



NOV 20 2006

TO: Elias A. Zerhouni, M.D.
Director
National Institutes of Health

FROM: Daniel R. Levinson *Daniel R. Levinson*
Inspector General

SUBJECT: Review of Royalty Payments for Intramural Inventions Received by the National Institutes of Health in Fiscal Year 2004 (A-03-04-03000)

Attached is a copy of our final report on royalty payments that the National Institutes of Health (NIH) received for intramural inventions in fiscal year (FY) 2004. Under its technology transfer program, NIH enters into license agreements to move new technologies developed in its laboratories to the private sector for further development and commercialization. NIH retains title to these licensed technologies and receives royalty payments from the licensees. The Office of Technology Transfer (OTT), within NIH's Office of Intramural Research, administers the technology transfer program.

Our objective was to determine whether OTT monitored the FY 2004 royalty payments that it received for intramural inventions and ensured timely collection of the payments.

For FY 2004, OTT did not adequately monitor the royalty payments that it received or ensure the timely collection of payments. Contrary to the requirements of the "United States Public Health Service Technology Transfer Manual" (the Manual), OTT did not review all licensee sales and earned royalty reports or require licensees that met the specified sales threshold to obtain compliance audits of earned royalties. (In FY 2004, auditors did complete OTT-contracted audits of one licensee that met the threshold and two licensees that did not meet the threshold.) OTT also did not take all steps required by the Manual to collect delinquent royalty payments, nor did it terminate license agreements or seek to impose interest and penalty charges. As a result of these weaknesses, OTT lacked assurance that royalty payments were reasonable and received in a timely fashion.

We recommend that NIH:

- finalize Chapter 310 of the Manual and implement a process to ensure that OTT performs and documents reviews of all sales and earned royalty reports;
- develop and follow a revised policy regarding audits of earned royalties; and

- enforce the requirement to send late notices, terminate delinquent license agreements when appropriate, and forward delinquent licensees to the NIH Debt Collection Office to be considered for interest and penalty charges.

In its comments on the draft report, NIH concurred with our first and third recommendations and stated that OTT had recently implemented revised processes and procedures to improve monitoring and collection of royalty payments. NIH disagreed with our draft report's second recommendation to enforce the requirement for licensees that meet the sales threshold to obtain compliance audits of earned royalties. NIH stated that OTT had been using a more effective system for identifying unpaid royalties by contracting with its own independent auditors and that OTT planned to revise its compliance audit policy.

We agree that OTT's current practice of contracting with its own independent auditors is more effective and that OTT should revise its compliance audit policy. Accordingly, we have modified our second recommendation.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Joseph J. Green, Assistant Inspector General for Grants and Internal Activities, at (202) 619-1175 or through e-mail at Joe.Green@oig.hhs.gov. Please refer to report number A-03-04-03000 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF ROYALTY PAYMENTS
FOR INTRAMURAL INVENTIONS
RECEIVED BY THE NATIONAL
INSTITUTES OF HEALTH IN
FISCAL YEAR 2004**



Daniel R. Levinson
Inspector General

November 2006
A-03-04-03000

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <http://oig.hhs.gov>

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR part 5.)

OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.



EXECUTIVE SUMMARY

BACKGROUND

The National Institutes of Health (NIH) promotes research conducted by grantees (extramural research) and its own laboratories (intramural research). Pursuant to 35 U.S.C. §§ 207 and 209, NIH may move new technologies developed through intramural research to the private sector for further development and commercialization under license agreements. This process is known as technology transfer.

The Office of Technology Transfer (OTT), within NIH's Office of Intramural Research, is responsible for administering the technology transfer program and complying with the requirements of the "United States Public Health Service Technology Transfer Manual" (the Manual). OTT's functions include negotiating, monitoring, and enforcing the provisions of license agreements; ensuring the collection of royalties from licensees; and following up on delinquent royalty payments. Royalty payments may include earned royalties as a percentage of licensed product sales, execution fees, minimum annual royalties, and patent fees. To monitor the accuracy of earned royalty payments, OTT is required to review licensees' sales and earned royalty reports. Also, licensees are required to obtain annual compliance audits if sales of licensed products total \$2 million or more in the year.

During fiscal year (FY) 2004, OTT collected \$56.3 million in intramural royalty payments from 419 licensees under 774 license agreements. Earned royalties accounted for more than 70 percent of the \$56.3 million.

OBJECTIVE

Our objective was to determine whether OTT monitored the FY 2004 royalty payments that it received for intramural inventions and ensured timely collection of the payments.

SUMMARY OF FINDINGS

For FY 2004, OTT did not adequately monitor the royalty payments that it received or ensure the timely collection of payments. Contrary to the Manual's requirements, OTT did not review all sales and earned royalty reports or require licensees that met the \$2 million threshold to obtain compliance audits of earned royalties. (In FY 2004, auditors did complete OTT-contracted audits of one licensee that met the threshold and two licensees that did not meet the threshold.) OTT also did not take all steps required by the Manual to collect delinquent royalty payments, nor did it terminate license agreements or seek to impose interest and penalty charges. As a result of these weaknesses, OTT lacked assurance that royalty payments were reasonable and received in a timely fashion.

RECOMMENDATIONS

We recommend that NIH:

- finalize Chapter 310 of the Manual and implement a process to ensure that OTT performs and documents reviews of all sales and earned royalty reports;
- develop and follow a revised policy regarding audits of earned royalties; and
- enforce the requirement to send late notices, terminate delinquent license agreements when appropriate, and forward delinquent licensees to the NIH Debt Collection Office to be considered for interest and penalty charges.

NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, NIH concurred with our first and third recommendations and stated that OTT had recently implemented revised processes and procedures to improve monitoring and collection of royalty payments. NIH disagreed with our draft report's second recommendation to enforce the requirement for licensees that meet the sales threshold to obtain compliance audits of earned royalties. NIH stated that OTT had been using a more effective system for identifying unpaid royalties by contracting with its own independent auditors and that OTT planned to revise its compliance audit policy. NIH's comments are included in their entirety as the Appendix.

We agree that OTT's current practice of contracting with its own independent auditors is more effective and that OTT should revise its compliance audit policy. Accordingly, we have modified our second recommendation.

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	1
Technology Transfer Program	1
Government Accountability Office Report.....	1
OBJECTIVE, SCOPE, AND METHODOLOGY	2
Objective	2
Scope	2
Methodology	2
FINDINGS AND RECOMMENDATIONS	3
MONITORING ROYALTY PAYMENTS	4
Standards and Policies	4
Inadequate Monitoring of Earned Royalty Payments	4
ENSURING TIMELY COLLECTION OF ROYALTY PAYMENTS	5
Policies and License Provisions	5
Insufficient Steps To Collect Delinquent Royalty Payments.....	6
POTENTIAL FOR MISSED ROYALTY INCOME OPPORTUNITIES	6
RECOMMENDATIONS	6
NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	7
APPENDIX	
NATIONAL INSTITUTES OF HEALTH COMMENTS	

INTRODUCTION

BACKGROUND

Technology Transfer Program

The National Institutes of Health (NIH) promotes research conducted by grantees (extramural research) and its own laboratories (intramural research). Pursuant to 35 U.S.C. §§ 207 and 209, NIH may move new technologies developed through intramural research to the private sector for further development and commercialization under license agreements. This process is known as technology transfer. NIH retains title to these licensed technologies and receives royalty payments from the licensees.

The Office of Technology Transfer (OTT), within NIH's Office of Intramural Research, is responsible for administering the technology transfer program and complying with the requirements of the "United States Public Health Service Technology Transfer Manual" (the Manual).¹ OTT's functions include securing patent protection for commercially viable technologies, negotiating licenses, monitoring and enforcing the provisions of license agreements, ensuring the collection of royalties, and following up on delinquent royalty payments.

OTT assesses royalties throughout the term of a license or when certain product development milestones are reached. Royalty payments may include earned royalties as a percentage of licensed product sales, execution fees, minimum annual royalties, and patent fees. To monitor the accuracy of earned royalty payments, OTT is required to review licensees' sales and earned royalty reports. Also, the Manual provides that licensees are required to obtain annual compliance audits if sales of licensed products total \$2 million or more in the year.

During fiscal year (FY) 2004, OTT collected \$56.3 million in intramural royalty payments from 419 licensees under 774 license agreements. Earned royalties accounted for more than 70 percent of the \$56.3 million. During the same period, OTT had a budget of about \$8 million and a staff of 58 full-time equivalents.

Government Accountability Office Report

In a July 2000 report, the Government Accountability Office (GAO) found that NIH had insufficient monitoring controls over licensees.² GAO recommended that NIH require biennial audits for all licensees with annual product sales over \$2 million and perform periodic reviews of licensees' semiannual royalty sales reports. GAO further

¹Two chapters of the Manual are relevant to this review. Chapter 308 was adopted in September 1994 and deals with procedures for auditing NIH licenses. Chapter 310 addresses procedures for license and royalty administration. It is dated August 2004 but was still in draft as of December 2005. OTT officials, however, told us that staff were required to comply with the requirements of the draft chapter during fiscal year 2004.

²"Improvements Needed in NIH's Controls Over Royalty Income" (GAO/AIMD-00-210).

recommended that NIH impose and collect interest and penalties from licensees delinquent in making royalty payments.

In commenting on the draft report, NIH disagreed with GAO's findings and recommendations regarding the need to strengthen royalty sales report monitoring and auditing controls. GAO responded that NIH should evaluate the risk of understated sales in semiannual reports, select and review those licensees with sales data that exhibit a risk of understatement, and sample the remaining licensees for review. Regarding delinquent payments, NIH agreed with GAO's recommendation to impose and collect interest and penalties. However, NIH said that only the NIH Debt Collection Office, not OTT, was authorized to impose interest and penalties.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether OTT monitored the FY 2004 royalty payments that it received for intramural inventions and ensured timely collection of the payments.

Scope

We reviewed a stratified sample of 112 payments drawn from a total population of 1,373 intramural royalty payments that OTT received during FY 2004. This population, which totaled approximately \$56.3 million, was associated with 774 license agreements representing 419 licensees. We selected FY 2004 because OTT had been undergoing a database transition, and FY 2004 was the most recent year for which data were available. We did not test the completeness of OTT's database.

We limited our review of internal controls to obtaining an understanding of how OTT monitored its license agreements and ensured that it complied with OTT policies and license provisions for the accurate and timely collection of royalty payments.

We performed our fieldwork from June 2004 through February 2005 at OTT in Rockville, Maryland.

Methodology

In performing this review, we:

- reviewed relevant Federal laws, regulations, OTT policies, and license agreement provisions;
- interviewed OTT officials to understand the process for collecting intramural royalty payments;
- surveyed a probe sample of 5 royalty payments;

- selected a stratified sample of 112 payments from the total population of 1,373 intramural royalty payments that OTT received in FY 2004, including:
 - one stratum of 12 payments totaling \$32.4 million (58 percent of the total FY 2004 royalty payments), which represented all payments over \$1 million, and
 - a second stratum of 100 payments totaling \$2.7 million, which we randomly selected from the remaining population of 1,361 payments (1,373 less 12 payments exceeding \$1 million);
- reviewed sales and earned royalty reports in the file folder for each sampled payment;
- reviewed the 97 license agreements associated with the 112 sampled payments to determine whether the agreements contained provisions for compliance audits and contract audits procured by NIH to verify product sales and royalty payments;
- determined, for the sampled payments that had compliance audit provisions in the license agreements and that met the dollar threshold for a compliance audit, whether OTT had a copy of the audit in its files;
- reviewed one discretionary contract audit report;
- determined whether OTT sent all required late notices for the late payments in our sample; and
- discussed our findings with OTT officials.

We conducted our review in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

For FY 2004, OTT did not adequately monitor the intramural royalty payments that it received or ensure the timely collection of payments. OTT did not perform and document reviews of all sales and earned royalty reports or require licensees that met the \$2 million sales threshold to obtain compliance audits of earned royalties. (In FY 2004, auditors did complete OTT-contracted audits of one licensee that met the threshold and two licensees that did not meet the threshold.) OTT also did not routinely follow up when licensees did not submit payments on time, nor did it terminate license agreements or seek to impose interest and penalty charges. As a result of these weaknesses, OTT lacked assurance that its royalty payments were reasonable and received in a timely fashion.

MONITORING ROYALTY PAYMENTS

Standards and Policies

To ensure that it receives accurate amounts of royalty income from licensees, OTT must have monitoring controls in place. The November 1999 “Standards for Internal Control in the Federal Government,” issued by GAO in accordance with the Federal Managers’ Financial Integrity Act of 1982, state that an entity should establish policies, develop procedures to carry out those policies, monitor the outcome, and maintain records to provide evidence of execution of control activities.

Draft Chapter 310 of the Manual requires each licensee whose license agreement specifies the payment of earned royalties to submit a sales and earned royalty report as documentation for each payment. OTT must review each report for mathematical accuracy. If the reported sales appear to be unexpectedly low or high, OTT may check the sales figures against other available sales data, such as annual reports, Securities and Exchange Commission filings, and marketing reports.

Chapter 308 of the Manual provides for two types of audits to ensure reasonable royalty payments:

- For a product that has been in commercial production for at least a year and that has annual sales of \$2 million or more, the licensee is required to obtain an annual, independent compliance audit of sales and earned royalty payments.
- At its discretion, OTT may contract with an audit firm to conduct an audit of any license agreement.

Inadequate Monitoring of Earned Royalty Payments

Reviews of Sales and Earned Royalty Reports

OTT did not review all sales and earned royalty reports for FY 2004 as required by draft Chapter 310 of the Manual. Although OTT is required to review the accuracy of all such reports by checking the calculation of earned royalties due, OTT officials stated that they had not reviewed all reports. Further, because OTT had no documentation evidencing these reviews, we could not quantify how many reviews it had completed. According to OTT officials, “monitoring of licensee sales reports was done in a limited fashion focusing primarily on those paying large amounts of royalties.”

Audits of Sales and Royalty Payments

Contrary to Chapter 308 of the Manual, OTT did not require licensees that met the \$2 million sales threshold to obtain compliance audits to verify the reasonableness of their reported product sales and their earned royalty payments.

OTT did not include in all license agreements the requirement for a compliance audit if sales totaled \$2 million or more. Our sample included 29 license agreements that contained provisions for earned royalties and that OTT had awarded since September 1994, the effective date of the audit requirement. Only 8 of the 29 agreements included an audit requirement. Four of the eight agreements should have resulted in audits because sales exceeded the \$2 million threshold specified in the agreements. However, OTT did not enforce the requirement to obtain audits for the four agreements.

In lieu of enforcing the requirement that licensees obtain compliance audits, OTT officials told us that they preferred to contract with audit firms directly to perform audits of selected license agreements. Unlike compliance audits, these audits are not required by the Manual.

Between FYs 1999 and 2004, OTT contracted for 13 audits of licensees with reported sales greater than \$2 million and recovered more than \$12 million in underreported earned royalties. In FY 2004, auditors completed three audits and initiated three others. The three audits completed in FY 2004 identified about \$514,000 in underreported royalty payments. For one of these three audits, sales met the dollar threshold, and for the two others, sales did not meet the threshold.

ENSURING TIMELY COLLECTION OF ROYALTY PAYMENTS

Policies and License Provisions

Draft Chapter 310 of the Manual requires OTT to send to licensees the following three notices of overdue payment within 90 days of the initial royalty due date:

- If OTT does not receive payment within 30 days of the initial due date, OTT must send a reminder notice to the licensee.
- If OTT does not receive payment within 60 days of the initial due date, OTT must send a second notice, including a warning that the license may be terminated if payment is not received within 15 days of the date of the notice.
- If OTT does not receive payment within 90 days of the initial due date and has received no indication of the licensee's intent to resolve the outstanding obligation, OTT must send a third and final notice of overdue payment. This notice must state that OTT may refer the licensee to the NIH Debt Collection Office and may initiate steps to terminate the license if the licensee does not resolve the outstanding obligation within 10 days of the final notice.

Furthermore, license agreements generally contain a provision stating: "Interest and penalties may be assessed by PHS [the Public Health Service] on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent PHS from exercising any other rights it may have as a consequence of the lateness of any payment."

Insufficient Steps To Collect Delinquent Royalty Payments

OTT did not take all steps required by draft Chapter 310 of the Manual or permitted by the license agreements to collect delinquent royalty payments in FY 2004. Of the 112 royalty payments sampled, 38 (34 percent) were more than 30 days late. However, as of the end of our fieldwork, OTT had not sent all required late notices, as depicted in the table below:

Late Notices Sent for Sampled Payments

<u>Days Late</u>	<u>Late Payments</u>	<u>First Notices</u>		<u>Second Notices</u>		<u>Final Notices</u>	
		<u>Required</u>	<u>Sent</u>	<u>Required</u>	<u>Sent</u>	<u>Required</u>	<u>Sent</u>
31–60 days	16	16	3				
61–90 days	6	6	2	6	0		
91+ days	<u>16</u>	<u>16</u>	<u>10</u>	<u>16</u>	<u>5</u>	<u>16</u>	<u>0</u>
Total	38	38	15	22	5	16	0

For the 16 sampled payments that were more than 90 days delinquent, OTT did not take action to terminate the license agreements as provided for in draft Chapter 310. In addition, although allowed under the license agreements, OTT did not take action to have interest and penalties assessed by the NIH Debt Collection Office for any of the delinquent payments sampled.

OTT officials explained that only the NIH Debt Collection Office could pursue debts, yet OTT had no documentation showing that it had referred any of the delinquent cases in our sample to that Office for further action.

POTENTIAL FOR MISSED ROYALTY INCOME OPPORTUNITIES

As a result of the weaknesses we identified, OTT could not be assured that all of its FY 2004 royalty payments were reasonable or received in a timely fashion, and NIH Institutes and Centers may not have received their full share of royalty income.

RECOMMENDATIONS

We recommend that NIH:

- finalize Chapter 310 of the Manual and implement a process to ensure that OTT performs and documents reviews of all sales and earned royalty reports;
- develop and follow a revised policy regarding audits of earned royalties; and
- enforce the requirement to send late notices, terminate delinquent license agreements when appropriate, and forward delinquent licensees to the NIH Debt Collection Office to be considered for interest and penalty charges.

NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its October 6, 2006, written comments on the draft report, NIH concurred with our first and third recommendations and stated that OTT had recently implemented revised processes and procedures to improve monitoring and collection of royalty payments. With respect to our third recommendation, NIH clarified OTT's organizational responsibility for terminating license agreements. We revised the wording of our third recommendation to reflect that clarification.

NIH disagreed with the draft report's second recommendation to enforce the requirement for licensees that meet the sales threshold to obtain compliance audits of earned royalties. NIH acknowledged that OTT had not strictly enforced the requirement. However, NIH stated that OTT had had little success in identifying unpaid royalties using the required method and that it had been using a more effective system—contracting with its own independent auditors rather than allowing licensees to employ their own. NIH added that OTT planned to revise its compliance audit policy and to submit a policy proposal to the PHS Technology Transfer Policy Board at its next meeting. This Board is the principal advisory board to NIH in establishing and modifying technology transfer policies.

We agree that OTT's current practice of contracting with its own independent auditors is more effective and that OTT should revise its compliance audit policy. Accordingly, we have modified our second recommendation.

We have included the complete text of NIH's comments as the Appendix.

APPENDIX



National Institutes of Health
Bethesda, Maryland 20892

OCT 6 2006

TO: Daniel R. Levinson
Inspector General, HHS

FROM: Director, NIH

SUBJECT: Comments on Draft Report

The National Institutes of Health (NIH) appreciates the opportunity to provide comments to the Office of Inspector General's draft report, *Review of Royalty Payments for Intramural Inventions Received by the National Institutes of Health in Fiscal Year 2004 (A-03-04-03000)*.

NIH generally concurs with the report's findings, but some findings and conclusions are based on outdated information that was collected over a year ago. As a result, the report does not fully describe the more recent accomplishments of the Office of Technology Transfer (OTT) in monitoring and collecting royalties.

The NIH comments to the draft report are attached. I hope you will include some of OTT's recent accomplishments in your final report.

A handwritten signature in black ink, appearing to read "E. Zerhouni", written over a horizontal line.

Elias A. Zerhouni, M.D.

Attachment

Comments of the National Institutes of Health (NIH) on the HHS Office of Inspector General's Draft Report, "Review of Royalty Payments for Intramural Inventions Received by the National Institutes of Health in Fiscal Year 2004" (A-03-04-03000)

Recommendation 1: Finalize Chapter 310 of the [U.S. Public Health Service Technology Transfer] Manual and implement a process to ensure that OTT performs and documents reviews of all sales and earned royalty reports.

NIH concurs with the recommendation to update the Manual. OTT has already implemented a series of revised processes and procedures to enhance its administration of royalty collections and its monitoring of submission of progress reports. Some of these new processes and procedures were implemented shortly after the OIG performed its review. In some cases, however, the draft report fails to mention information that is relevant to the findings.

When the OIG performed its review, there were only two full-time staff dedicated to monitoring the activities of over 1,500 active and nearly 1,400 inactive licenses. NIH now dedicates significantly more resources for monitoring and enforcement of royalty payments than any other Federal agency. In the past two years, OTT has tripled the number of FTEs devoted to monitoring and enforcement, from two to six.

OTT also reorganized in August 2004: a new Chief, Monitoring and Enforcement Branch, was selected in February 2005, and a new Royalties Administrator was hired in April 2005. Starting in January 2004, OTT began revising Manual Chapters 308 and 310, as well as model agreements and standard operating procedures. It has been testing different approaches in an effort to develop a new set of best practices in the collection of royalties. Before finalizing changes to the Manual, however, OTT has needed time to test, develop, and establish updated guidelines, procedures, and best practices.

OTT will submit an updated version of Chapter 310 for approval by the PHS Technology Transfer Policy Board at its next meeting.

The report does not mention that the OTT Monitoring and Enforcement Branch has other responsibilities, including negotiating and settling patent infringement cases, amending license agreements, terminating noncompliant licensees, negotiating royalty repayment plans, pursuing overdue royalty collections from administrators of bankrupt licensees, identifying and billing payments owed after license execution, and managing NIH-contracted licensee audits.

The report also fails to mention TechTracS, OTT's database of NIH and Food and Drug Administration (FDA) patent, licensing, and Cooperative Research and Development Agreement activities. One of the modules in TechTracS is an electronic tracking system for the collection and verification of sales and earned royalty reports. Thanks to TechTracS, late notices are now printed automatically, with dates recorded and copies

sent to OTT staff for follow-up. OTT now sends payment notices 30 days in advance of the due date.

During the first year of operation (fiscal year 2003) of TechTracS, the number of identified due sales and earned reports jumped from 160 to nearly 450. Finally, in fiscal year 2005, OTT implemented a system to identify all sales reports that have been reviewed.

In conclusion, OTT has collected over 99 percent of the \$58.7 million in royalties owed to NIH in fiscal year 2004. It is still pursuing the remaining payments due and believes that it will be successful in collecting most of them by the end of this fiscal year. OTT has made significant enhancements to its processes and procedures to fully and effectively collect, analyze, document, manage, and report on royalties owed to NIH.

Recommendation 2: Enforce the requirement for licensees that meet the sales threshold to obtain compliance audits of earned royalties.

NIH acknowledges that OTT has not strictly enforced the requirement that licensees obtain annual compliance audits if their annual sales from license agreements exceed \$2 million. The report, however, does not mention that OTT has had little success in identifying unpaid royalties using the required method, and that it has been using a far more effective system for identifying unpaid royalties—contracting with its own independent auditors rather than allowing licensees to employ their own.

Seven compliance audits contracted by licensees between 1994 and 1998 showed no underpayments (the policy also allowed the licensees to deduct the cost of the audits from their royalty payments). However, subsequent independent audits, contracted and paid for by NIH, of the same seven licensees found \$11 million in unpaid royalties (and the licensees had to fully reimburse NIH for the cost of the audits). Other NIH-funded audits performed since 1998 have yielded another \$2 million in underpayments.

These experiences have convinced OTT that it needs to revise its compliance audit policy, doing away with annual audits paid for and contracted by licensees in favor of a more flexible system of audits that cover several years of agreements involving large annual sales. The revised policy proposal will be submitted to the PHS Technology Transfer Policy Board at its next meeting.

Recommendation 3: Enforce the requirement to send late notices and, when appropriate, refer delinquent licensees to the NIH Debt Collection Office to be considered for interest and penalty charges and possible termination of the license agreements

NIH concurs with the recommendation that late notices should be sent and delinquent licensees should be referred in a timely manner, as required by Manual Chapter 310.

OTT can, and does, collect additional royalties from delinquent licensees, and OTT will submit a policy revision formalizing this practice to the Public Health Service Technology Transfer Policy Board for approval in December 2006. OTT currently refers delinquent licensees to OFM for interest and penalty charges after OTT exhausts all possible avenues for collecting delinquent payments.

As for terminating license agreements, only OTT has delegated authority to do so. OTT currently terminates license agreements before forwarding them to the General Ledger Branch, OFM, for action. OTT reviews delinquent licensees for possible termination on a monthly basis. After 180 days, NIH is required to refer delinquent accounts to the Debt Management Branch, HHS Program Support Center, for further action.

10/6/06