Translation from Italian to English

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RADIATION PROTECTION REPORT REGARDING THE RX EQUIPMENT BAGGAGE CHECK

Article 61-79 of the Legislative Decree no. 230/95 – Legislative Decree no. 241/00

Digitally signed by Bîrsan Vitalie
Date: 2023.10.16 10:51:08 EEST
Reason: MoldSign Signature
Location: Moldova

Ed. 01 rev. 00	**January 28, 2013**

SUMMARY

Attachments:

- ***Calibration Certificate of the Instrumentation Used;***
- ***Certificate proving the registration with the Qualified Expert name list;***
- ***Radiological Protection Internal Rules.***

1 Introduction

The drafting of this report has been carried out based on the Legislative Decree no. 230/95 and on the international recommendations, as applicable.

This report is being prepared for the sole purposes of radiation protection: it is beyond my attributions and competences of Qualified Expert to refer and assess other risks that exist at the work place, which is the object of this report or other risks resulting from the incorrect use of the equipment.

The data, the elements and all the information necessary for the drafting of this report have been provided by the device manufacturing company and collected by the undersigned.

The purpose of the analysis has been that of investigating the framework of the potential hypotheses that could give rise to hazardous events, with harmful consequences for the operators, for the overall work environment and for the population.

On January 28, 2013, radiometric measurements have been conducted, aiming at establishing the dose intensity during the operation of the following baggage check devices:

MODEL	S/N	max kV	max mA
FEP ME 640 AMX	051784001	150	0.5
FEP ME 640 LP SA	053939001	150	0.5
FEP ME 640	052384009	150	0.5
FEP ME 975 HC	120980001	160	1.5

In the following paragraphs, the measurement methods and the related results will be presented, with the resulting dose estimate for the operators, employed for the use of these devices, under normal and correct operating conditions.

2 System Description

X-ray System for the baggage and package security checks.

The equipment's specific techniques are attached to this report.

3 Operation – Risk Assessment

The systems are used for the package checks, with video representation, by means of the chromatic code of the materials representing the objects contained inside the package.
The package is being irradiated while transiting the conveyor belt and at the same time, the related images are being provided on the screen.
The system is capable of distinguishing the density of the parts that make up the baggage.

3.1 Protection Devices

Taking into consideration the manufacturing characteristics of the systems examined (screening, lead rubber strips for the baggage entry and exit) and those related to the irradiation techniques, the protections mentioned above guarantee the protection of the operators and that of the population.

4 Exposure Assessment

Certain measurements have been conducted, during the transit of a package, with maximum irradiation technique.

Radiations: X Rays **Quality Factor: 1**

Simulator: package to be inspected.

i.s.s. = inf. to instrumental sensitivity

The tool used: Fluke mod. 451P Survey ionization chamber – calibration certificate: 1/12/2011.

The fund measured = 0.12 – 0,14 µSv/h

On the equipment's external surfaces, exposure intensity measurements have been conducted, within the maximum operating conditions; the **maximum values measured** around the equipment are reported in the following tables:

FEP ME 640 AMX – s/n 051784001	
Point of measurement	**Maximum intensity measured, including the fund µSv/h**
In contact with the External walls of the System – upper side	0.13
In contact with the External walls of the System – side	0.18
Entry/Exit of the Package in contact with the Lead Rubber Strips	0.22
Position of the operator at 60 cm from the X-ray source	Does not exceed the fund
Position of the operator, at the end of the roller conveyor	0.18
Personal reference group of the population in the adjacent rooms	Does not exceed the fund

FEP ME 640 LP SA – s/n 053939001	
Point of measurement	**Maximum intensity measured, including the fund µSv/h**
In contact with the External walls of the System – upper side	0.12
In contact with the External walls of the System – side	0.19
Entry/Exit of the Package in contact with the Lead Rubber Strips	0.22
Position of the operator at 60 cm from the X-ray source	Does not exceed the fund
Position of the operator, at the end of the roller conveyor	0.18
Personal reference group of the population in the adjacent rooms	Does not exceed the fund

FEP ME 640 – s/n 052384009	
Point of measurement	**Maximum intensity measured, including the fund µSv/h**
In contact with the External walls of the System – upper side	0.13
In contact with the External walls of the System – side	0.20
Entry/Exit of the Package in contact with the Lead Rubber Strips	0.16
Position of the operator at 60 cm from the X-ray source	Does not exceed the fund
Position of the operator, at the end of the roller conveyor	0.14
Personal reference group of the population in the adjacent rooms	Does not exceed the fund

FEP ME 975 HC s/n 120980001	
Point of measurement	**Maximum intensity measured, including the fund µSv/h**
In contact with the External walls of the System – upper side	0.14
In contact with the External walls of the System – side	0.16
Entry/Exit of the Package in contact with the Lead Rubber Strips	0.29
Position of the operator at 60 cm from the X-ray source	Does not exceed the fund
Position of the operator, at the end of the roller conveyor	0.16
Personal reference group of the population in the adjacent rooms	Does not exceed the fund

5 Dose Estimate

In view of the equipment's operating methods and correct use, as indicated in the user manual, taking into consideration the protections put in place (screenings, lead rubber strips at the entry and exit of the baggage) and the results of the conducted measurements, the following external irradiation doses are being estimated:

The personnel operating the equipment	**< 1 mSv/year**
Population	**< 1 mSv/year**

Referring to the dose limits defined by the Legislative Decrees no. 230/95 and 241/00, to the data reported in the table above and under normal operating conditions, the dose limits set for the population are not being exceeded.
In this context, the personnel may be categorized as NOT EXPOSED, for the purposes of the Radiation Protection, and the personal dosimetry equipment is not considered to be necessary.
This assessment will have to be re-examined, anyway, by the Qualified Expert of the facility where the equipment is to be used, according to the work activity and workload related specificities.

6 Justification Principle

Having considered the benefit obtained by the operation of the equipment subject to the checks from the point of view of the risk involved under normal operating conditions, for the

operators, the population and the environment, **the practice must be considered widely justified.**

7 Conclusions

From the results of the conducted assessments, the operation of the examined equipment:

- under normal operating conditions,
- complying entirely with radiological protection internal rules,

does not involve a justified, unacceptable or undue radiation risk for the population, the environment and for the operators, which, under the above-mentioned operating conditions, is not likely to exceed the dose limits for the population, provided by the Legislative Decree no. 230/95, subsequently amended and supplemented.

Qualified Expert
Engineer Alessandro Sarandrea
2nd Degree – no. [illegible]

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GCL Calibration Certificate

Report No: AC-3660-15163
Calibration: As Calibrated
Results: In Tolerance

NVLAP
FOR THE SCOPE OF ACCREDITATION UNDER NVLAP CODE 200648-0

Manufacturer: Fluke Biomedical
Model: 451P-DE-SI-RYR Asset No: n/a
Serial No: 3660
Model Description: Pressurized Ion Chamber Survey Meter

Date Calibrated: 1-Dec-11

Customer: NEW UNIT

Date Received: 1-Dec-11

739.52 mmHg
21.77 degrees Celsius
42.4 % Relative Humidity

Customer's Requested Due Date: 1-Dec-12

NOTES

This calibration is traceable to international standards. Dose equivalent conversion factors are taken from HPS N13.11-2001 and ICRU Report 47-1992. This report must not be used to claim product recertification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.

The calibration is warranted to be within specified accuracy limits, at the time of calibration. In the event of a calibration error, our liability is limited to standard recalibration cost.

Proper function and reliability of the instrument described in this document are highly dependent upon handling and use. It is recommended the user establish a technique to monitor the constancy of the instrument response before and after its return to the manufacturer.

This certificate shall not be reproduced except in full, without the written approval of the calibration laboratory.

If there are any problems with the calibration of the instrument, please contact the Calibration Laboratory Director.

Calibrated by: Kay, Rodger Date: 1-Dec-11
Technician

Reviewed by: Date: 1-Dec-11
Clare Grehofsky, Director GCL

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FLUKE
Biomedical

Report No: AC - 3660-15163

Check Source Reading	N/A

Rate Calibration							
Source	Distance (cm)	No. of Atten	UUT Range	Units	Reference Rate	UUT Rate	% Error
20 Ci Cs-137	974.96	5	0 to 5	uSv/hr	1.8	1.747	-2.94 - Pass
20 Ci Cs-137	949.31	4	0 to 5	uSv/hr	3.6	3.449	-4.19 - Pass
20 Ci Cs-137	945.68	3	0 to 50	uSv/hr	18	18.12	0.67 - Pass
20 Ci Cs-137	924.10	2	0 to 50	uSv/hr	36	35.89	-0.31 - Pass
20 Ci Cs-137	934.79	1	0 to 500	uSv/hr	180	177.5	-1.39 - Pass
20 Ci Cs-137	944.56	0	0 to 500	uSv/hr	360	355.8	-1.17 - Pass
2000 Ci Cs-137	811.68	3	0 to 5	mSv/hr	1.8	1.813	0.72 - Pass
2000 Ci Cs-137	795.72	2	0 to 5	mSv/hr	3.6	3.577	-0.64 - Pass
2000 Ci Cs-137	813.16	0	0 to 50	mSv/hr	36	35.76	-0.67 - Pass

Dose Calibration					
Integration Calibration Point	UUT Range	Units	Reference Exposure	UUT Exposure	% Error
2000 Ci Cs-137, 100 sec	0 to 500	uSv	100	99.6	-0.40 - Pass

Calibration Procedure: CAL-450-451.pdf

Calibration Description: The 451P-DE-SI-RYR has an operating range of 0 to 50 mSv/hr. The unit is exposed through the side of the detector and calibrated on all ranges. All readings were corrected for background. The % Error was calculated using Equation 1.

Envioronmental Constraints: The 451P-DE-SI-RYR survey meter is designed to read accurately from -20 to 50C. The unit is pressurized, therefore, requires no air density corrections.

Calibration Uncertainty: 3.6% with 2.2% associated with the uncertainty of the source.

Accuracy Requirement: 10% of Reading

Equation 1: $$\%Error = \frac{100 * (UUT - Reference)}{Reference}$$

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INTERNAL SAFETY RULES

(ART. 61/c, Legislative Decree no.230/95)

These internal protection rules must be available for consultation in those places frequented by the workers, who must scrupulously comply with these rules.

1) The maintenance works on the equipment are only allowed to be carried out by the qualified personnel of the equipment's provider Company; cleaning works that involve opening the equipment and removing its protection systems are not allowed either, except when carried out by the provider Company's qualified personnel;
2) The use of the equipment must be allowed only to the authorized personnel, specifically trained for its correct use;
3) The operator or the operators who use the equipment will have to scrupulously follow the operating procedures provided in the manufacturer's instruction manual;
4) Do not dismantle or modify the system, for any reason, since such operations might lead to very strong electric shocks;
5) Do not insert the equipment's body parts into the control room. In case one of the components jams or blocks, always turn the system off before removing that component;
6) Follow the safety rules during the system's operation and maintenance;
7) Before using the equipment, the employees will have to check the correct operation of the warning lights and signals;
8) Use the equipment only if all its components and functions are intact and operational;
9) Check periodically the integrity of the lead rubber strips;
10) Do not try to remove the system's components and deactivate its functions;
11) Keep the signposting "Radiation Danger" on the equipment;
12) In case of fire, flooding of the premises, the operating personnel will have to secure the equipment, deactivating its power supply;
13) The employees who use the equipment will have to inform the Manager or the Person in charge about potential hazardous situations that might occur.
14) As for the equipment not in use, disconnect the key of the control console

FREQUENCY OF CHECKS AND ASSESSMENTS

ENVIRONMENTAL SURVEILLANCE ASSESSMENTS: YEARLY
RADIATION PROTECTION DEVICE CHECK: YEARLY
MEASUREMENT TOOL CHECK: YEARLY

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2nd Degree – no. 2001 No. 2001

SARANDREA
HSE MANAGEMENT

La sottoscritta MARCU ALINA BIANCA, interprete e traduttrice giurata per le lingue straniere italiano ed inglese, in base all'autorizzazione n.31329, rilasciata l'08.04.2011, dal Ministero Romeno della Giustizia, attesto l'esattezza della traduzione fatta dall'italiano all'inglese, che è conforme al documento originale che mi è stato presentato, attesto che il testo presentato è stato tradotto interamente, senza omissioni e che, mediante la traduzione, il contenuto ed il senso del testo non sono stati distorti.

INTERPRET ŞI TRADUCĂTOR AUTORIZAT
MARCU ALINA BIANCA

I, the undersigned MARCU ALINA BIANCA, certified translator and interpreter for Italian and English, under the authorization no.31329, issued on 04/08/2011, by the Romanian Ministry of Justice, certify the accuracy of the translation performed from Italian to English, in compliance with the original document that has been submitted to me, that the submitted text has been fully translated, without omissions and that, by translating it, the content and meaning of the text have not been distorted.

CERTIFIED INTERPRETER AND TRANSLATOR
MARCU ALINA BIANCA

Traducător şi Interpret Autorizat
MARCU ALINA-BIANCA
Aut. M.J. Nr. 31329 / 2011
Limbile Engleză - Italiană