Application to Amend
Materials License 20-32465-02E
and
SS&D NR-1101-D-102-E
to add
TIMON and OrthoTIMON

Response to NRC Letter dated March 2, 2015

Bruker Detection Corp.

April 27, 2015

Original

Prepared by:

IRSC
International Radiation Safety Consulting, Inc.
7 Cabot Place 3rd Floor, Stoughton, Massachusetts 02072, USA

April 27, 2015

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Eric Reber, General Engineer
Materials Safety Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852

SUBJECT: Your letter dated March 2, 2015, Request for additional information; Bruker Amendment request dated January 2, 2015

Dear Mr. Reber:

This package is in response to your subject letter and provides the details required by each of your concerns.

Our consultant is Radiation Safety Consulting, Inc. (IRSC). Its personnel are authorized to discuss our application with you on our behalf.

If you have any questions, feel free to call me at (978) 663-3660 Ext 1307 or send email to George.Gleason@BrukerDetection.US.

Sincerely,

George A. Gleason

George A. Gleason
Radiation Safety Officer

General

1. *On Page3 of your amendment request, Section 1. Summary information (10.1), you stated that the device manufacturer is Bruker Daltonik GmbH. However, the manufacturer listed in your Registration Certificate NR-1101-D-102-E is Bruker Saxonia Analytic GmbH. Please provide us with accurate manufacturer information.*

   Response: The official name of the company in Germany is (Bruker Daltonik GmbH)

Description of Product/Construction

2. *On Page 4 of your amendment request, Section 1.5 Registration of Sources as Part of a Device, you indicated that the sources listed in NR-1101-D-102-E would be used in the TIMON and OrthoTIMON device models. Please note that some of this information is inaccurate and be aware that Registration Certificate NR-136-S-185-S has been superseded by Registration Certificate MA-1059-S-185-S, issued by the Commonwealth of Massachusetts. Please provide an accurate list of sources with their corresponding source model, capsule designation (if applicable), source manufacturer, isotope, maximum activity, ANSI/ISO classification, and registration certificate number.*

   Response:

   We are aware that registration NR-136-S-185-S has been superseded by Registration Certificate MA-1059-S-185-S. We apologize for any confusion this referenced has caused.

Model	Manufacturer	Isotope	Maximum Activity	ANSI/ISO Classification	SS&D
NER-004	E&Z Isotope Products Laboratories	Ni-63	2.7 mCI (100 MBq)	77C32211	CA-0406-S-214-S
NER-004P	E&Z Isotope Products Laboratories	Ni-63	2.7 mCI (100 MBq)	77C32211	CA-0406-S-214-S
NBCD	QSA Global, Inc.	Ni-63	2.7 mCI (100 MBq)	77C4X212	MA-1059-S-185-S
BNI 3.441	RITVERC GmbH	Ni-63	2.7 mCI (100 MBq)	ISO/98/C43121	NA

3. *On Page 5 of your amendment request, Section 2. Conditions of Use (10.2), you stated that TIMON and OrthoTIMON device models can detect and identify ultralow levels of toxic chemical weapon agents and critical toxic industrial chemicals, including chlorine. On page 6 of your request Section 3 Construction of the Product (10.3), subheading Materials of Construction, you stated that localized corrosion may occur if the models are exposed to halides, particularly chlorine or chlorine compounds. Please describe what effects halides and/or chloride compounds may have on the IMS detector cell and the Ni-63 source.*

   Response: Samples introduced into the detector interface with a hydrophobic membrane layer prior to entering the ionization region. This membrane layer creates a sealed system and only

transmits a small amount of the sample vapor stream into the detector. In addition, the components in the sample path are coated to prevent corrosion from vapor samples. The localized corrosion mentioned in Section 3 Construction of the Product (10.3), subheading Materials of Construction, is made in reference to large quantities of liquid chlorine or chlorinated compounds being introduced into the detector. The IMS system only needs a small amount of sample (i.e. nanograms of material) in order to perform an analysis. If an excessive amount of sample is introduced into the pneumatic system, it will be "backflushed" out of the induction tube.

4. *The engineering drawings titled "Basic Device TIMON" and "Basic Device OrthoTIMON" provided in Attachment E, include the dimensions of both models. However, in some instances, these dimensions do not match those provided in the TIMON and OrthoTIMON Operator Manuals in Attachments I and J of your amendment request. Some of the dimensions include accessories such as wheels, air inlets, power, and Ethernet connections, while others do not. Please provide the dimensions for both models that should be referenced in your Registration Certificate.*

Response:

TIMON - The dimensions of the TIMON are given in the drawing "Basic Device TIMON" (see Attachment A). The data in the Product Specification Sheet are related to the housing without Mounting Brackets and connectors. The data in the user manual will be changed corresponding to the data of the Product Specification Sheet in the next version of the manual.

OrthoTIMON - The correct dimensions of the OrthoTIMON are given in the drawing "Basic Device OrthoTIMON" (see Attachment B). The data for the depth of the housing will be changed in the next version of the manual. The data are changed in Product Specification Sheet.

5. *In your amendment request, you stated that the "measuring tube and source configurations" for the TIMON and OrthoTIMON device models are the same as the "measuring tube and source configurations" in the Bruker RAID Series of devices listed in your current registration certificate. However, we noted that there are difference in dimensions between the IMS detection cell/"measuring tube" that are intended to be used in the TIMON and OrthoTIMON device models, and the IMS detection cell measuring tube" currently used.*

Response: Both dimensions are correct. The length of the IMS detection cell (drawing in the documents NR-1101-D-102-e) is related to the end of the membrane chamber without gas inlet connector. The drawing OR0010G003 shows the length of the cell with the gas inlet connector.

The length of the tubes can differ slightly due to the manufacturing technology. The total length including gas inlet connector is

150 $\pm$ 1 mm for the IMS cell of the RAID devices and

151 $\pm$ 1 mm for the IMS cell of the TIMON OrthoTIMON revices

6. *In the RAID Series. Please provide a description of the similarities and differences between the appropriate RAID Series of devices and TIMON and OrthoTIMON models, as well as similarities and differences between the TIMON/OrthoTIMON IMS detection cell/"measuring tube" and the RAID Series IMS detection cell/"measuring tube". A table format is preferred.*

Response: RAID & TIMON Devices Contrast and Comparison

Model	Radionuclide	Activity	Portability	Use
RAID-M100	Ni-63	2.7mCi	Portable	Field Analysis
RAID-XP	Ni-63	2.7mCi	Portable	Field Analysis
ARFCAM	Ni-63	2.7mCi	Non-portable	Facility Monitoring
RAID-AFM	Ni-63	2.7mCi	Non-portable	Facility Monitoring
RAID-S2	Ni-63	2.7mCi	Non-portable	Shipboard monitoring
IPDS-LR	Ni-63	2.7mCi	Non-portable	Shipboard monitoring
uRAID	Ni-63	2.7mCi	Portable	Field Analysis
TIMON	Ni-63	2.7mCi	Non-portable	Facility Monitoring
OrthoTIMON	Ni-63	2.7mCi	Non-portable	Facility Monitoring

RAID & TIMON Measuring Tube Contrast and Comparison

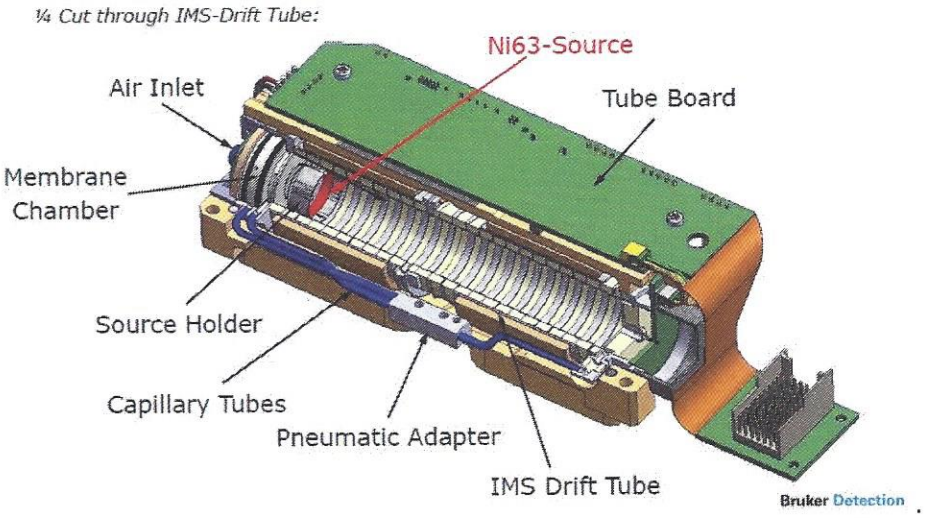
	RAID device Measuring Tube	TIMON/OrthoTIMON Measuring Tube
General design	Similar to TIMON/OrthoTIMON	Similar to RAID devices
Construction elements	Similar to TIMON/OrthoTIMON	Similar to RAID devices
Technology of the IMS tube manufacturing	Soldering	Gluing

7. *In Attachment E, you provided engineering drawings for the TIMON device model; however, you did not provide detailed engineering drawings for OrthoTIMON device model. Please provide engineering drawings with dimensions and tolerances for OrthoTIMON device model that includes the IMS detection cell/"measuring tube" and the FT-IR sensor unit.*

   Response: See Attachment C, Drawing "Basic Device OrthoTIMON Sensor Unit".

8. *Please provide an engineering drawing that shows the cross sectional view of the "measuring tube" shown in Drawing Number "OR 0100 G 003" in Attachment E. The drawing can be similar to the drawing of the IMS detection cell included in Attachment 4 of your current Registration Certificate NR-1101-D-102-E.*

   Response: See Attached D, "Measuring Tube Source Location, TIMON and OrthoTIMON".



Measuring Tube Source Location

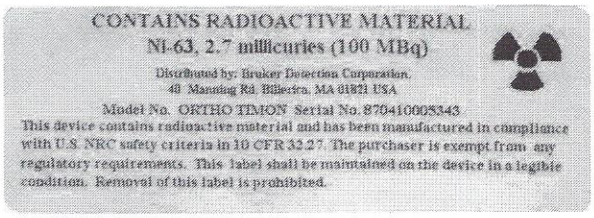
9. *On page 6 of your amendment request, you stated that "The TIMON and OrthoTIMON devices are manufactured with Bruker machined screws in the measuring tube assembly which require a Bruker tool to dismantle." Please provide details on the tamper-proofing measures. Please note that your current Registration Certificate states that the source assembly in the RAID Series of devices contains four tamper-resistant screws; please confirm if this is also the case for the TIMON and OrthoTIMON device models. If the tamper-proofing measures are different for the TIMON and OrthoTIMON device models, please provide a description.*

   Response: The Tamper-proofing measures are the same as the as previous RAID service devices the company use Torx screws which require a Bruker tool to dismantle.

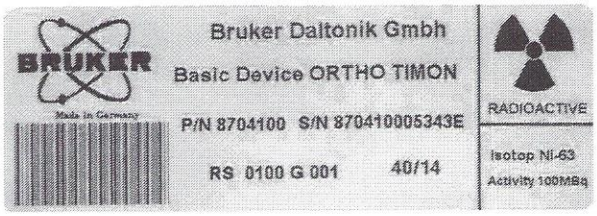
Labeling

10. *On Page7, you provided copies of the labels that will be located on the right side cabinet. Please note that the label shown in "Figure 1- Source Information Label, Cabinet Surface," contains your former distributor name "Bruker Daltonics NBC Detection Corporation." Please provide a copy of the label with the current distributor name and address.*

    Response: New labels ------- The name has been corrected



Distribution Label



Manufacturing Label

11. *On Page 8, you provided a copy of the label that will be located on the "measuring tube." Please provide the dimensions of this label.*

    Response: Measuring tube dimensions are 1.25 inches high by 1.5 inches wide.

Conditions of Use

12. *Please provide the estimated working life of the TIMON and OrthoTIMON device models.*

    Response: The recommended working life of these devices is 10 years based on the source manufacturer's recommendations after which the user should arrange for the source to be inspected and assessed by a qualified authority to extend its working life or returned to the manufacturer or other licensed disposal facility.

13. *Please provide the likely environment to which the devices will be subjected to during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during*

use, handling, storage, and transportation. In your response please include maximum allowable temperature, vibration, shock, corrosion, etc.

Response:

Environmental Parameter	TIMON Product Specification	OrthoTIMON Product Specification
Storage Temperature	-20 °C to + 60 °C	-10 °C to +60 °C
Operating Temperature	-10 °C to +50 °C	0 °C to +50 °C (*)
Operating Humidity	5% to 95% RH, non – condensing	5% to 95% RH, non – condensing
Ambient Pressure Range	400 mbar to 1400 mbar, absolute	700 mbar to 1300 mbar, absolute
Maximum Vibration	Stationary mounting, Civil use, no special data for vibration	Stationary mounting Civil use, no special data for vibration
Maximum Shock	Stationary mounting, Civil use, no special data for maximum shock	Stationary mounting Civil use, no special data for maximum shock
Maximum Corrosion	no special data for corrosion	no special data for corrosion

14. *Please describe the actions to be taken at the end of the working life of the TIMON and OrthoTIMON device models.*

Response: The recommended working life of these devices is 10 years based on the source manufacturer's recommendations. The end user many dispose of the device as normal refuse at the end of its useful life or it may be returned to the manufacturer or other licensed disposal facility.

15. *On Page5 of your amendment request, Section 2, Conditions of Use (10.2), you stated that both the TIMON and OrthoTIMON device models are permanently installed air monitoring systems. However, in the OrthoTIMON product brochure in Attachment D, you stated that OrthoTIMON device model can be mounted on a "transportable frame" to permit it to be taken to assembly rooms and other areas. Please clarify this discrepancy. If the OrthoTIMON device model is to be registered as a movable device, please (1) describe how the device is to be mounted to "the transportable frame" and (2) provide the maximum conditions of use for the OrthoTIMON device model in the case that it is mounted on a "transportable frame."*

Response: In the U.S. market, both of the TIMON and OrthoTIMON shall only be sold as stationary instruments and not as mobile devices.

Prototype Testing/Historical Use

16. *On Page9 of your amendment request, Section 5 Prototype Testing (10.5), you stated that the same "measuring tube and source configurations" have been provided in Bruker's RAID Series devices currently listed in your Registration Certificate. However, you have not provided sufficient information about the prototype testing for the TIMON and OrthoTIMON device models, as required by 10 CFR 32.26 (b)(11) and (12) and by 10 CFR 32.210 (c). You may provide justification as to why prototype testing for theTIMON and OrthoTIMON device models is not necessary; this may include a comparison to the registered models in the RAID series. The guidance in NUREG-1556, Volume 3, Revision 1, Section 10.5, "Prototype Testing," provides the various methods of prototype testing that are acceptable to the NRC. Alternatively, you may provide a copy of the device testing referenced in Attachment B for both the TIMON and OrthoTIMON device models.*

Response: The following tests were performed with TIMON/OrthoTIMON devices:

Prototype Testing	TIMON	OrthoTIMON
EMC, Emission corresponding EN 61326-1	Passed	Passed
EMC, Immunity corresponding EN 61326-1,	Passed	Passed
IP Degree	IP 42	IP 42
Climatic Tests corresponding IEC 60068-2-1, IEC 60068-2-2	passed	passed
Safety corresponding EN 61010-1	passed	passed

See attached documents:

- Test Report, EMC, OrthoTIMON, Attachment E1
- Test Report, EMC, TIMON, Attachment E2
- Test Report, Environmental Tests, TIMON, Attachment E3
- Test Report, IP Test, OrthoTIMON, Attachment E4

17. *The test certificates in Attachment B of your amendment request indicated that the ISO 2919 classification for the TIMON and OrthoTIMON device models is C22222. Please clarify whether this classification is for the IMS detection cell/"measuring tube", the sensor unit, or the entire device.*

Response: The classification is for the measuring cell of the TIMON and OrthoTIMON is C22222.

Radiation Profiles

18. *In Attachment G of your amendment request, you stated that the calibration due dates for the Ludlum Model 3 survey meter and the Ludlum Model 9DP1 survey meter are 6/30/2014 and 2/21/2014. These*

calibration due dates differ from those provided in the certificates of calibrations for both survey meters. Please clarify the due date discrepancy for both survey meters.

Response: The Radiation Profiles used the Calibration date from the calibration certificates rather than the Calibration Due dates. See Attachment F.

19. *The radiation profiles provided in Attachment G of your amendment request identify the Model surveyed as TIMON. Please clarify if both TIMON and OrthoTIMON device models were surveyed. If only the TIMON device model was surveyed, please explain why only this model was surveyed and how the radiation profiles are applicable to the OrthoTIMON device model. If the OrthoTIMON device model was surveyed, please provide the radiation profiles.*

Response: See Attachment G radiation profiles for the OrthoTIMON.

Quality Assurance

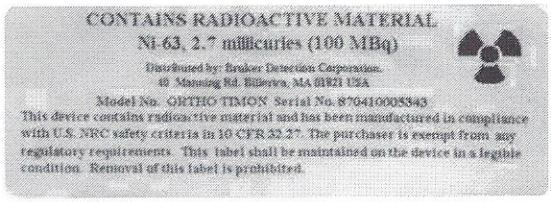
20. *Please confirm that there have been no changes to the Quality Assurance program that Bruker Detection Corporation committed to in Registration Certificate NR-1101-D-102-E.*

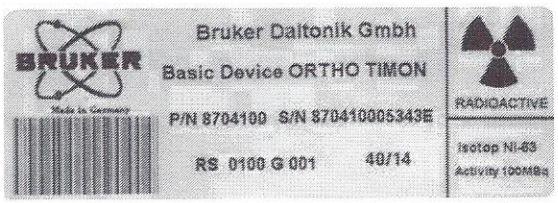
Response: There have been no changes to the quality assurance program that we committed to in registration NR-1101-d-102-E

Accompanying Documentation

21. *Figure 2-3 in Section 2.5.1 of the TIMON Operator Manual and Figure 2-5 in Section 2.6.1 of the OrthoTIMON Operator Manual identify the location of the labels that will be included on both devices. However, neither operator manual references the label required by 10CFR32.29, which Bruker committed to including on each device on Page7 of 11 in the amendment request. Please provide revised Operator Manuals for both devices that include all of the labels required for distribution in the U.S.*

Response: Bruker Detection Corp will include the following labels on the enclosure and in an insert for each of the instrument operator manual for each device sold in the united states.





REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE

22. *In Item 1.5, Registration of Sources as Part of a Device, of your application you wrote that, in addition to other sources, Isotope Products Laboratories Model NER-004 or Model NER-004P sources would be used in the devices. Sealed Source and Device Registration Certificate No. NR-1101-D-102-E and License No. 20-32465-02E list the manufacturer of these source models as "Eckert & Ziegler Isotope Products, Inc."*

    Please confirm the name of the manufacturer of the Model NER-004 and NER-004P sealed sources.

    Response: The manufacturer of the Model NER-004 and NER-004P sealed sources is Eckert & Ziegler Isotope Products, Inc.

23. *10 CFR 32.26 (b)(8) requires that applications include the total quantity of byproduct material expected to be distributed in the product annually.*

    Your application did not address the requirement of 10 CFR 32.26 (b)(8).

    Please provide the total quantity of byproduct material expected to be distributed in the product annually.

    Response: The marketing projection is to sell 24 instruments a year. Projected total activity is 64.8 mCi (2.4 GBq).

24. *10 CFR 32.29(b)(1)(i) requires that each person licensed under 10 CFR 32.26 shall label or mark each detector so that each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing the following statement: "CONTAINS RADIOACTIVE MATERIAL."*

    Contrary to the above, the device labels submitted in section 4.1 of your application do not meet the requirement of 10 CFR 32.29(b)(1)(i).

    Please provide labels, copies of labels, or markings that meet the requirement in 10CFR32.29(b)(1)(i).

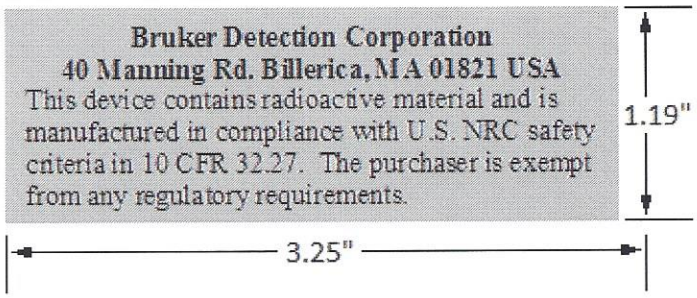
    Response: Corrected. See the "Distribution Label" above.

25. *10 CFR 32.29 (b)(3) requires that the external surface of the point-of-sale package has a legible, readily visible label or marking containing the items in 10CFR 32.29(b)(3)(i), (ii),and (iii).*

    Your application did not address the requirements in 10 CFR 32.29 (b)(3) concerning point of-sale labeling and marking.

    Please provide labels, copies of labels, or markings that meet the requirements in 10CFR 32.29 (b)(3) for point-of-sale packages.

    Response: The following label will be attached to the point of sale package.



Point of Sale Package Label

26. *10 CFR 32.27 requires that an applicant for a license under 10 CFR 32.26 shall demonstrate that the product is designed and will be manufactured so that the requirements of 10 CFR 32.27 are met.*

In Attachment H, External and Internal Dose Calculations, of your application you provided information concerning external and internal doses that may be received by an end user of a Bruker TIMON device and also provided information concerning possible incineration of the device, but the information you provided is not oriented toward all of the specific safety criteria of 10 CFR 32.27. Furthermore, the OrthoTIMON device was not addressed within this context.

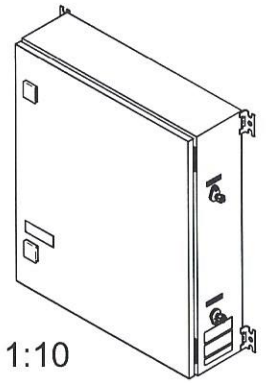
Please provide additional information for the Bruker TIMON and OrthoTIMON devices to demonstrate that these products are designed and will be manufactured so that each of the specific safety criteria in 10CFR32.27 are met In preparing your response, you should address each of the specific circumstances described in 10CFR 32.27. You may wish to consultsection2.15 of NUREG-1717, Systematic Radiological Assessment of Exemption for Source and Byproduct Materials, which provides guidance on meeting the safety criteria of 10 CFR 32.27.

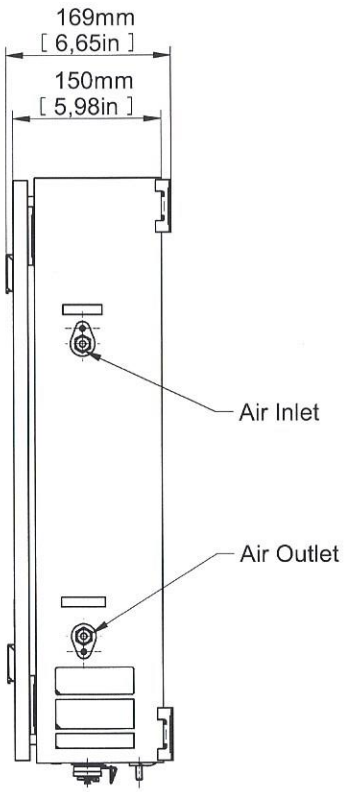
Response: See Attachment H - "Bruker TIMON and OrthoTIMON Response to NRC Questions"

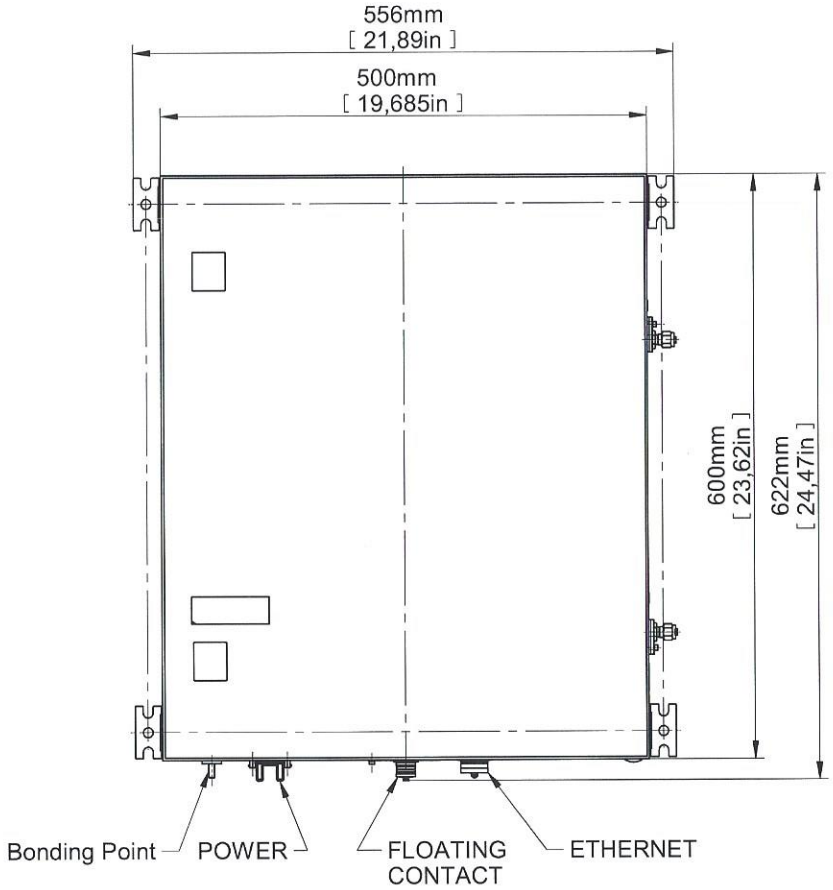
27. *In the Estimated Use Time Basis section of your application, you wrote, "63Ni is a low energy, pure beta-emitting radioisotope. Therefore there is no radiation from the source that is detectable outside the TIMON metal cabinet (Fig.1). In the TIMON Preregistration Survey you wrote that external dose rates were indistinguishable from background dose rates. However, in paragraph 3.a., you wrote, "Direct bremsstrahlung radiation measurements were made with the device intact, source installed. At a distance of 5 cm, the measured dose rate was 0.1 mrem per hour."*

Please provide additional information that clarifies these seemingly contradictory statements with regard to external dose rates. In preparing your response, you may wish to consult section 2.15.5 of NUREG-1717, Systematic Radiological Assessment of Exemption for Source and Byproduct Materials, which addresses external dose rates from gas and aerosol detectors containing Ni-63.

Response: See Attachment H - "Bruker TIMON and OrthoTIMON Response to NRC Questions".

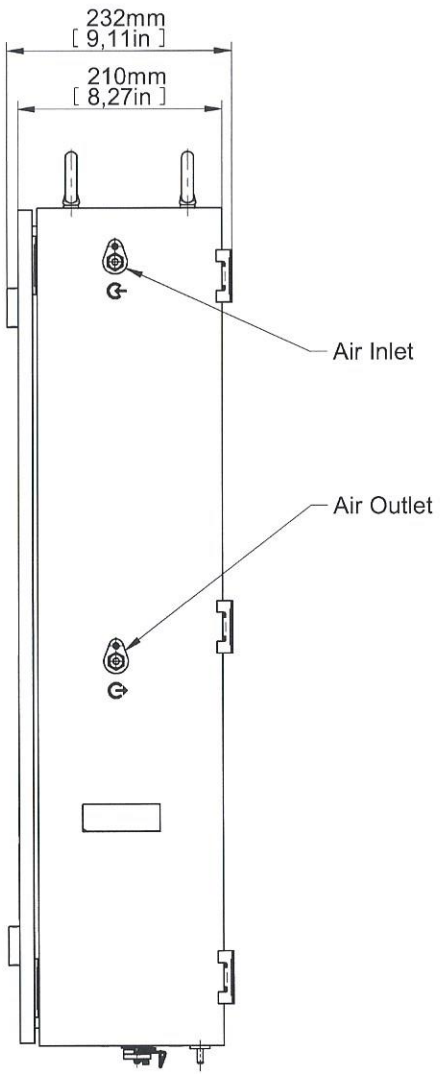


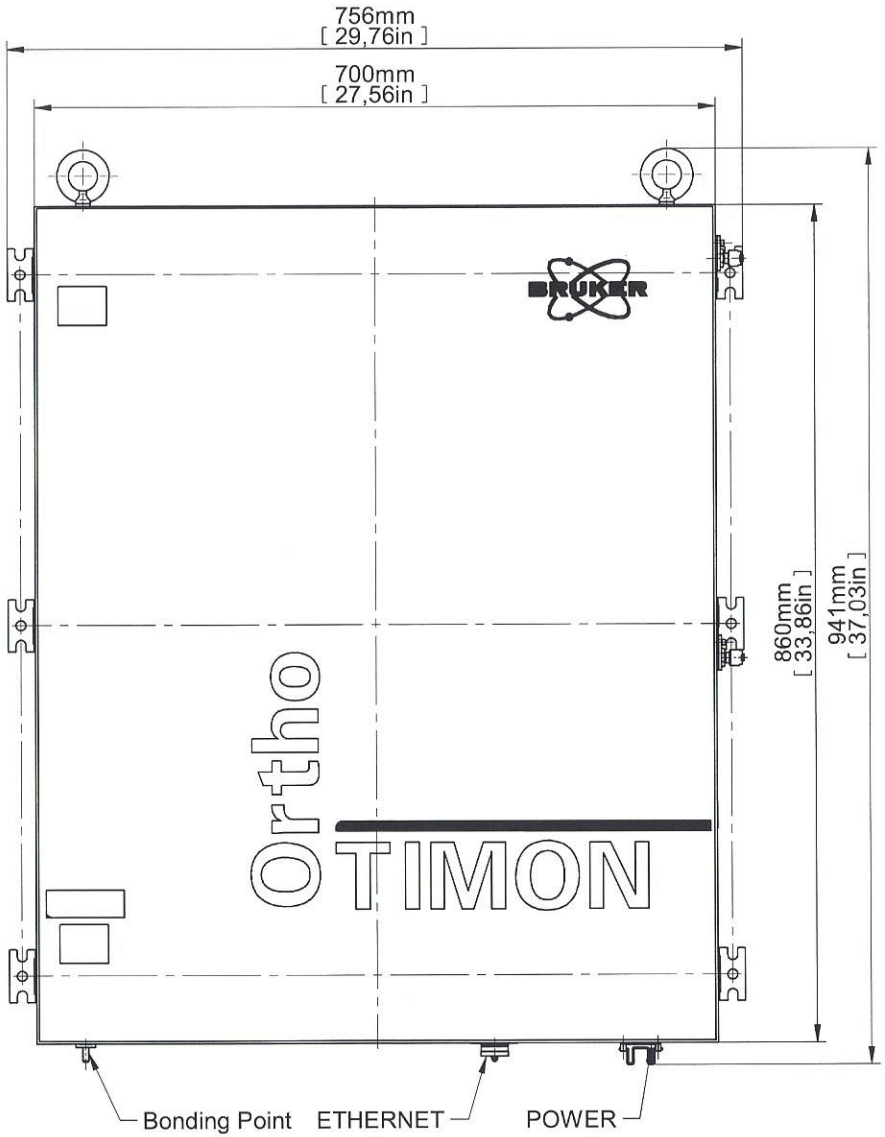


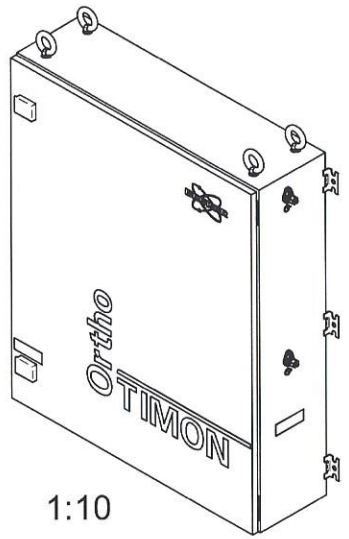


Document: Assembly Drawing		Scale: 1:5	Drawn: Heike.Matthes	Technical Reference: Matthes		Approved: Burgartz
BRUKER	Title: Basic Device TIMON					Material Number:
	Document Number: TM 0010 G 001	Revision: A	Date: 11.12.2014	Language: eng	Sheet: 1/1	Weight: 21,374 kg ±5%

A3



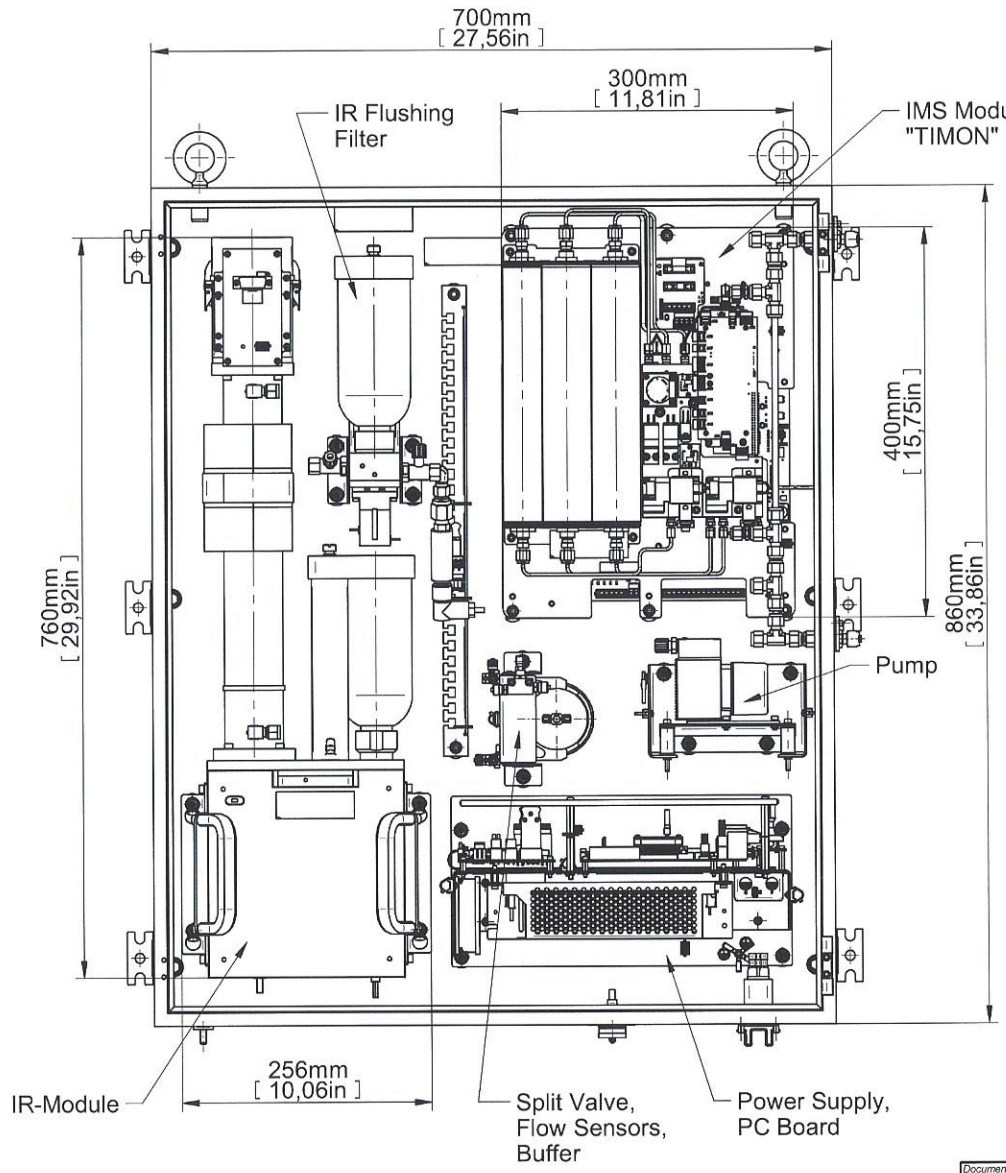


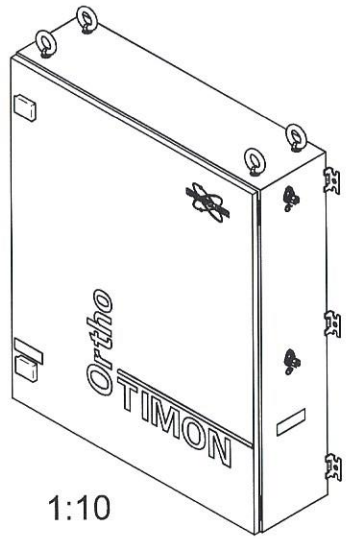


1:10

Document: Assembly Drawing		Scale: 1:5	Drawn: Heike.Matthes	Technical Reference: Matthes	Approved: Burgartz	
BRUKER	Title: Basic Device OrthoTIMON					Material Number:
	Document Number: OR 0010 G 001	Revision: A	Date: 30.04.2014	Language: eng	Sheet: 1/1	Weight: 53,293 kg ±5%

A3





1:10

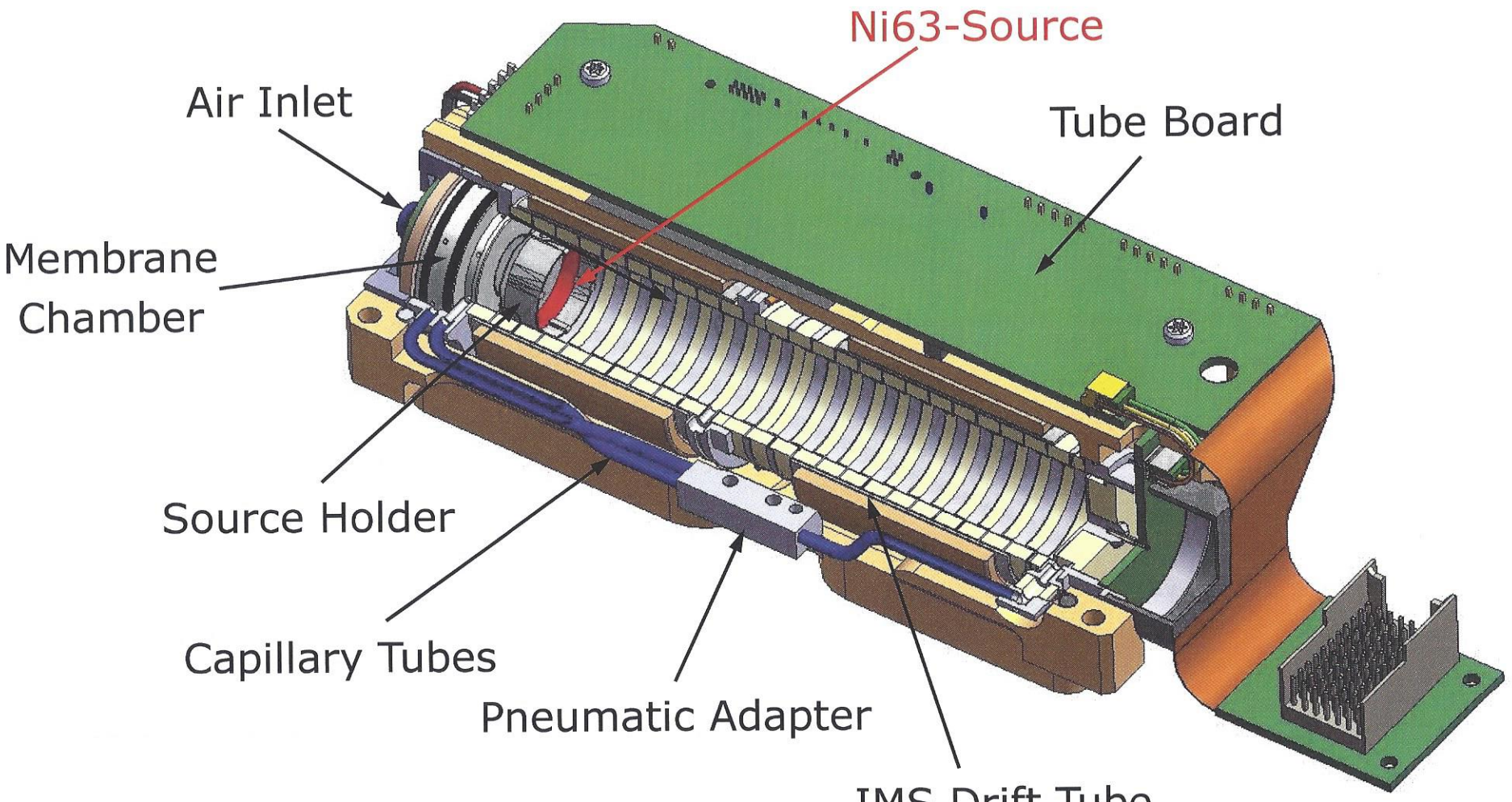
Document: Assembly Drawing		Scale: 1:5	Drawn: Heike.Matthes	Technical Reference: Heike.Matthes		Approved: Burgartz
BRUKER	Title: Basic Device OrthoTIMON					Material Number:
	Document Number: OR 0010 G 005	Revision: A	Date: 20.04.2015	Language: eng	Sheet: 1/1	Weight: 53,583 kg ±5%

A3

TIMON/OrthoTIMON

2.1 Location of the radioactive Ni63-source

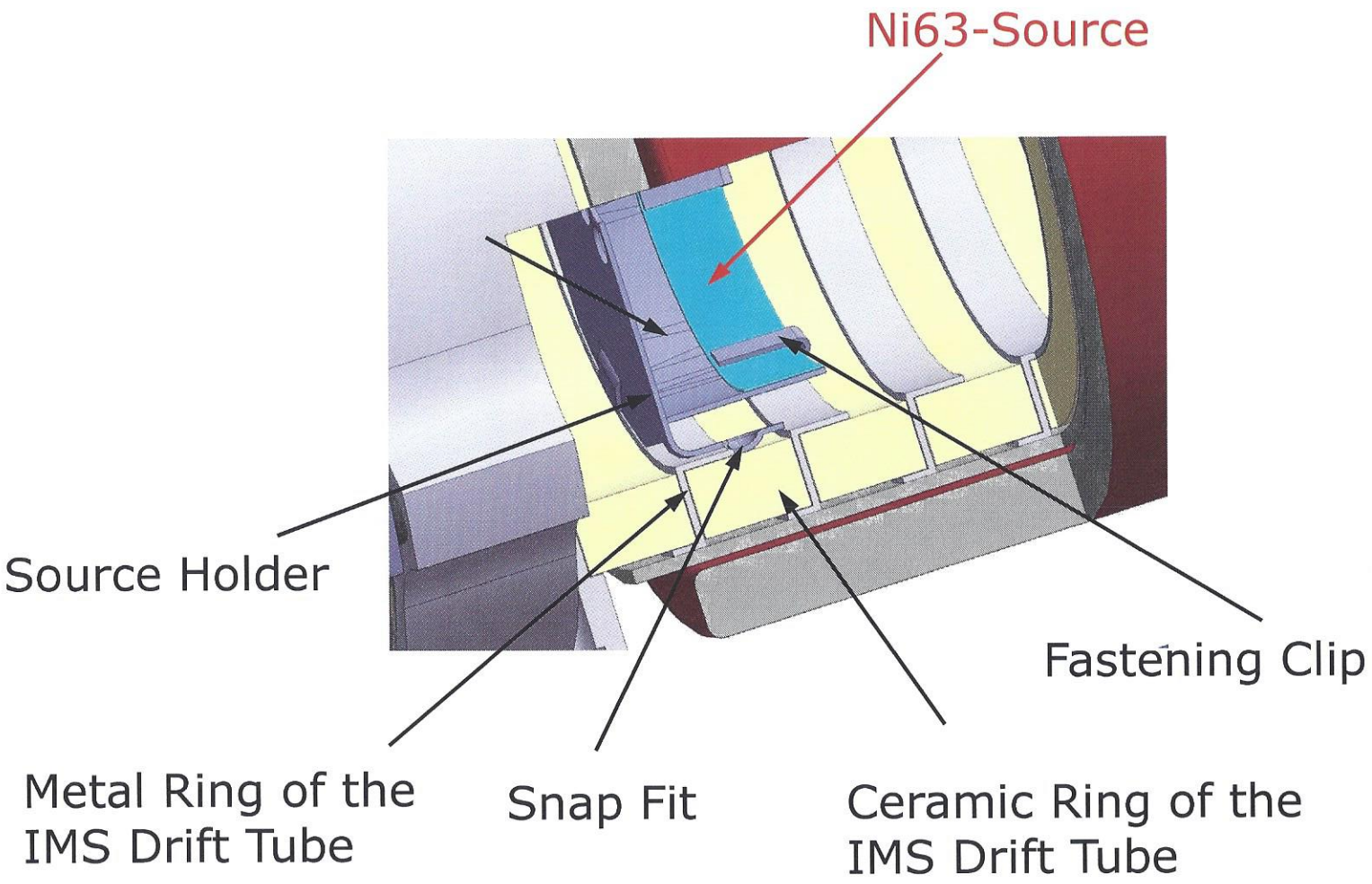
¼ Cut through IMS-Drift Tube:



TIMON/OrthoTIMON

2.1 Fixation of the radioactive Ni63-source

Part of the IMS-Drift Tube:



TIMON/OrthoTIMON

2.2 Description of the Components

Radiation Source:

- Ni-63, 100 MBq
- Dimension: 48mm x 3mm x 0.1mm
- Ni-63 electrodeposited on an inactive Nickel foil
- Source is placed in a cylindrical source assembly made of high-grade steel
- Source is fixed by 6 fastening clips
- Source holder is fixed by 4 snap fits at the IMS tube
- Source holder is inserted into the IMS tube by a special tool. After removing of the tool the snap fits latch at the predetermined position.
- Sources are provided by the companies Eckert & Ziegler or RITVERC with part and serial numbers and corresponding certificates

Measuring Tube:

- Construction, dimensioning and material of the measuring tube provide a safe enclosure and a protected-type covering of the radiation source (ISO 2919 Classification: C22222)
- Consists of brazed ceramic and metal rings
- Contamination test after inserting of the source
- Leakage test after final assembling

TIMON/OrthoTIMON

2.2 Description of the Components

Pneumatic Module:

- Consists of
  - Measuring tube
  - Pneumatic block (aluminum alloy)
  - Drying filter (contains molecular sieve)
- The source is located in the closed inner gas circuit
- The membrane forms the connection between the inner and outer gas circuit

Protected-type enclosure

- The radiation source cannot be removed without wilful damaging
- The construction provides protection against accidental access by unauthorized persons

Test protocol: 1074-14-EE-14-PP002
Dated: 2014-04-10
Test engineer: Schubert, M.

SLG Prüf- und Zertifizierungs GmbH

Customer: Bruker Daltonik GmbH
Permoserstrasse 15
04318 Leipzig, Germany

Contact person:
Beyer, Achim
Phone: 0341 2431-551

Order/Contract: 4500355353

Manufacturer: Bruker Daltonik GmbH
Permoserstrasse 15
04318 Leipzig, Germany

Test acc. to: Test plan of customer "Test Plan for OrthoTIMON_Rev 2" dated 2014-04-09
With reference to:
IEC 61326-1:2012

Directive:
☐ EMC ☐ MDD
☐ R&TTE ☐ car .....
☐ LVD ☐ .....

Kind of test:
☐ CE EMC type test ☐ CE EMC random test ☐ R&D test ☐ Partial tests
☐ Standard type test ☐ Statement of notified body ☐ Test plan of notified body ☑ Test plan of customer
☐ Expert valuation ☐ CB EMC Scheme

Test sample:
Kind of product: Detection system
Type: OrthoTIMON
Serial No.: 870410004703
Protection class: I
Version of sample: .....
Date of delivery: 2014-04-08

Duration of test: from 2014-04-08 to 2014-04-10 **Date of test stage:** .....

Emission		Standard	Remark	Pass	Fail
Radio frequency disturbance voltage	☑	CISPR 11	Group 1, class B	☑	☐
Radio frequency disturbance current	☑	CISPR 22	Class B	☑	☐
Radiated electromagnetic field strength	☑	CISPR 11	Group 1, class B	☑	☐
Harmonics	☑	IEC 61000-3-2	Class A	☑	☐
Voltage fluctuations and flicker	☑	IEC 61000-3-3		☑	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐
Immunity					
ESD	☑	IEC 61326-1	Requirements of table 2	☑	☐
Burst (fast transients)	☑	IEC 61326-1	Requirements of table 2	☑	☐
Surge 1.2/50 µs	☑	IEC 61326-1	Requirements of table 2	☑	☐
Injected currents	☑	IEC 61326-1	Requirements of table 2	☑	☐
Radiated electromagnetic fields	☑	IEC 61326-1	Requirements of table 2	☑	☐
Magnetic field with power frequency	☑	IEC 61326-1	Requirements of table 2	☑	☐
Voltage dips and interruptions	☑	IEC 61326-1	Requirements of table 2	☑	☐
	☐			☐	☐
	☐			☐	☐
	☐			☐	☐

Test result: ☑ Pass ☐ Fail ☐ without

Remark: This test protocol is only a brief information. All information on the performed EMC tests and the description of the test sample are part of the complete EMC test report 1074-14-EE-14-PB001.

tested:

Schubert, M.
EMC-Lab

Test protocol: 1046-12-EE-12-PP002
Dated: 2012-03-02
Test engineer: Wittwer

SLG Prüf- und Zertifizierungs GmbH

Customer: Bruker Daltonik GmbH
Permoserstrasse 15
04318 Leipzig, Germany

Contact person:
Voigt, Thomas
Phone: 0341-2431-478

Order/Contract: EB105-29935

Manufacturer: Bruker Daltonik GmbH
Permoserstrasse 15
04318 Leipzig, Germany

Test acc. to: Customer's test plan "Project hardware Quality Plan" TM 0100G 001, revision 01 (2012-02-02) + additional arrangements during the test, referring to: EN 61326-1:2006

Directive:
☑ EMC ☐ MDD
☐ R&TTE ☐ car .....
☐ LVD ☐ .....

Kind of test:
☐ CE EMC type test ☐ CE EMC random test ☐ R&D test ☐ Partial tests
☐ Standard type test ☐ Statement of notified body ☐ Test plan of notified body ☑ Test plan of customer
☐ Expert valuation ☐ CB EMC Scheme

Test sample:
Kind of product: Gas trace detector
Type: Basic Device TIMON (276300 / TM 0100G 001)
Serial No.: 27630003983 Version of sample: ---
Protection class: I Date of delivery: 2012-02-21

Duration of test: from 2012-02-21 to 2012-02-22 **Date of test stage:** ---

Emission		Test plan referring to standard:	Remark	Pass	Fail
Radio frequency disturbance voltage	☑	EN 61326-1	Limits acc. CISPR 11, Group 1, Class B	☑ 21.02.	☐
Radiated electromagnetic field strength	☑	EN 61326-1	Limits acc. CISPR 11, Group 1, Class B	☑ 21.02.	☐
Harmonics	☑	EN 61326-1	Limits acc. EN 61000-3-2, Class A	☑ 22.02.	☐
Voltage fluctuations and flicker	☑	EN 61326-1	Limits acc. EN 61000-3-3	☑ 22.02.	☐
Immunity					
ESD	☑	EN 61326-1	Industrial requirements	☑ 22.02.	☐
Burst (fast transients)	☑	EN 61326-1	Industrial requirements	☑ 22.02.	☐
Surge 1.2/50 µs	☑	EN 61326-1	Industrial requirements	☑ 22.02.	☐
Injected currents	☑	EN 61326-1	Industrial requirements	☑ 21.02.	☐
Radiated electromagnetic fields	☑	EN 61326-1	Industrial requirements	☑ 21.02.	☐
Voltage dips and interruptions	☑	EN 61326-1	Industrial requirements	☑ 22.02.	☐
Magnetic field with power frequency	☑	EN 61326-1	Industrial requirements	☑ 22.02.	☐

Test result: ☑ Pass ☐ Fail ☐ without

Remark: This test protocol is only a brief information. All information on the performed EMC tests and the description of the test sample are part of the complete EMC test report.

approved:
Cromm
EMC-Lab

tested:
Wittwer
EMC-Lab

TESTING THE WORLD
FOR TOMORROW

Customer:

Bruker Daltonik GmbH
Mr. Voigt
Quality Assurance
Permoserstr. 15
04318 Leipzig

Environmental Lab
Materials Lab
Fire Lab
New Technologies

RST Rail System Testing GmbH
Philipp-Pforr-Straße 10
16761 Hennigsdorf

Fon +49 (0)3302 49982 0
Fax +49 (0)3302 49982 15

www.rst-labs.de
info@rst-labs.de

Test Report No. P50-12-0205e_Zert

Environmental Tests

Order No.: 50-12-0290 (3383)
Date: 25/07/2012
Test engineer: Mr. Huster
Documentation: hw/lr/hb

This report includes 1 page.

phone: 03302 49982 50

Delivery date specimen:	09/07/2012
Test date:	09/07/2012 until 20/07/2012
Specimen:	1 Basic Device TiMON (specimen No. 50-12-3383-1)
Relevant specification:	– Climate and IP Degree of protection tests according to customer specification – Evaluations
Objective:	Proof of operability of the Basic Device TiMON during and after the individual tests.
Results:	The Basic Device TiMON was tested according to the relevant specification. No changes were detected in comparison with the initial state of the Basic device at the inspections after the tests. The operability of the tested Basic Device TiMON was ensured at each control time according to the relevant specification. The protection degree IP42 is ensured for the tested Basic Device TiMON (specimen No. 50-12-3383-1).

(This certificate is valid only in conjunction with the detailed test report.)

Rita Förster
Environmental Lab

TESTING THE WORLD
FOR TOMORROW

Customer:
Bruker Daltonik GmbH
Branch Leipzig
Mrs. Matthes
Research or development
Permoserstr. 15
04318 Leipzig

Environmental Lab
Materials Lab
Fire Lab
New Technologies

RST Rail System Testing GmbH
Philipp-Pforr-Straße 10
16761 Hennigsdorf

Fon +49 (0)3302 49982 0
Fax +49 (0)3302 49982 15

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info@rst-labs.de

Test Certificate No. P50-13-0513_1-Zert-1-en

Environmental Tests

Order No.:	50-13-0513	This certificate includes 1 page.
Date:	11/11/2013	
Test engineer:	Mr. Huster	
Documentation:	hw/hb	phone: 03302 49982 50

Delivery date specimen:	06/11/2013
Test date:	06/11/2013
Specimen:	1 piece Basic Device OrthoTIMON (specimen No. 50-13-0513)
Relevant specification:	Degrees of protection provided by enclosures (IP-Code) according to DIN EN 60529 (edition 09/2000)
Objective:	Proof of the degree of protection IP42
Results:	A very small quantity of water penetrated into the enclosure during the water test. The operability and safety of the device are not impaired by this. The access to the hazardous parts with an access and an object probe was not possible. The protection degree IP42 is ensured for the tested Basic Device OrthoTIMON (specimen No. 50-13-0513-1).

(This certificate is valid only in conjunction with the detailed test report.)

Bernd Sommerfeld
Head of the Environmental Lab

IRSC
International Radiation Safety Consulting, Inc.

Successful Device Approvals

December 19, 2014

George A. Gleason – Radiation Safety Officer
Bruker Detection Corporation
40 Manning Rd.
Billerica, MA 01821

RE: TIMON Pre-registration Survey

Dear Mr. Gleason:

On December 18, 2014 I surveyed your TIMON product cabinet in preparation for the device registration. Two surveys were performed using two survey instruments and in accordance with the guidelines prescribed in ANSI/HPS N43.8-2008, *Classification of Industrial Ionizing Radiation Gauging Devices*.

Device surveyed:	Manufacturer:	Bruker Daltonik GmbH
	Model:	TIMON
	Serial No:	8L7630003988
	Radionuclide:	Ni-36
	Activity:	2.7mCi (100 MBq)

This device does not have a shutter so no on/off measurements were required. The room temperature was approximately 70^0 F.

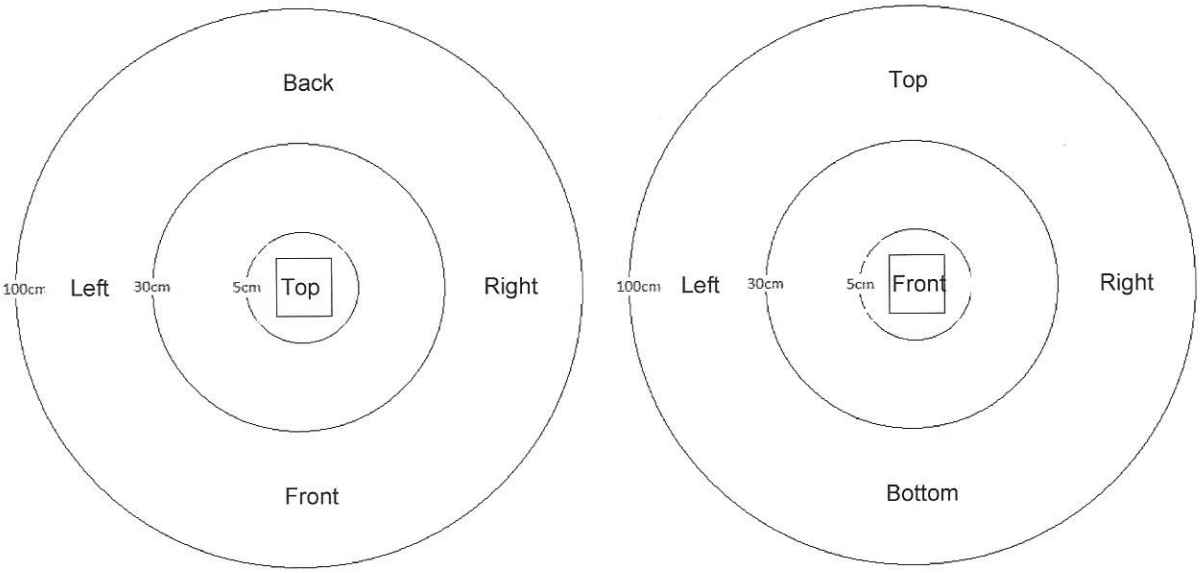
The results of these surveys were indistinguishable from background readings and are contained in the pages that follow. If you have any questions please contact me at 978.703.4416 or send email to dbeek@irsc-inc.com.

Sincerely,

Douglas M Beek
Associate Consultant

7 Cabot Place, 3rd Floor, Stoughton, MA 02343 USA
Ph. 877.266.0794 (U.S.)
781.767.2176 (outside U.S.) Fax: 781.207.0453 www.irsc-inc.com

Radiation Profile



Background: 0.03 mR/hr

Measurements	5 cm	30 cm	100 cm
Front	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Back	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Top	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Bottom	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Left Side	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Right Side	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr

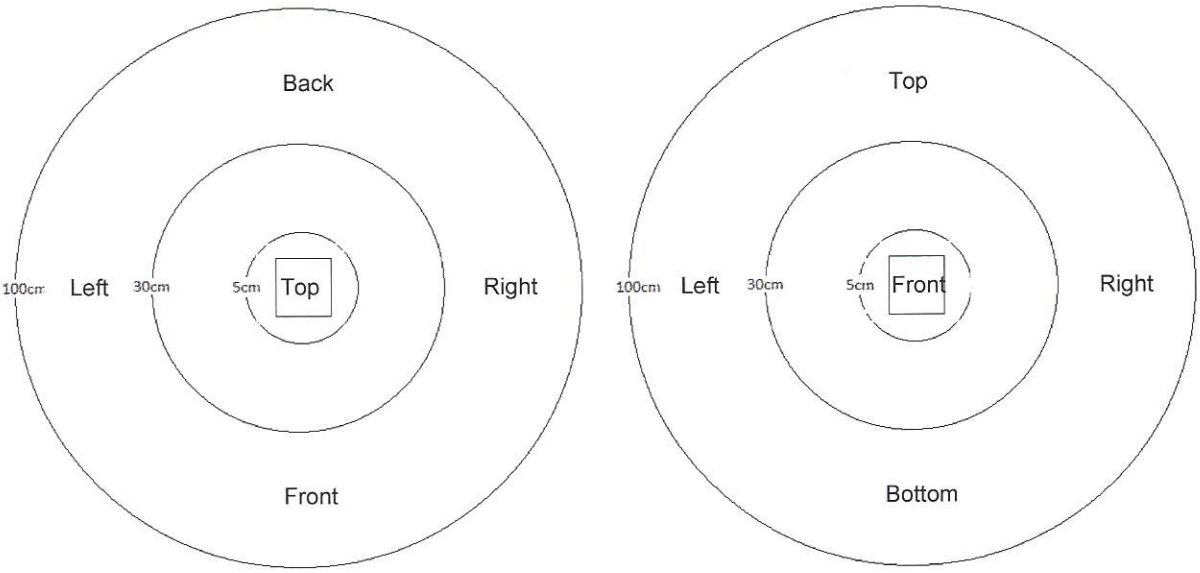
DEVICE

Manufacturer: TIMON
Model: Bruker Daltonik GmbH
Serial No: 8L7630003988
Radionuclide: Ni-63
Activity: mCi (MBq) 2.7mCi (100 MBq)

SURVEY INSTRUMENT

Manufacturer: Ludlum
Model: 3
Serial No. 220681
Probe Serial No. PR291209
Calibration due date: 6/30/2015

Radiation Profile



Background: 0.03 mR/hr

Measurements	5 cm	30 cm	100 cm
Front	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Back	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Top	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Bottom	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Left Side	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr
Right Side	0.03 mR/hr	0.03 mR/hr	0.03 mR/hr

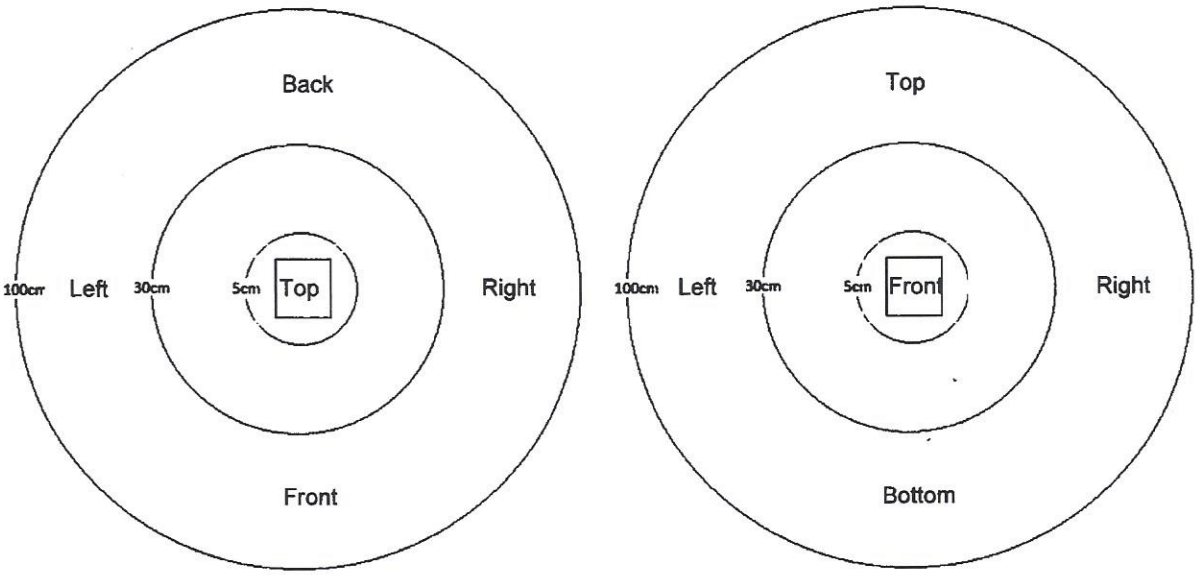
DEVICE

Manufacturer: TIMON
Model: Bruker Daltonik GmbH
Serial No: 8L7630003988
Radionuclide: Ni-63
Activity: mCi (MBq) 2.7mCi (100 MBq)

SURVEY INSTRUMENT

Manufacturer: Ludlum
Model: 9DP1
Serial No. 25004627
Probe Serial No. N/A
Calibration due date: 2/21/2015

Radiation Profile



Background: 0.03 mR/hR

Measurements	5 cm	30 cm	100 cm
Front	0.03	0.03	0.02
Back	0.04	0.03	0.02
Top	0.03	0.03	0.02
Bottom	0.03	0.03	0.02
Left Side	0.04	0.03	0.02
Right Side	0.04	0.03	0.02

DEVICE

Manufacturer: BRUKER
Model: ORTHO TIMON
Serial No: 870410005343
Radionuclide: Ni-63
Activity: mCi (MBq) 2.7mCi

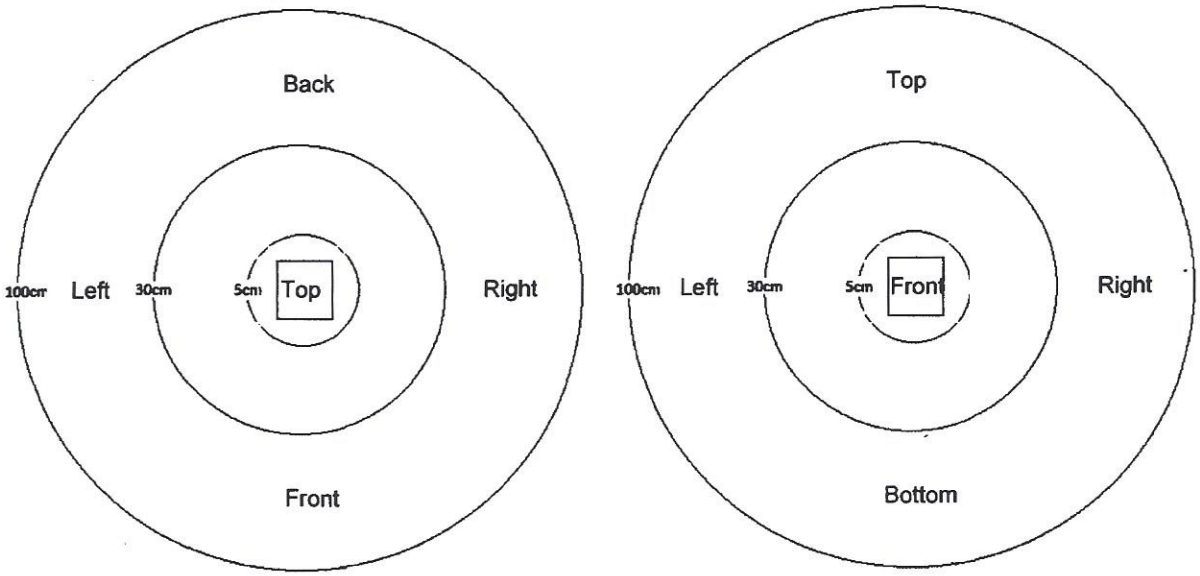
SURVEY INSTRUMENT

Manufacturer: LUDLUM
Model: 9DP-1
Serial No. 260006028
Probe Serial No. 10N CHAMBER
Calibration due date: 16 Sep 2015

Performed by: GEORGE A GLEASON RSO
Signature: George A Gleason

Date: APRIL 27 2015

Radiation Profile



Background: 2.5 X 0.1 MR HR

Measurements	5 cm	30 cm	100 cm
Front	2.0	2.5	2.5
Back	2.0	2.5	2.5
Top	2.5	2.5	2.5
Bottom	2.5	2.5	2.5
Left Side	2.5	2.5	2.5
Right Side	2.5	2.5	2.5

DEVICE

Manufacturer: BRUKER
Model: ORTHO TIMON
Serial No: 870410005343
Radionuclide: Ni-63
Activity: mCi (MBq) 2.2 mCi

SURVEY INSTRUMENT

Manufacturer: LUDLUM
Model: 3
Serial No. 220681
Probe Serial No. PR291209
Calibration due date: 6/30/2015

Performed by: GEORGE A GLEASON
Signature: George A Gleason

Date: APRIL/27/2015

International Radiation Safety Consultants, Inc.

Bruker TIMON and Ortho TIMON

Response to NRC Questions

K. Paul Steinmeyer, RRPT
4/3/2015

Question 26. 10 CFR 32.27 requires that an applicant for a license under 10 CFR 32.26 shall demonstrate that the product is designed and will be manufactured so that the requirements of 10 CFR 32.27 are met.

In Attachment H, External and Internal Dose Calculations, of your application you provided information concerning external and internal doses that may be received by an end user of a Bruker TIMON device and also provided information concerning possible incineration of the device, but the information you provided is not oriented toward all of the specific safety criteria of 10 CFR 32.27. Furthermore, the OrthoTIMON device was not addressed within this context.

Please provide additional information for the Bruker TIMON and OrthoTIMON devices to demonstrate that these products are designed and will be manufactured so that each of the specific safety criteria in 10 CFR 32.27 are met. In preparing your response, you should address each of the specific circumstances described in 10 CFR 32.27. You may wish to consult section 2.15 of NUREG-1717, Systematic Radiological Assessment of Exemption for Source and Byproduct Materials, which provides guidance on meeting the safety criteria of 10 CFR 32.27.

Response to Question 26

Ortho TIMON and the Bruker TIMON

The radioactive source portion of the Ortho TIMON is exactly the same as the Bruker TIMON. The Ortho TIMON, however, includes a long range laser chemical hazard identification system. Any difference between these two models does not affect this safety analysis and should have no impact on this application. In this response the term TIMON will refer collectively to the Ortho and to the basic model of the TIMON.

Compliance with 10 CFR 32.27 Safety criteria.

PROPOSED USES

The Bruker TIMON is a wall-mounted point toxic gas detector for indoor applications. The system features detection, identification and quantification libraries for chemical weapon agents and selected toxic industrial gases. The system is supplied in an unobtrusive metal cabinet without indicator lights or supplier's branding so that it does not attract unwanted attention.

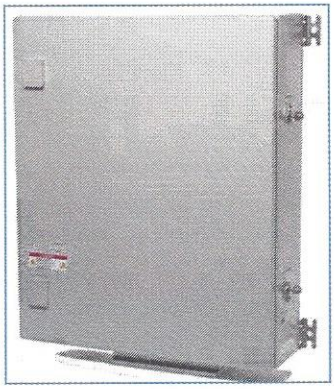


Figure 1. Exterior view of the TIMON.

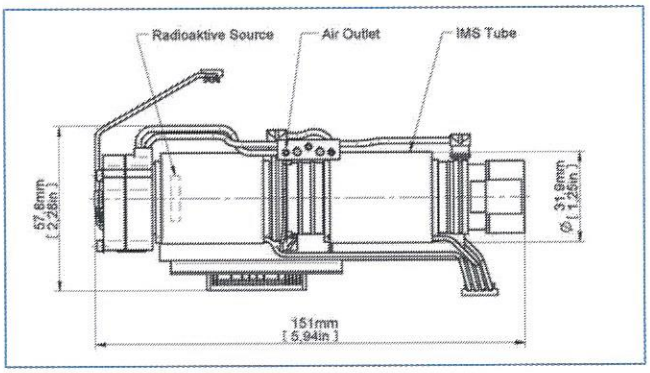


Figure 2. Drawing of portion of TIMON interior showing the protected location of the ^{63}Ni source within the IMS tube.

§32.27(a)

Response

External Radiation Dose: There is no detectable particle or photon radiation outside the metal case in which the TIMON is contained. There is also no detectable radiation outside the IMS tube which surrounds the radioactive source inside the TIMON case. Therefore there is no individual or group likely to receive *any* direct radiation from one or any larger quantity of these devices in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product.

While servicing the product there is no need for the technician to access the interior of the IMS tube that contains the radioactive source. Accessing the source would require destruction of the IMS tube. It is therefore unlikely that the external radiation dose in any one year, to any individual or group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the doses listed in rows a and b in the table below.

	Part of body	Column 1 (rem)
a	Whole body; head and trunk: active blood-forming organs; gonads; or lens of eye	0.005
b	Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.075
c	Other organs	0.015

***Dose Commitment*:**

Attributes of Nickel 63

Source: 2.7 mCi (100 MBq), one sealed source per device

Half-life: 100.1 years

Melting point: 1455°C (2651 °F)

Boiling (Vaporization) Point: 2900 °C (5252 °F)

Considering all credible accident scenarios where the radioactive material in the TIMON might be released, fire has been judged to be the most likely. Both structure fires and commercial incinerators were considered.

1. Structure Fire

Firemen[1] report that in structure fires temperatures are reached that soften steel to the point that it sags or bends from the weight of materials attached to it. The melting temperature of steel is approximately 1370°C (2500°F). This is far below the vaporization temperature of nickel (2900 ºC or 5252 °F), so the nickel component of this radioactive source is unlikely to produce respirable particles (caused by vaporization of the radioisotope and condensation of the vapor upon cooling) in a structure fire.

2. Incineration—Commercial Incinerator

Commercial incinerators[2] run at a burn temperature of 1427°C (2600°F). This is also less than the melting point, and well below the vaporization point of nickel, so the nickel component of this radioactive source is unlikely to produce respirable particles (caused by vaporization of the radioisotope and condensation of the vapor upon cooling) if one or more sources is inadvertently sent to a commercial incinerator.

a. Calculation of Internal Dose from Incineration

Notwithstanding the evidence presented above, this calculation will estimate the internal dose to the persons most likely to receive the largest dose in the case of destruction and theoretical vaporization of one of these devices by fire.

Assumptions:

- A single unit is accidentally incinerated
- Fraction of Ni-63 vaporized and released[3] = 0.01% (0.0001)
  - 2.7 mCi × 0.0001 = 0.27 µCi
- Efficiency of emissions control equipment at the incinerator = 90%
  - Per cent (fraction) released = 10% (0.1)
- Combustion air flow rate = 120,000 $\frac{ft^3}{min}$
- Combustion time = 15 minutes

Calculating the concentration of aerosolized Ni-63 emitted during the burn:

$$2.7\,\text{mCi} \times 0.0001 \times 0.1 \times \frac{1000\,\mu\text{Ci}}{1\,\text{mCi}} \times \frac{\text{min}}{120{,}000\,\text{ft}^3} \times \frac{1}{15\,\text{min}} \times \frac{1\,\text{ft}^3}{2.832\text{E}+4\,\text{cm}^3} = \frac{5\text{E}-13\,\mu\text{Ci}}{\text{cm}^3}$$

[1] Hebron (CT) Volunteer Fire Department, personal communication, November 8, 2006.
[2] Bridgeport RESCO, Bridgeport, CT. Personal communication with Vincent Langoni, Plant Manager.
[3] NUREG 1717 paragraph 2.15.5.4 "...a release factor of 0.01% is assumed for the ^{63}Ni and ^{241}Am sources inside the chemical detectors."

4. Internal Dose Summary

This concentration is 8000 times less than the W-class DAC value for Ni-63 given in 10 CFR 20 Appendix B Table 2 Column 1 (i.e., 4E-9 µCi/mL) $\left(\frac{4E-9\ \mu Ci/cm^3}{5E-13\ \mu Ci/cm^3} = 8000\right)$. A person breathing air at the DAC concentration for 24 hours per day for a year (i.e., 8,760 hours) would receive a CEDE of 50 mrem. Reducing this dose by a factor of 8000 results in a CEDE of 0.006 mrem. In an incineration incident it is conservatively estimated that exposure time would be no more than 10 hours. This would reduce the (theoretical) internal dose by a factor of 876, resulting in a projected internal dose of 0.000007 mrem. This conservatively derived annual dose, even if actually delivered, would be negligible.

Based on the information provided above, it is unlikely that the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the doses listed in row c in the table above.

§32.27(b)

The Ni-63 source in the TIMON is solidly affixed within a protective tube referred to as the IMS tube. In turn, the IMS tube is securely mounted within the TIMON case. As described in the response to question 27 (below) the IMS tube provides more than adequate shielding to absorb any electron-induced *bremsstrahlung* radiation. The instrument case is made of steel and is sufficiently robust to easily survive in the harshest industrial environments. Therefore it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

§32.27(c)

The Ni-63 source in the TIMON is solidly affixed within a protective tube referred to as the IMS tube. In turn, the IMS tube is securely mounted within the TIMON case. As described in the response to question 27 (below) the IMS tube provides more than adequate shielding to absorb any electron-induced *bremsstrahlung* radiation. The case is made of steel and is sufficiently robust to easily survive in the harshest industrial environments. Even under conditions of a serious industrial accident, no radiation dose–external or internal–should be delivered to any person. There is no internal shielding that could shift or melt, and there is no shutter assembly that could malfunction to cause any measureable radiation dose to personnel. Therefore, in use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table below.

Part of body	Column II (rem)
Whole body; head and trunk: active blood-forming organs; gonads; or lens of eye	0.5
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	7.5
Other organs	1.5

Finally, based on all the information provided above, the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table below.

Part of body	Column III (rem)
Whole body; head and trunk: active blood-forming organs; gonads; or lens of eye	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200
Other organs	50

Question 27. In the Estimated Use Time Basis section of your application, you wrote, "^{63}Ni is a low-energy, pure beta-emitting radioisotope. Therefore there is no radiation from the source that is detectable outside the TIMON metal cabinet Fig.1). "In the TIMON Pre-registration Survey you wrote that external dose rates were indistinguishable from background dose rates. However, in paragraph 3.a., you wrote, "Direct bremsstrahlung radiation measurements were made with the device intact, source installed. At a distance of 5 cm, the measured dose rate was 0.1 mrem per hour."

Please provide additional information that clarifies these seemingly contradictory statements with regard to external dose rates. In preparing your response, you may wish to consult section 2.15.5 of NUREG-1717, Systematic Radiological Assessment of Exemption for Source and Byproduct Materials, which addresses external dose rates from gas and aerosol detectors containing Ni-63.

Response to Question 27.

Please ignore the following sections of the previously submitted safety analysis, and substitute the information in this response.

The statement quoted in Question 27 ("Direct *bremsstrahlung* radiation measurements were made with the device intact, source installed. At a distance of 5 cm, the measured dose rate was 0.1 mrem per hour.") was made in error. The statement from the TIMON Pre-registration Survey ("...external dose rates were indistinguishable from background dose rates.") was correct. Additional information on the *bremsstrahlung* issue is provided below.

The ^{63}Ni-induced Bremsstrahlung Issue

NUREG 1717 recognizes[4] that "In the continuous spectrum of *bremsstrahlung* resulting from beta decay of radionuclides, the number of photons per unit energy decreases rapidly with increasing energy between zero (0) and a maximum energy equal to the endpoint energy of the continuous spectrum of beta particles, and the energies of most of the photons are only a small fraction of the beta endpoint energy (Evans, 1955)." Thus, for example, NUREG goes on to say that "when the endpoint energy of the beta spectrum is a few hundred keV, the energies of most of the photons in the spectrum of *bremsstrahlung* are a few tens of keV or less." Following that logic, ^{63}Ni, with a beta endpoint energy of 66.945±0.005 keV (100%), the energies of most *bremsstrahlung* photons would be in the range of 6 or 7 keV. Low-energy photons are very strongly attenuated in any material.

For example, ^{63}Ni contained in a stainless steel sleeve 2.5 mm thick,

$$I = I_o \, e^{-\mu_{en} x}$$

Where

I = attenuated dose rate

I_o = unattenuated dose rate = 0.1 mrem/h (assumed for this illustration)

[4] NUREG 1717, section A.4.1.1.

μ_{en} = the linear energy absorption coefficient $\left(\frac{\text{cm}^2}{\text{g}}\right) = 8.265E + 1\frac{cm^2}{g}$ (for 6 keV photons[5])

x = shield thickness (cm) = 2.5 mm = 0.25 cm

$\rho_{Fe} = 7.87\frac{g}{cm^3}$

$$\frac{\mu_{en}}{\rho} \times \rho_{Fe} = \left(8.265E + 1\frac{cm^2}{g}\right)\left(7.87\frac{g}{cm^3}\right) = \frac{650.5}{cm}$$

If I_o = 0.1 mrem/h, (from *bremsstrahlung* induced in the 0.25m stainless steel covering over the ^{63}Ni source), then

$$\text{I} = (0.1)\ \text{e}^{-\left(\frac{650.5}{cm}\right)(0.25\ \text{cm})}$$

$$I = \left(0.1\frac{mrem}{h}\right)(2E - 71) \approx 0$$

Conclusion

It can be concluded, then, that there is no detectable photon radiation from ^{63}Ni-induced *bremsstrahlung* outside the 2.5 mm sleeve (referred to as the IMS tube) which surrounds the radioactive source.

April 3, 2015

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[5] From NIST (http://physics.nist.gov/PhysRefData/XrayMassCoef/ElemTab/z26.html)