



NOTICE OF VIOLATION (Corporation) AVIS DE VIOLATION (Société)

Date of Notice / Date de l'avis: January 26, 2015

AMP Number / Numéro de SAP: 2015-AMP-03

Violation committed by / Violation commise par : Isologic Innovative Radiopharmaceuticals Ltd.	Amount of penalty / Montant de la sanction: \$2,170 Due date/Date d'échéance du paiement: February 25, 2015
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Violation

Failure of consignor or carrier to act in accordance with paragraphs 501 to 547 of the *IAEA Regulations*. Specifically: Exceeding the limit of 4 Bq/cm² for beta and gamma emitters on the external surface of a package.

In violation of sub-section 16(4) of the *Packaging and Transport of Nuclear Substances Regulation*.

Relevant Facts / Faits pertinents

I, André Régimbald, Director General of the Directorate of Nuclear Substance Regulation and Designated Officer authorized by the Canadian Nuclear Safety Commission (CNSC) to issue notices of violation, believe on reasonable grounds that Isologic Innovative Radiopharmaceuticals Ltd. (Isologic) committed the above violation. The relevant facts to the violation are:

- Isologic holds CNSC licence number 15012-4-16.0 authorizing the company to process and distribute unsealed nuclear substances (radiopharmaceuticals).
- Early on August 12, 2014, Isologic delivered 10 Type A packages of radiopharmaceuticals in two separate shipments to three hospitals in the Montreal area. The total quantity of radiopharmaceuticals in each package ranged from 20 GBq to 820 GBq of Technetium-99m. Tc99m has a short half-life of 6 hrs.
- On August 12, 2014, a technologist at one of the hospitals reported to her supervisor that her left hand became contaminated after handling the packages from the first shipment performed by Isologic.
- At 8:45 am on August 12, 2014, the same hospital informed Isologic that the hospital had received contaminated packages from Isologic.
- Around 10:30 am on August 12, 2014, the same hospital received the second shipment of packages from Isologic.



- At 10:45 am on August 12, 2014, the same hospital contacted Isologic to inform them that contamination was found on the packages of the second shipment.
- On August 12, 2014, the Isologic driver who delivered the packages to the hospital had his right hand contaminated while he performed both shipments to the hospital.
- On September 9, 2014, the CNSC received wipe test results from the three hospitals confirming that seven of the ten packages delivered by Isologic in two separate shipments on August 12, 2014 were contaminated above the CNSC regulatory limit.

Based on my review of this matter and a consideration of the 7 factors in section 5 of the CNSC *Administrative Monetary Penalties Regulations*, the amount of the penalty was determined by having regard to the following:

1. Compliance history: A review of Isologic's compliance history over the past five years revealed no transportation events of contaminated Type A packages delivered by Isologic prior to August 12, 2014, and no CNSC orders issued to the company.
2. Intention or negligence: Isologic demonstrated negligence since on two occasions on August 12, 2014, a total of seven type A packages containing nuclear substances prepared and delivered by Isologic failed to meet the CNSC requirements for non-fixed contamination on external surfaces of packages. However, the violation does not appear to have been intentional.
3. Actual or potential harm: Two (2) Nuclear Energy Workers were contaminated as a result of this violation: one hospital worker received an extremity dose of approximately 0.030 mSv, and the driver of the Isologic vehicle received an extremity dose of approximately 0.64mSv. The contamination presented a low risk to the two workers.
4. Competitive or economic benefit: There does not appear to have been any competitive or economic benefit as a result of this violation.
5. Efforts to mitigate or reverse effects: Having knowledge of a first contaminated shipment of Type A packages on August 12, 2014, efforts made by Isologic were ineffective in preventing a second contaminated shipment on the same day. Following these events, Isologic made changes to the preparation of packages being shipped to hospitals and modified operational procedures to verify that packages leaving Isologic met CNSC requirements for non-fixed contamination on external surfaces of packages.
6. Assistance to Commission: Isologic has provided information to the Commission as requested throughout the CNSC review of the event.
7. Attention of Commission: Isologic reported the August 12, 2014 event to the CNSC on August 14, 2014. Sub-section 29(1) of the *General Nuclear Safety and Control Regulations* requires that licensees must immediately report such an event to the CNSC.



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)

(a) Category of Violation / Catégorie de violation			
Category A/Catégorie A <input type="checkbox"/>	Category B/Catégorie B <input checked="" type="checkbox"/>	Category C/Catégorie C <input type="checkbox"/>	
(b) Penalty Range / Barème de sanction			
	Category Catégorie	Minimum	Maximum Maximum - Minimum
	A	\$1 000	\$12 000 \$11 000
	B	\$1 000	\$40 000 \$39 000
	C	\$1 000	\$100 000 \$99 000
(c) Determining Factors / Facteurs déterminants			
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, +1, +2, +3, +4, +5		0
2. Intention or negligence / Intention ou négligence	0, +1, +2, +3, +4, +5		+1
3. Actual or potential harm / Dommages réels ou potentiels	0, +1, +2, +3, +4, +5		0
4. Competitive or economic benefit / Avantage économique ou concurrentiel	0, +1, +2, +3, +4, +5		0
5. Efforts to mitigate or reverse effects/ Efforts pour atténuer ou neutraliser les effets	-2, -1, 0, +1, +2, +3		0
6. Assistance to Commission / Aide apportée à la Commission	-2, -1, 0, +1, +2, +3		-1
7. Attention of Commission / Violation déclarée à la Commission	-2, -1, 0, +1, +2, +3		+1
	Total		+1
	+ 29 ⁽¹⁾ [rounded to 2 decimal points/arrondi à 2 décimales près]=		.03
	x 39,000		1,170
	[difference between category maximum and minimum/ écart entre le montant minimal et le montant maximal] =		
	+ \$ 1000 [minimum for the category/montant minimal pour la catégorie] =		2,170

⁽¹⁾29 being the maximum value of regulatory significance / ⁽¹⁾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 within **30 days** of the date of the notice in writing by contacting:

Marc Leblanc
Commission Secretary
Canadian Nuclear Safety Commission
280 Slater Street
Ottawa ON K1P 5S9

Facsimile: (613) 995-5086
Telephone: (613) 995-6506
E-mail: interventions@cnsccsn.gc.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 dans les **30 jours** suivant la date de l'avis, par écrit en communiquant avec :

Marc Leblanc
Secrétaire de la Commission
Commission canadienne de sûreté nucléaire
280, rue Slater
Ottawa (Ontario) K1P 5S9

Télécopieur: 613-995-5086
Téléphone: (613) 995-6506
Courriel: interventions@cnsccsn.gc.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

André Régimbald

Designated Officer/Fonctionnaire désigné

2015 / 01 / 26

Date

Telephone/Téléphone: 613-993-7699

Email/Courriel: Andre.Regimbald@cnsccsn.gc.ca