for the Accredited Unit:*  
DNV GL BUSINESS ASSURANCE  
FINLAND OY AB

---

**Kimmo Haarala**  
*Management Representative*

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

DNV GL BUSINESS ASSURANCE FINLAND OY AB – KEILASATAMA 5, 02150 ESPOO, FINLAND - +358 10 292 4200 - WWW.DNVBA.FI



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# DNV BUSINESS ASSURANCE

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# MANAGEMENT SYSTEM CERTIFICATE

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Certificate No. 46394-2009-AE-FIN-FINAS

*This is to certify that*

## **METSO AUTOMATION OY PROCESS AUTOMATION SYSTEMS**

**Lentokentänkatu 11, 33900 Tampere; Finland  
Kehräämöntie 3, 87100 Kajaani; Finland**

*has been found to conform to the Management System Standard:*

**ISO 14001:2004**

*This Certificate is valid for the following product or service ranges:*

**Sales, development, project execution, manufacturing and customer service of process automation systems.**

*Initial Certification date:*

**13 September 2000 –  
11 February 2009**

*This Certificate is valid until:*

**31 December 2017**

*The audit has been performed under the supervision of*

**Jari Hallstén  
Lead Auditor**



*Place and date:*

**Espoo, 29 December 2014**

*for the Accredited Unit:*  
**DNV GL BUSINESS ASSURANCE  
FINLAND OY AB**

**Kimmo Haarala  
Management Representative**

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

DNV GL BUSINESS ASSURANCE FINLAND OY AB – KEILASATAMA 5, 02150 ESPOO, FINLAND - +358 10 292 4200 - WWW.DNVBA.FI



Safety Analysis

8. NR-0596-D-110-G: BG-V or BG-V with Air

- a. This device can be safely operated by persons not having training in radiological protection
- b. Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10CFR Part 20.
- c. Under accident conditions associated with handling, storage and use, it is unlikely that any person would receive an external radiation dose or does commitment in excess of the dose to the appropriate organ as specified in the following chart:

PART OF THE BODY	rem	Sv
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15	0.15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200	2.00
Other organs	50	0.50

9. NR-0596-D-113-G: PaperIQ Series

- a. This device can be safely operated by persons not having training in radiological protection
- b. Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10CFR Part 20.
- c. Under accident conditions associated with handling, storage and use, it is unlikely that any person would receive an external radiation dose or does commitment in excess of the dose to the appropriate organ as specified in the following chart:

PART OF THE BODY	rem	Sv
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15	0.15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200	2.00
Other organs	50	0.50



10. NR-0596-D-114-G: PaperLab Filler Module

- a. This device can be safely operated by persons not having training in radiological protection
- b. Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10CFR Part 20.
- c. Under accident conditions associated with handling, storage and use, it is unlikely that any person would receive an external radiation dose or does commitment in excess of the dose to the appropriate organ as specified in the following chart:

PART OF THE BODY	rem	Sv
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15	0.15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200	2.00
Other organs	50	0.50