



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

October 14, 2021

Lluís Sole, CEO
Lumondi Inc.
27 West 24th Street
Suite 700b
New York, NY 10010

**SUBJECT: LUMONDI INC. - NRC INSPECTION REPORT NO. 030-37460/2021-001 AND
NOTICE OF VIOLATION**

Dear Mr. Sole:

This refers to the routine, announced remote inspection conducted between July 20 and October 6, 2021, of your licensed activities. The inspection was an examination of activities conducted under exempt distribution license 04-23929-01E as they relate to compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of observations of exempt products for distribution, selected examination of procedures and representative records, and interviews with personnel. The preliminary inspection findings were discussed with you during an exit meeting on October 6, 2021.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

You are required to respond to this letter and must follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC Web site at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. Information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

L. Sole

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If you have any questions regarding this matter, please contact Steve Shaffer of my staff at (610) 337-5225 or by electronic mail to steve.shaffer@nrc.gov

Thank you for your cooperation.

Sincerely,

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-37460
License No. 04-23929-01E

Enclosure:
Notice of Violation

cc w/ enclosure
State of New Jersey

LUMONDI INC. - NRC INSPECTION NO. 030-37460/2021-001 AND NOTICE OF VIOLATION
DATED OCTOBER 14, 2021

DOCUMENT NAME:

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NAME	SShaffer	CCahill			
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NOTICE OF VIOLATION

Lumondi Inc.
New York, New York

Docket No. 030-37460
License No. 04-23929-01E

During an NRC inspection conducted between July 20 and October 6, 2021, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

1. License Condition 14 of NRC License 04-23929-01E, Amendment No. 1, dated December 10, 2015, requires that the licensee is authorized to distribute the self-luminous timepieces series specified in letter dated November 24, 2015, or letter dated June 10, 2016. License Condition 10 further specifies that the licensee shall request an amendment to the license if it intends to distribute any additional timepiece series not authorized by the license or if it intends to distribute any timepieces with hydrogen-3 activity exceeding the activity authorized in 10 CFR 30.15(a)(1).

Contrary to the above, between December 10, 2017, and October 6, 2021, the licensee failed to limit its distribution to only the self-luminous timepieces series specified in letter dated November 24, 2015, or letter dated June 10, 2016, and failed to request an amendment to the license if it intended to distribute any additional timepiece series not authorized by the license. Specifically, the licensee distributed models self-luminous timepieces that were not specified in letter dated November 24, 2015, or letter dated June 10, 2016, and failed to request an amendment to the license to distribute these self-luminous timepieces. This violation is a repeat from the previous inspection in 2016.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d)

2. 10 CFR 32.16 requires licensees that transfer certain items containing byproduct material to submit annual reports of all transfers of those items. Lumondi's licensed material is transferred in items covered under this regulation. Also, License Condition 13 specifically states that the licensee shall file periodic reports as specified in 10 CFR 32.16.

Contrary to the above, Lumondi did not submit transfer reports required by 10 CFR 32.16. Specifically, for the years 2018, 2019, 2020, and 2021 transfer reports were not submitted prior to the inspection which started July 20, 2021.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d)

Pursuant to the provisions of 10 CFR 2.201, Lumondi Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be

issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 14th day of October 2021