Scanningless Multiphoton Microscopy with Diffraction-Limited Axial Resolution

Description of Invention: The technology offered for licensing is a scanningless multiphoton microscope for performing 3-dimensional imaging that achieves diffraction-limited resolution. The microscope combines temporal multiplexing with spatial dispersion to achieve diffraction-limited resolution without having to mechanically scan the sample (a field of view up to 30x30 microns). The wide-field excitation of the sample allows imaging rates in excess to prior art multiphoton microscopes while still achieving diffraction-limited axial resolution. The microscope includes a laser source that generates a femtosecond laser beam that passes through a stair-step optic having a variable thickness piece of glass arranged such that each "strip" of the laser beam is delivered at a different relative delay. Each strip exits the stair-step optic and is imaged onto the surface of a diffraction grating by two imaging lenses and a mirror. The diffraction grating sends the different wavelengths that compose each horizontal strip of the laser beam in different directions. Another pair of lenses, such as the imaging lens and objective lens (e.g., high numerical aperture objective) images and de-magnifies the surface of the diffractive grating into a biological sample that causes an excitation to occur in the sample. The ensuing excitation generates fluorescence in the sample confined to the focal plane of the objective lens, where the excitation is maximized. The fluorescence is collected through the objective lens and then by a CCD camera.

Applications:

• The invention provides a high resolution multiphoton microscopy device to the laboratory instrumentation market.

• The uses of such a device would predominantly be for research in biological imaging.

• The device provides the ability to image a large frame rapidly and with relatively low energy and thus without burning the sample or destroying subcellular structures.

Inventors: Hari Shroff and Andrew York (NIBIB).

Patent Status: U.S. Provisional Application No. 61/385,409 filed 22 Sep 2010 (HHS Reference No. E–105–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contacts:

• Uri Reichman, Ph.D., MBA; 301–435–4616; *UR7a@nih.gov.*

• Michael Shmilovich, Esq.; 301–435–5019; *ShmilovichM@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Biomedical Imaging and Bioengineering Section on High Resolution Optical Imaging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this invention. Please contact Dr. Henry Eden at *edenh@mail.nih.gov* for more information.

Myosin-Based Protein-Protein Interaction Assay

Description of Invention: Investigators at the National Institute on Deafness and Other Communication Disorders (NIDCD) have developed an assay for the detection of protein-protein interactions in living cells. This assay uses readily-available reagents and straightforward techniques that avoid the difficulty of purifying proteins or generating antibodies required for other binding studies. Proof-of-concept for this assay has been demonstrated, and a manuscript is in preparation for publication.

This technology utilizes a molecular motor, myosin X, which migrates along actin filaments within cells. A protein fused to a fragment of myosin X will carry its binding partners to the cell periphery. Since the myosin fusion protein and its partner are labeled with different fluorescent tags, an unambiguous fluorescence overlap will be visible as discrete points along the periphery of the cell. The inventors have designed a number of cDNAs for the construction of fusion proteins appropriate for such an assay.

Available for licensing are a variety of cDNAs which may be used for generating fluorescently-tagged myosin X fusion proteins, for use in the assay described above. Also available are a number of constructs incorporating other fluorescently-tagged myosins, kinesins, myosin and kinesin binding partners and a variety of PDZ scaffold proteins. Further details of the available cDNAs are available upon request.

Applications:

• Identification of protein-protein binding interactions in living cells.

• DNA-based tools for study of myosins, trafficking, signaling complexes and other research focusing on molecular motors.

Advantages:

• Assay avoids the need to purify proteins or generate antibodies for binding studies.

• Protein-protein interactions can be unambiguously identified.

Development Status: Proof of concept has been demonstrated.

Inventors: Erich T. Boger, Inna A. Belyantseva, Thomas B. Friedman (NIDCD).

Relevant Publication: Belyantseva IA et al. Myosin-XVa is required for tip localization of whirlin and differential elongation of hair-cell stereocilia. Nat Cell Biol. 2005 Feb;7(2):148–156. [PubMed: 15654330]

Patent Status: HHS Reference Nos. E–069–2009/0, E–069–2009/1, E–069–2009/2, E–069–2009/3, E–069–2009/4, E–069–2009/5, E–069–2009/6, and E–069–2009/7—Research Tool. Patent protection is not being sought for this invention.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Tara L. Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Dated: November 9, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–28847 Filed 11–15–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0448]

Guidance for Industry, Mammography Quality Standards Act Inspectors, and Food and Drug Administration Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13." This document is intended to assist mammography facilities and their personnel in meeting the requirements of the Mammography Quality Standards Act (MQSA) regulations.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency

guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles Finder, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4646, Silver Spring, MD 20993–0002, 301–796–5710.

SUPPLEMENTARY INFORMATION:

I. Background

MQSA (Pub. L. 102–539) was signed into law on October 27, 1992, to establish national quality standards for mammography. It is codified at 42 U.S.C. 263b. The MQSA requires that, in order to lawfully provide mammography services after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification Agency (section 354(b) of the MQSA, (42 U.S.C. 263b(b))). In June 1993, the authority to approve accreditation bodies and State certification agencies and to certify facilities was delegated by the Secretary to FDA (June 10, 1993, 58 FR 32543). On October 28, 1997, FDA first published final regulations implementing the MQSA in the **Federal Register** (part 900 (21 CFR part 900)). The MQSA has twice been amended since its enactment, through the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (Pub. L. 105–248 and 108–365).

This guidance updates the Policy Guidance Help System (PGHS) and addresses or contains the following:

1. Updated contact information for accreditation bodies and certification agencies;
2. General guidance regarding Additional Mammography Reviews;
3. Previously approved alternative standards;
4. Centers for Medicare and Medicaid Services reimbursement;
5. Mechanisms to inform physicians and patients of mammography results;
6. Mammographic modality and its impact on personnel requirements;
7. Clarification of the personnel 6-month exemption period;
8. Information on calibrating the air kerma measuring instrument;
9. Medical physicist involvement as it applies to cassette replacement;
10. Full Field Digital Mammography (FFDM) and use of single-use cushion pads;
11. Quality control testing of computer controlled compression devices;
12. Mammography equipment evaluations of laser printers;
13. Quality control testing of monitors and laser printers;
14. Mammography equipment evaluations of new FFDM units; and
15. Mammography equipment evaluations of off-site laser printers and monitors.

The draft of this guidance was made available in the **Federal Register** of October 9, 2009 (74 FR 52242). The comment period closed on January 7, 2010. During the public comment period, 4 respondents submitted a total of 14 comments. In addition, the National Mammography Quality Assurance Advisory Committee reviewed the draft guidance during its January 25, 2010, meeting and provided additional comments. FDA reviewed and considered all the comments and in response FDA has modified the draft guidance as follows by:

1. Providing the most current accreditation body and certification Agency contact information;
2. Clarifying that original or lossless compressed digital image files may be acceptable for record transfer;
3. Clarifying the conditions under which an Additional Mammography Review conducted by an outside entity would be acceptable to FDA;
4. Deleting the question and answer dealing with image labeling;
5. Modifying the section on the use of attestation to include attesting to the specific mammographic modality included in personnel's initial training;
6. Clarifying the guidance on the use of non-invasive kilovolts peak (kVp) meters; and
7. Recommending the inclusion of cushion pad(s) when performing automatic exposure control testing.

In November 1998, FDA compiled all to-date final FDA guidances related to MQSA and put them into a computerized searchable database called the PGHS. The PGHS is available on the Internet at: *http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm*.

FDA periodically updates the information in the PGHS and this document serves as a further update. Individuals wishing to receive automatic notification of future updates may subscribe to our E-mail ListServ by visiting *http://service.govdelivery.com/service/subscribe.html?code=USFDA_45* and following the directions.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1695 to identify the guidance you are requesting.

IV. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 900 have been approved under OMB control number 0910–0309.

V. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 10, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–28762 Filed 11–15–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1344–CN]

RIN 0938–AP89

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2011; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction notice.

SUMMARY: This document corrects a technical error that appeared in the notice published in the July 22, 2010 **Federal Register** entitled, "Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2011."

DATES: *Effective Date.* This correction is effective for IRF discharges occurring on or after October 1, 2010 and on or before September 30, 2011.

FOR FURTHER INFORMATION CONTACT: Susanne Seagrave, (410) 786–0044.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2010–17621 of July 22, 2010 (75 FR 42836), there was a technical error that we are identifying and correcting in the "Correction of Errors" section below. The provisions in this correction notice are effective as if they had been included in the document published July 22, 2010. Accordingly, the corrections are effective October 1, 2010.

II. Summary of Errors

In the July 22, 2010 notice (75 FR 42836), we applied our established formula for calculating the national cost-to-charge (CCR) ceiling. Using that formula, the national CCR ceiling should have been calculated to be 1.61. It was inadvertently listed on page 42856 as 2.94 due to a calculation error. Thus, we are correcting page 42856 to reflect the correct result of the application of the established formula. The corrected national CCR ceiling is 1.61 for FY 2011.

III. Correction of Errors

In FR Doc. 2010—17621 of July 22, 2010 (75 FR 42836), make the following corrections:

1. On page 42856, in column 1, in line 23 from the top of the page, the value "2.94" is corrected to read "1.61."

2. On page 42856, in column 1, in line 25 from the top of the page, the value "2.94" is corrected to read "1.61."

IV. Waiver of Proposed Rulemaking and Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). We also ordinarily provide a 30-day delay in the effective date of the provisions of a rule in accordance with section 553(d) of the APA (5 U.S.C. 553(d)). However, we can waive both notice and comment procedures and the 30-day delay in effective date if the Secretary finds, for good cause, that such procedures are impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons into the notice.

The policies and payment methodology expressed in the FY 2011 IRF PPS notice (75 FR 42836) have previously been subjected to notice and comment procedures. This correction notice merely provides a technical correction to the FY 2011 notice, and does not make substantive changes to the policies or payment methodologies that were expressed in that notice. Therefore, we find it unnecessary to undertake further notice and comment procedures with respect to this correction notice. We also believe that it is in the public interest (and would be contrary to the public interest to do otherwise) to waive notice and comment procedures and the 30-day delay in effective date for this notice. This correction notice is intended to ensure that the FY 2011 IRF PPS notice accurately reflects the payment methodologies and policies expressed in the notice, and that the correct information is made available to the public. Therefore, we find good cause to waive notice and comment procedures and the 30-day delay in the effective date for this correction notice.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 9, 2010.

Dawn L. Smalls,

Executive Secretary to the Department.

[FR Doc. 2010–28814 Filed 11–15–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: President's Cancer Panel.

Date: December 14, 2010.

Time: 8 a.m. to 4:45 p.m.

Agenda: The Future of Cancer Research: Accelerating Scientific Innovation.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6C10, Bethesda, MD 20892.

Contact Person: Abby B. Sandler, PhD, Executive Secretary, Chief, Institute Review Office, Office of the Director, 6116 Executive Blvd., Suite 220, MSC 8349, National Cancer Institute, NIH, Bethesda, MD 20892–8349, (301) 451–9399, *sandlera@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one