



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

August 26, 2020

Steve Patterson, CEO
Quantel USA, Inc.
49 Willow Peak Drive
Bozeman, MT 59718

SUBJECT: QUANTEL USA LICENSE AMENDMENT AND NOTICE OF
VIOLATION 030-35151/2020-001

Dear Mr. Patterson,

This letter refers to the Nuclear Regulatory Commission's (NRC) review of the change of control that was submitted to the NRC Region IV office by Quantel USA Inc., in an amendment request dated April 17, 2020. The change of control supporting documentation stated that the group KEOPSYS-QUANTEL (parent company of Quantel USA Inc.) changed ownership to LUMIBIRD S.A. (Lumibird). Quantel USA Inc. became a subsidiary of Lumibird on May 17, 2018, which resulted in the indirect change of ownership of Quantel USA Inc. In addition, the change of control documentation stated that Quantel USA Inc., agreed to abide by all statements, representations, procedures, conditions, and commitments made by Lumibird.

Based on the license amendment request dated April 17, 2020, for the change of control, the NRC determined that one Severity Level IV violation of the NRC requirements occurred. The violation involved the failure to obtain the NRC's consent in writing prior to the change of control associated with radioactive materials License Number 25-27639-01. Licensees are expected to notify the NRC of a change of control, and/or transfer of ownership in a timely manner, allowing the NRC enough time to carry out its statutory mandate of ensuring that licensed materials are adequately secured, and that public health and safety and the environment are protected.

This violation, and the detailed circumstances surrounding it, is cited in the enclosed Notice of Violation (NOV).

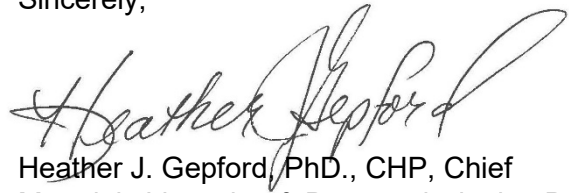
The failure to seek required NRC approval before the implementation of a significant change in licensed activities that has radiological or programmatic significance, such as a change in ownership, is normally considered to be a Severity Level III violation. However, since the change of ownership resulted in little or no adverse impact on radiological or programmatic activities, the violation is categorized as a Severity Level IV violation in accordance with the NRC Enforcement Policy.

You are required to respond to this letter, and should follow the instructions specified in Information Notice 96-28 when preparing your response. For your convenience, "Suggested Guidance Relating to Development and Implementation of Corrective Action," can be found in

the NRC website at: <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. If you have additional information that you believe the NRC should consider, you may provide it in your response to the NOV. The NRC review of your response to the NOV will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at www.nrc.gov/reading-rm/adams.html. Should you have any questions concerning this inspection, please contact Michelle Hammond of my staff at 817-200-1127.

Sincerely,

A handwritten signature in black ink, appearing to read "Heather J. Gepford". The signature is fluid and cursive, with a large loop at the end.

Heather J. Gepford, PhD., CHP, Chief
Materials Licensing & Decommissioning Branch
Division of Nuclear Materials Safety

Docket No.: 030-35151
License No.: 25-27639-01
Control No.: 618643

Enclosure:
Notice of Violation

NOTICE OF VIOLATION

Quantel USA, Inc.
Bozeman, Montana

Docket: 030-35151
License: 25-27639-01

In a letter dated April 17, 2020, for a change of control that occurred on May 17, 2018, a violation of the NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 CFR 30.34(b) requires, in part, that no license issued or granted pursuant to the regulations shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

Contrary to the above, on May 17, 2018, the licensee transferred control of the NRC License 25-27639-01 without the Commission, after securing full information, finding that the transfer was in accordance with the provisions of the Act and giving its consent in writing. Specifically, the group KEOPSY-S-QUANTEL (parent company of Quantel USA Inc.) changed ownership to LUMIBIRD S.A. (Lumibird), which constituted a change of control under 10 CFR 30.34(b), prior to notifying the NRC and receiving consent.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d.7).

Pursuant to the provisions of 10 CFR 2.201, Quantel USA Inc., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (NOV). We request you also email your response to Mary.Muessle@nrc.gov. 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 or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, 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 NOV, 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, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Enclosure

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected, and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld, and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Dated this 26th day of August 2020

QUANTEL USA LICENSE AMENDMENT AND NOTICE OF VIOLATION 030-35151/2020-001
DATED – AUGUST, 26, 2020.

DISTRIBUTION:

SMorris, ORA
AVegel, ORA
MMuessle, DNMS
LHowell, DNMS
HGepford, DNMS
MHammond, DNMS
PSilva, DNMS
R4DNMS_MLDB

Steve Patterson, CEO
SPatterson@lumibird.us

ADAMS ACCESSION NUMBER: ML20239B053

<input checked="" type="checkbox"/> SUNSI Review By: MMH	ADAMS: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Sensitive <input checked="" type="checkbox"/> Non-Sensitive	<input type="checkbox"/> Non-Publicly Available <input checked="" type="checkbox"/> Publicly Available	Keyword NRC-002
OFFICE	DNMS/MLDB	C:MLDB		
NAME	MMHammond	HJGepford		
SIGNATURE	/RA/	/RA/		
DATE	8/12/2020	8/26/2020		

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