

October 14, 2014

GL-49904

GUARDO PIREZ OYOLA  
PFIZER PHARMACEUTICAL  
HIGHWAY 2, KM 58.2  
BARCELONETA, PR 00617

SUBJECT: APPLICABLE REGULATIONS FOR GENERALLY LICENSED DEVICES  
CONTAINING BYPRODUCT MATERIALS AND AUTHORIZED PURSUANT TO  
10 CFR PART 31

You are receiving the attached table(s) of applicable sections of the U.S. Nuclear Regulatory Commission's (NRC's) regulations because you have recently acquired one or more generally licensed devices authorized under Title 10 of the *Code of Federal Regulations* (10 CFR Part 31), or under equivalent regulation of an Agreement State. Please review the requirements of 10 CFR Part 31 and other applicable regulations which can be accessed by opening NRC web site link <http://www.nrc.gov/reading-rm/doc-collections/cfr/>.

Please verify that you have the appropriate regulatory sections provided to you by comparing the information about the generally licensed devices as indicated by the label on the outside of the device. For safety reasons, DO NOT TRY TO DISMANTLE any device to verify this information. If you are uncertain how to identify device labels, contact the device manufacturers/distributors or an appropriately authorized service agent for this information.

No response to this letter is requested; however, if you have specific questions regarding regulatory requirements or your responsibilities as a general licensee, please call (301) 415-6004, email [Hector.Rodriguez-Luccioni@nrc.gov](mailto:Hector.Rodriguez-Luccioni@nrc.gov), or visit <http://www.nrc.gov/materials/medical.html>. In addition you may submit your queries to the attention of GLTS Project Manager, U.S. Nuclear Regulatory Commission, Office of Federal and State Materials and Environmental Management Programs, Division of Materials Safety and State Agreements, Washington, DC 20555-0001.

Sincerely,  
/RA/

Hector Rodriguez-Luccioni, General Engineer  
Licensing Branch  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs

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Office of Federal and State Materials and  
Environmental Management Programs

Distribution:  
MSSA r/f

**ML14287A662**

<b>Office</b>	FSME	FSME
<b>Name</b>	HRodriguez	MKotzalas
<b>Date</b>	10/06/2014	10/09/2014

**OFFICIAL RECORD COPY**

**Regulatory requirements for certain detecting, measuring, and controlling devices and certain devices for producing light or an ionized atmosphere generally licensed under 10 CFR 31.5**

	<b>Subject</b>	<b>Applicable Regulation</b>
1	Report theft or loss of licensed material	10 CFR 20.2201
2	Notification of incidents	10 CFR 20.2202
3	Exempt concentrations	10 CFR 30.14(d)
4	Terms and conditions of licenses	10 CFR 30.34(a)-(e)
5	Bankruptcy notification	10 CFR 30.34(h)
6	Transfer of byproduct material	10 CFR 30.41
7	Reporting requirements	10 CFR 30.50
8	Records	10 CFR 30.51
9	Inspections	10 CFR 30.52
10	Tests	10 CFR 30.53
11	Modification and revocation of licenses and registration certificates	10 CFR 30.61
12	Right to cause the withholding or recall of byproduct material	10 CFR 30.62
13	Violations	10 CFR 30.63
14	Terms and conditions	10 CFR 31.2
15	Categories of users and types of devices	10 CFR 31.5 (a) and (b)(1)
16	Receipt of device	10 CFR 31.5(b)(2)
17	Labels on device	10 CFR 31.5(c)(1)
18	Testing	10 CFR 31.5(c)(2)
19	Testing and service	10 CFR 31.5(c)(3)
20	Records of testing	10 CFR 31.5(c)(4)
21	Malfunction of or damage to the device	10 CFR 31.5(c)(5)
22	Abandonment	10 CFR 31.5(c)(6)
23	Device export restrictions	10 CFR 31.5(c)(7)
24	Restrictions on and reporting of transfers of the device	10 CFR 31.5(c)(8)
25	Transfer of the device to a general licensee	10 CFR 31.5(c)(9)
26	Other applicable regulatory requirements	10 CFR 31.5(c)(10)
27	Respond to written requests from NRC	10 CFR 31.5(c)(11)
28	Appointment of a responsible person	10 CFR 31.5(c)(12)
29	Register appropriate devices	10 CFR 31.5(c)(13)(i)

**Regulatory requirements for certain detecting, measuring, and controlling devices and  
certain devices for producing light or an ionized atmosphere generally licensed under 10  
CFR 31.5**

	<b>Subject</b>	<b>Applicable Regulation</b>
30	Annual registration of the device	10 CFR 31.5(c)(13)(ii) and 10 CFR 31.5(c)(13)(iii)
31	Report changes in mailing address	10 CFR 31.5(c)(14)
32	Do not hold devices not in use more than 2 years	10 CFR 31.5(c)(15)
33	No manufacture or import authorized	10 CFR 31.5(d)
34	Maintenance of records	10 CFR 31.21
35	Violations	10 CFR 31.22
36	Civil penalties	10 CFR 31.23