



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555 - 0001

September 23, 2013

Sekisui Diagnostics, Inc.  
ATTN: Christina Perry  
Compliance Specialist  
6659 Top Gun Street  
San Diego, CA 92121

Dear Ms. Perry:

This letter verifies receipt of the completed NRC Form 483 dated September 19, 2013. This form is a condition of the general license under 10 CFR 31.11 authorizing in-vitro testing with byproduct material under a general license.

The form has been assigned registration number **9337**. When making changes to any of the information on the form, please reference the registration number and address the correspondence to the Director, Office of Federal and State Materials and Environmental Management Programs, Washington, DC 20555.

If you have any questions or need further assistance, please contact me at (301) 415-8140.

Sincerely,

A handwritten signature in cursive script that reads "Traci Kime".

Traci Kime  
Licensing Assistant  
Licensing Branch  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosure: NRC Form 483 - 9344

### REGISTRATION CERTIFICATE -- *in vitro* TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Estimated burden per response to comply with this mandatory collection request: 8 minutes. The validated registration serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the byproduct material. Send comments regarding burden estimate to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0038), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number.

1. NAME AND ADDRESS OF APPLICANT (See Instruction 3.B. below)

Sekisui Diagnostics LLC  
6659 Top Gun Street  
San Diego, CA 92121

TELEPHONE NUMBER (Include Area Code):

(858) 777-2600

2. APPLICATION (Check one box only)

I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of by product materials for:

- Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine.
- The above-named clinical laboratory.
- The above named hospital.
- Veterinarian in the practice of veterinary medicine.

INSTRUCTIONS

- A. Submit this form to:  
Source Safety and Security Branch (T-8 E24)  
Division of Materials Safety & State Agreements  
and Environmental Management Programs  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001
- (At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)
- B. In the box above, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed.

4. REGISTRATION

REGISTRATION NUMBER:

9337

For The U.S. Nuclear  
Regulatory Commission



*Christina Perry*

9-23-13

(If this an initial registration, leave this space blank - number to be assigned by NRC. If this is a change of information from a previously registered general license, include your registration number.)

5. If place of use is different from address listed above, give complete address.

6. CERTIFICATION

I hereby certify that:

- A. All information in this registration certificate is true and complete.
- B. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.
- C. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director of Nuclear Material Safety and Safeguards within 30 days from the effective date of such change.
- D. I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the U.S. Nuclear Regulatory Commission.

PRINTED OR TYPED NAME AND TITLE OF APPLICANT

Christina Perry, Compliance Specialist

SIGNATURE

*Christina Perry*

DATE

9/19/13

**WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.**