



## Notice of Violation (Corporation) Procès-verbal (Société)

**Date of notice / Date de l'avis: December 3, 2015**

**AMP number / Numéro de SAP: 2015-AMP-06**

<b>Violation committed by / Violation commise par:</b> Elekta, Inc.  400 Perimeter Center Terrace Suite 50  Atlanta GA 30346 USA	<b>Amount of penalty / Montant de la sanction:</b>  <b>\$ 15,820 (Canadian Dollars)</b>
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### Violation

Use of uncertified Class II prescribed equipment.

Specifically: Installed and upgraded Class II prescribed equipment rendering it uncertified contrary to *Section 10(a) of the Class II Nuclear Facilities and Prescribed Equipment Regulations*.

Category B / Catégorie B

### Relevant facts / Faits pertinents

I, Colin Moses, Director General of the Directorate of Nuclear Substance Regulation and Designated Officer authorized by the Canadian Nuclear Safety Commission (CNSC) to issue notices of violations, believe on reasonable grounds that Elekta, Inc. committed the above violation. The facts relevant to the violation and the penalty calculation are:

1. Elekta LTD (Crawley, UK) is a manufacturer of medical linear accelerators. Elekta, Inc. Region North America (RNA) is based in Georgia U.S.A., sells this equipment in Canada and holds a Class II Prescribed Equipment independent service provider licence (CNSC licence 13364-1-17). Under this licence, Elekta, Inc. performs installations, servicing and equipment upgrades in radiation therapy clinics across Canada.
2. On November 5, 2015 Elekta, Inc. informed the CNSC that multiple Synergy and Infinity units had been upgraded with an Agility<sup>TM</sup> beam shaping device (Agility head). A modification of this nature changes the equipment characteristics and requires a new CNSC prescribed equipment certificate. Elekta, Inc. performed the upgrades without obtaining the necessary prescribed equipment certificates from the CNSC. Licensees operating this equipment were not informed that these upgrades had invalidated their equipment certificates. Elekta, Inc. has indicated that the first upgrade of this type was performed in August 2012.



3. The Agility head, when configured with the hardware kit for Flattening Filter Free (FFF) mode coupled with the installation of Integrity software 3.2, allows operation of the equipment in “FFF mode”. This can result in changes to the radiation beam profile of the equipment and influence the instantaneous dose rates around the facility. While the updated devices may have the capability of operating in the FFF mode, a software key from Elekta, Inc. is required to operate the equipment in this mode. Elekta, Inc. has confirmed that no licensees have been provided this key.
4. Elekta, Inc. did not make their customers aware that the changes made to the equipment were of such significance that the users would be required to revalidate the safety case for their facility prior to operating the equipment in the FFF mode.
5. On November 9, 2015, a CNSC Inspector issued the Order 571 to Elekta, Inc. The order required Elekta, Inc. to stop installations of uncertified configurations of medical accelerators and stop performing upgrades to already operating medical linear accelerators in Canada that render them uncertified. The Order also required Elekta, Inc. to establish and submit to the CNSC an interim procedure describing the process for planning and execution of upgrades to Class II prescribed equipment in operation. Other actions required to be taken by the licensee are described in Order 571.
  - a. According to information that is currently available, Elekta, Inc. performed 41 upgrades or installations of new units to configurations not currently certified in Canada.
  - b. According to Elekta Inc.’s procedures for upgrading the equipment with the Agility head, Elekta Inc.’s service engineers operated (used) the uncertified configurations of the equipment following the upgrades with the Agility head, as part of the set up, calibration, and customer acceptance testing.
  - c. On November 12, 2015, Elekta, Inc. confirmed in a letter that they ceased upgrades and installation of new equipment with configurations not reflected in the certificate, thus complying with action #1 of Order 571. Elekta, Inc. also submitted information indicating that it complied with actions 2, 4, and 5. This information is under review. There is no immediate concern that licensees will operate their equipment in the FFF mode.
6. Compliance history relevant to this violation:
  - a. This was the second order issued to Elekta, Inc. for a similar circumstance. On June 1, 2010, the CNSC issued Order 837 for installation of an uncertified model of prescribed equipment, the Elekta Infinity.
    - i. As a result of the Order 837 Elekta, Inc. revised their procedures to clearly state that they must contact the CNSC prior to any change which may invalidate the certificate of Class II prescribed equipment. These actions were reviewed and accepted by CNSC staff.
    - ii. The first Agility upgrades were offered to customers in 2012. The CNSC was not contacted prior to installing the Agility upgrades, in non-compliance with the above noted procedure. Elekta, Inc.
  - b. In July 2011, CNSC inspectors conducted a Type I inspection of Elekta, Inc. which included site visits at user sites and the head office of Elekta, Inc. RNA. CNSC staff found that Elekta, Inc. did not maintain records of valid licences of their customers and that Elekta, Inc. did not incorporate Canadian regulations in their programs. The list of customers submitted by Elekta,



Inc. to the CNSC on October 19, 2015 in response to a CNSC request included outdated licence numbers and customer names.

- c. In 2012 and 2014, CNSC staff performed Type II inspections in which Elekta, Inc. was cited for not following procedures when conducting servicing operations at customer sites.

Based on my review of this matter and a consideration of the seven factors in section 5 of the *Administrative Monetary Penalties Regulations (Canadian Nuclear Safety Commission)*, the amount of the penalty was determined having regard to the following relevant facts:

1. Compliance history: Assessed score = 4

A review of Elekta, Inc.'s compliance history revealed that this is the second time Elekta, Inc. was found to be in violation of *Section 10(a)* of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*. In June of 2010, the CNSC issued Elekta, Inc. Order 837 for use of uncertified Class II prescribed equipment. During a CNSC inspection conducted in July 2011, Elekta, Inc. demonstrated limited awareness of Canadian regulations and licence conditions. In two other CNSC inspections conducted in October 2012 and May 2014, Elekta, Inc. was cited for not following procedures when servicing equipment.

2. Intention or negligence: Assessed score = 2

Negligence was demonstrated in the licensee's failure to follow their own procedures. Elekta, Inc. was also negligent in that they did not inform their customers that the upgrades/installations would result in the device certificates being invalidated, and that their licences may not therefore authorize operation of this equipment. At this point there is no information which would indicate an explicit intention to commit this violation.

3. Actual or potential harm: Assessed score = 1

The upgrades with the Agility head did not affect patient treatments. The licensee has confirmed that the Flattening Filter Free (FFF) mode has not been activated on any of the units operating in Canada. Although Elekta, Inc. has indicated that no users of their equipment have been issued the software licence key to operate in this mode, should this have taken place, it would have invalidated the safety case for all the facilities affected, and potentially resulted in high dose rates in some areas surrounding the facility.

4. Competitive or economic benefit: Assessed score = 4

Accelerator models with the Agility head require a new certificate. The fees associated with certification of prescribed equipment are set out in *Schedule 2* of the *Cost Recovery Fees Regulations*. Upgrades offered by Elekta, Inc. are a source of income for the company. Accelerated installation could provide a competitive advantage to Elekta, Inc. over similar products offered by other vendors. Since 2012, Elekta, Inc. performed 41 upgrades or installations of new units to configurations not allowed by the certificate in Canada.

5. Efforts to mitigate or reverse effects: Assessed score = 2

Elekta, Inc. was aware of the problem with the certification of the equipment configured with the Agility head, but did not immediately inform licensees of the issue or cease upgrades or installation of the uncertified equipment until ordered to do so by the CNSC. Further, Elekta, Inc. notified the CNSC that technicians had upgraded Elekta Synergy Platform units (049-0003) to other certified equipment



(Synergy, 049-0015, and Synergy S, 049-0016). However, affected licensees were only contacted on November 12, 2015, after the CNSC directed Elekta, Inc. to do so.

6. Assistance to Commission: Assessed score = -1

The representative of the licensee, the Radiation Safety Officer (RSO), has been forthcoming in providing information requested by the Commission staff.

7. Attention of Commission: Assessed score = -1

The RSO promptly informed the Commission upon becoming aware that the upgrades/installations with the Agility head had been performed prior to obtaining the necessary certificate.



## Penalty calculation / Calcul de la sanction:

(See *Administrative Monetary Penalties Regulations (Canadian Nuclear Safety Commission) SOR/2013-139*)  
(Veuillez consulter le *Règlement sur les sanctions administratives pécuniaires de la Commission canadienne de sûreté nucléaire, DORS/2013-139*)

<b>(a) Category of violation / Catégorie de violation</b>			
Category A / Catégorie A <input type="checkbox"/>	Category B / Catégorie B <input checked="" type="checkbox"/>	Category C / Catégorie C <input type="checkbox"/>	
<b>(b) Penalty range / Barème de sanction</b>			
Category / Catégorie	Minimum	Maximum	Maximum – Minimum
A	\$1 000	\$12 000	\$11 000
<b>B</b>	<b>\$1 000</b>	<b>\$40 000</b>	<b>\$39 000</b>
C	\$1 000	\$100 000	\$99 000
<b>(c) Determining factors / Facteurs déterminants</b>			
Factors / Facteurs	Scale of regulatory significance / Échelle de l'importance sur le plan réglementaire	Assessed score / Pondération évaluée	
1. Compliance history Antécédents en matière de conformité	0 <input type="checkbox"/> +1 <input type="checkbox"/> +2 <input type="checkbox"/> +3 <input type="checkbox"/> +4 <input checked="" type="checkbox"/> +5 <input type="checkbox"/>	4	
2. Intention or negligence Intention ou négligence	0 <input type="checkbox"/> +1 <input type="checkbox"/> +2 <input checked="" type="checkbox"/> +3 <input type="checkbox"/> +4 <input type="checkbox"/> +5 <input type="checkbox"/>	2	
3. Actual or potential harm Dommages réels ou potentiels	0 <input type="checkbox"/> +1 <input checked="" type="checkbox"/> +2 <input type="checkbox"/> +3 <input type="checkbox"/> +4 <input type="checkbox"/> +5 <input type="checkbox"/>	1	
4. Competitive or economic benefit Avantage économique ou concurrentiel	0 <input type="checkbox"/> +1 <input type="checkbox"/> +2 <input type="checkbox"/> +3 <input type="checkbox"/> +4 <input checked="" type="checkbox"/> +5 <input type="checkbox"/>	4	
5. Efforts to mitigate or reverse effects Efforts pour atténuer ou neutraliser les effets	-2 <input type="checkbox"/> -1 <input type="checkbox"/> 0 <input type="checkbox"/> +1 <input type="checkbox"/> +2 <input checked="" type="checkbox"/> +3 <input type="checkbox"/>	2	
6. Assistance to Commission Aide apportée à la Commission	-2 <input type="checkbox"/> -1 <input checked="" type="checkbox"/> 0 <input type="checkbox"/> +1 <input type="checkbox"/> +2 <input type="checkbox"/> +3 <input type="checkbox"/>	-1	
7. Attention of Commission Violation déclarée à la Commission	-2 <input type="checkbox"/> -1 <input checked="" type="checkbox"/> 0 <input type="checkbox"/> +1 <input type="checkbox"/> +2 <input type="checkbox"/> +3 <input type="checkbox"/>	-1	
<b>Total</b>		<b>11</b>	
÷ 29 <sup>(1)</sup> [rounded to 2 decimal points / arrondi à 2 décimales près]=		<b>0.38</b>	
<b>x \$39,000</b>			
[total] =		<b>\$14,820</b>	
<b>+ \$ 1000 [minimum for the category / montant minimal pour la catégorie] =</b>		<b>\$15,820</b>	

<sup>(1)</sup>29 being the maximum value of regulatory significance / <sup>(1)</sup>29 étant la valeur maximale de l'importance sur le plan réglementaire



## To request a review / Pour présenter une demande de révision

As a person subject to an administrative monetary penalty, you have the right to request a review of the amount of the penalty or the facts of the violation, or both. Your request must be made in writing indicating the reasons why you are requesting a review and providing supporting information.

If you choose to request a review, you must do so in writing by January 4, 2016 to:

Canadian Nuclear Safety Commission  
c/o Marc Leblanc  
Commission Secretary  
P.O. Box 1046, Station B  
Ottawa, Ontario K1P 5S9

Fax: (613) 995-5086  
Telephone: (613) 995-6506  
Email:  
[cnscc.interventions.ccsn@canada.ca](mailto:cnscc.interventions.ccsn@canada.ca)

En tant que personne faisant l'objet d'une sanction administrative pécuniaire, vous avez le droit de demander une révision du montant de la pénalité ou des faits quant à la violation, ou des deux. Vous devez présenter votre demande par écrit, y indiquer pourquoi vous demandez une révision et inclure toute information à l'appui de votre demande.

Si vous demandez une révision, vous devez le faire par écrit avant le 4 janvier 2016 en communiquant avec :

Commission canadienne de sûreté nucléaire  
a/s Marc Leblanc  
Secrétaire de la Commission  
C.P. 1046, succursale B  
Ottawa (Ontario) K1P 5S9

Télécopieur : 613-995-5086  
Téléphone : 613-995-6506  
Courriel :  
[cnscc.interventions.ccsn@canada.ca](mailto:cnscc.interventions.ccsn@canada.ca)

## Payment / Paiement

You may pay this administrative monetary penalty by sending a cheque to:

Receiver General for Canada  
c/o Canadian Nuclear Safety Commission  
Finance Division  
P.O. Box 1046, Station B  
Ottawa, Ontario K1P 5S9

For other payment methods and further instructions, please refer to the attached *Notice of Payment Due*.

**Should you neither pay the penalty nor exercise your right to a review, you will be considered as having committed the violation and will be liable to the penalty set out herein.**

Cette sanction administrative pécuniaire peut être payée par chèque libellé au nom du :

Receveur général du Canada  
a/s Commission canadienne de sûreté nucléaire  
Division des finances  
C.P. 1046, succursale B  
Ottawa (Ontario) K1P 5S9

Pour de l'information sur les autres méthodes de paiement et d'autres instructions, veuillez consulter le document *Avis de paiement dû* ci-joint.

**Si vous ne payez pas la sanction et n'exercez pas votre droit de révision, on considérera que vous avez commis la violation et vous serez passible de la sanction mentionnée aux présentes.**



## Issued by / Délivré par

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Colin Moses

Designated Officer / Fonctionnaire désigné

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Date

Telephone / Téléphone: 613-993-7699

Email / Courriel: colin.moses@canada.ca