



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 8, 2005

Docket No. 03010611
Control No. 135928

License No. 29-16223-01

Stuart Magloff
Vice President of Worldwide Operations
Ortho-Clinical Diagnostics, Inc.
1001 US Highway 202
Raritan, NJ 08869-0606

SUBJECT: ORTHO-CLINICAL DIAGNOSTICS, INC., ISSUANCE OF LICENSE RENEWAL,
CONTROL NO. 135928

Dear Mr. Magloff:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify the NRC in writing of any change in mailing address.
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license
 - a) when you decide to terminate all activities involving materials authorized under the license; or
 - b) if you decide not to acquire or possess and use authorized material.
4. Request and obtain a license Amendment before you:

- a) change Radiation Safety Officers;
 - b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or
 - c) add or change the areas of use, or addresses of use identified in the license application or on the license; or
 - d) change the name or ownership of your organization.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

S. Magloff
Ortho-Clinical Diagnostics, Inc.

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Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosures:

1. Amendment No. 12
2. 10 CFR Parts 19, 20, 21, 30, 71, 170, and 171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974
5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions
(Enforcement Policy)

cc:

Timothy D. Goddeyne, Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML050400140.wpd

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NAME	JNicholson/JJN		EUllrich/EXU					
DATE	02/08/2005		02/08/2005					

OFFICIAL RECORD COPY

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Ortho-Clinical Diagnostics, Inc.</p> <p>2. 1001 US Highway 202 Raritan, New Jersey 08869-0606</p>	<p>In accordance with the application dated October 27, 2004,</p> <p>3. License number 29-16223-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date February 28, 2015</p> <p>5. Docket No. 030-10611 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen-3</p> <p>B. Carbon-14</p> <p>C. Phosphorus-32</p> <p>D. Iodine-125</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 200 millicuries</p> <p>B. 100 millicuries</p> <p>C. 5 millicuries</p> <p>D. 100 millicuries</p>
<p>9. Authorized use:</p> <p>A. through D. Research and development as defined in 10 CFR 30.4.</p>		

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1001 US Highway Route 202, Raritan, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of, Timothy D. Goddeyne. Licensed material in Subitem 6.D. shall be used by, or under the supervision of Don Gulyas and Sandra Orimilikwe.
- B. The Radiation Safety Officer for this license is Timothy D. Goddeyne.
12. Licensed material shall not be used in or on human beings.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-16223-01Docket or Reference Number
030-10611

Amendment No. 12

13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding.
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 28, 2005

For the U.S. Nuclear Regulatory Commission

Original signed by Elizabeth Ullrich

Date February 8, 2005

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By

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406