Health Canada / Santé Canada

Healthy Environments and Consumer Safety Branch / Direction générale, Santé environnementale et sécurité des consommateurs

Product Safety Program
Consumer and Clinical Radiation Protection Bureau
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Your file *Votre référence*

Our file *Notre référence*

File No.:1114-2-4

May 12, 2009

Mr. Michael Gray
Director Radiation Safety and Compliance
Rapiscan Systems Inc.
2805 Columbia Street
Torrance, CA 90503, USA

Dear Mr. Gray:

Re: Rapiscan 620XR and 620DV X-ray Systems

X-ray equipment is federally regulated in Canada under the Radiation Emitting Devices Act (REDA). The REDA provides the statutory authority to promulgate standards for x-ray equipment. The REDA Regulation specifies the design, construction, and performance criteria for x-ray equipment. *Pursuant to the REDA, all x-ray equipment shall comply with the applicable Regulation before they can be imported, sold, leased, demonstrated or distributed in Canada.* The responsibility for regulatory compliance rests with the x-ray equipment manufacturer and its marketing agent(s). Any violation of the REDA is a criminal offence. The REDA and Regulation may be consulted at the following web site:

http://www.canlii.org/ca/regu/crc1370/

The referenced products, Rapiscan 620XR and 620DV X-ray Systems, are manufactured by Rapiscan Systems Inc., 2805 Columbia Street, Torrance, CA 90503, USA. A company, Primex Security Security Systems Limited, 5460 Canotek Road, Unit 112, Ottawa, ON K1J 9H2, Canada, has indicated to this Bureau that it is an agent marketing Rapiscan X-ray Systems in Canada; **we request from the manufacturer written confirmation and contact details on all its agents marketing such products in Canada by May 24, 2009.**

On March 9, 2009, Mr. Steven Norris, Radiation Safety Officer, acting on behalf of the manufacturer of the referenced x-ray systems, forwarded a technical submission and specific materials in respect of compliance of Rapiscan 620XR and 620DV X-ray Systems:

(A) Rapiscan X-ray Systems Operator Manual- Rapiscan 600 Series Dual and Single View Security X-ray Systems, No. 9210740, February 2009.

(B) Rapiscan X-ray Systems Maintenance Manual- Rapiscan 600 Series Security X-ray Systems, No. 9210741, February 2009.

(C) A CD that contains several documents:

Canada

(i) Final Acceptance Test Check List; Form R-0533-7;
(ii) Global Procedure for Radiation Emission Testing; WI-0023 Rev 4. 02/09/09;
(iii) Radiation Emission Test Record; Form R-0047; and
(iv) Various radiation warning labels and signs, including a copy the Operation and Maintenance Manuals (A) and (B) listed above.

The March 9, 2009 technical submission was in response to a Bureau initiated letter dated January 12, 2009, that was directed to the x-ray system manufacturer regarding items of noncompliance and queries associated with a Rapiscan 519 X-ray System. ***The x-ray system manufacturer has notified the Bureau that the Rapiscan Model 519 X-ray system is now obsolete, and it will not be available for sale in Canada.***

The x-ray system manufacturer has therefore considered the information (items of noncompliance and queries) contained in the January 12, 2009 letter in its preparation of the March 9, 2009 technical submission and supportive documentation in respect of the Rapiscan 620XR and 620DV X-ray Systems. The suffix 'XR' refers to models that contain one x-ray tube with its associated detector and imaging accessories, called Single View, whereas the suffix 'DV' refers to models that are designed with 2 x-ray tubes equipped with the corresponding detectors and imaging accessories and are called Dual View. The basic model is the Rapiscan 620XR; other models differ primarily in tunnel sizes and appearances. The Rapiscan 620 XR and 620 DV models are classed as baggage x-ray inspection systems, and the applicable REDA Regulation is Schedule II, Part IV, Baggage Inspection X-ray Devices. ***Models of the Rapiscan 600 Series which are classed as baggage x-ray inspection systems include:***

Model 618XR	
Model 620XR	***Model 620DV***
Model 622XR	
Model 624XR	
Model 626XR	
Model 627XR	***Model 627DV***
Model 628XR	***Model 628DV***

Based on the materials submitted and information developed on the Rapiscan 620XR and 620DV models, an evaluation pursuant to the REDA and the applicable REDA Regulation (Schedule II, Part IV, Baggage Inspection X-ray Device) identified several items of non-compliance and queries that require resolution. This information was communicated to Mr. S. Norris in an email communication dated April 7, 2009.

Several communications were exchanged between the X-ray Systems manufacturer and the Bureau in order to affect resolution of the items of non-compliance and queries. In summary, it would appear that Rapiscan Systems Inc. of Torrance, California, USA, the X-ray System manufacturer, has in place at its manufacturing facility a quality assurance testing/check program in respect of the models that comprise Rapiscan 600 Series X-ray Systems listed above, prior to shipment. At the customer's premises, there appears to be a similar quality assurance testing or check program, which constitutes part of Rapiscan Systems Inc. installation and commissioning procedures, and which is in place to ensure conformance with the Regulation; revised stray radiation testing procedures

constitute part of this program. Panels that provide access to the critical components (x-ray tube/collimator assemblies, collimator shielding and the detectors) are equipped with interlocks. There is affixed a footmat that meets the requirement of section 2(4)(b)(i) of the applicable REDA Regulation. *Rapiscan Systems Inc. of Torrance, California, USA, will implement certain corrective actions to ensure regulatory compliance of* ***the x-ray systems listed above*** *before they are imported, sold, leased, demonstrated or distributed in Canada:*

1. Section 2(1) Regulation Section 5 REDA
Issue modified Operation and Maintenance Manuals, identified as (A) and (B) above, which contain revised radiation protection information and designed safety features in respect of the models that comprise the Rapiscan 600 Series listed above.

2. Section 2(3)(h)(ii) Regulation
(i) Ensure that a warning label that bears the x-ray tube logo and states "Warning. Do not insert any part of the body when system is energized. X-Ray Hazard" and its French equivalent is placed at the entrance and exit ends of the tunnel, where materials first enter or exit the tunnel and in clear view of any person approaching those openings (as per Rapiscan Systems Inc. email communication of Mr. S. Norris dated April 23, 2009).

(ii) Ensure that a warning label that bears the x-ray tube logo and states "Warning. Unauthorized Personnel Prohibited. Service Personnel Must Secure Power and Consult Appropriate Maintenance Manuals." and its French equivalent is placed on each access panel and internally on the x-ray tube collimator assembly, collimator protective boxes and the diode detector boxes (as per Rapiscan Systems Inc. email communication of Mr. S. Norris dated April 23, 2009).

(iii) Ensure that a warning label that bears the x-ray tube logo and states "Caution X-rays. Warning. X-rays are emitted when this control panel is energized and the exposure switch is activated. Unauthorized use is prohibited." and its French equivalent is placed on the control console (as per Rapiscan Systems Inc. email communication of Mr. S. Norton dated April 23, 2009).

(iv) Ensure that a POWER ON label is affixed on the control panel (as per Rapiscan Systems Inc. email communication of Mr. S. Norton dated April 23, 2009).

3. Section 2(4)(b)(ii) Regulation
Ensure that stainless steel solid shrouds which extend at least 50 cm from the last layer of lead drapes at the entrance and exit ends of the irradiation tunnel, which do not contain cut out sections, and which, when appropriately affixed, the ends form a 'vertical plane' with the conveyor are affixed (as per Rapiscan Systems Inc. letter of Mr. S. Norris dated March 9, 2009).

4. Section 3 Regulation
Ensure modified test procedures for stray radiation testing (Global Procedure for Radiation Emission Testing; WI-0023 Rev4. 02/09/09) and reporting (Radiation Emission Test Record; Form R-0047) are utilized (as per Rapiscan Systems Inc. letter of Mr. S. Norris dated March

9, 2009).

At the time **any model Rapiscan X-ray Systems 600 Series** is sold, leased or distributed in Canada, we request that Rapiscan Systems Inc., 2805 Columbia Street, Torrance, CA 90503, USA. or its marketing agent(s) provide us the customers's name, address and telephone number.

Yours sincerely,

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