

hour × 48 hours (*i.e.*, two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = \$13,536. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be \$24,675 + \$13,536 = \$38,211. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2019 will be \$38,211.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2019

Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications and certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2019, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2019 based on the fully supported FTE hourly rates for FY 2019 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 4 provides an overview of the estimated fees for other fee categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2019
Renewal application fee for recognized accreditation body ...	\$21,350
Renewal application fee for directly accredited certification body .....	28,999
Annual fee for certification body directly accredited by FDA ....	21,056

V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application.

For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the invoice date. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: August 24, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
[FR Doc. 2018–18802 Filed 8–29–18; 8:45 am]  
**BILLING CODE 4164–01–P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
National Institutes of Health  
National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting.  
The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, NIBIB Team-based R25 Review (2019/01).  
*Date:* September 24, 2018.  
*Time:* 10:00 a.m. to 5:00 p.m.  
*Agenda:* To review and evaluate grant applications.  
*Place:* National Institutes of Health, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892 (Virtual Meeting).  
*Contact Person:* Ruixia Zhou, Ph.D., Scientific Review Officer, National Institute

of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 957, Bethesda, MD 20892, 301–496–4773, [zhour@mail.nih.gov](mailto:zhour@mail.nih.gov).  
Dated: August 23, 2018.  
**David D. Clary,**  
*Program Analyst, Office of Federal Advisory Committee Policy.*  
[FR Doc. 2018–18769 Filed 8–29–18; 8:45 am]  
**BILLING CODE 4140–01–P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
National Institutes of Health  
National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments  
**AGENCY:** National Institutes of Health, HHS.  
**ACTION:** Notice.

**SUMMARY:** This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is by webcast only and is open to the public. Registration is requested for oral comment and is required to access the webcast. Information about the meeting and registration are available at <http://ntp.niehs.nih.gov/go/165>.

**DATES:**  
*Meeting:* October 9, 2018; 1:00–4:00 p.m. (EDT).  
*Written Public Comment Submissions:* Deadline is October 1, 2018.  
*Oral Comments:* Deadline is October 1, 2018.  
*Registration to view the webcast:* Deadline October 9, 2018.  
Registration to view the meeting via the webcast is required.

**ADDRESSES:**  
*Meeting Webpage:* The preliminary agenda, registration, and other meeting materials are at <http://ntp.niehs.nih.gov/go/165>.  
*Webcast:* The meeting will be webcast; the URL will be provided to those who register for viewing.  
**FOR FURTHER INFORMATION CONTACT:** Dr. Mary Wolfe, Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 984–287–3209, Fax: 301–451–5759, Email: [wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov). Hand Deliver/ Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.