

August 18, 2014

GL-725087

DIANN APPELEGATE
PARAGON MEDICAL INC
8 MATCHETTE DRIVE
PIERCETON, IN 46562

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, 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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Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

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| Date | 08/06/2014 | 08/07/2014 |

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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

| | Subject | Applicable Regulation |
|----|---|------------------------------|
| 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

| | Subject | Applicable Regulation |
|----|--|--|
| 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 |