

July 2000

FINANCIAL
MANAGEMENT

Improvements Needed
in NIH's Controls Over
Royalty Income



G A O

Accountability * Integrity * Reliability



United States General Accounting Office
Washington, D.C. 20548

Accounting and Information
Management Division

B-285582

July 21, 2000

The Honorable Tom Bliley
Chairman
Committee on Commerce
House of Representatives

The Honorable Fred Upton
Chairman, Subcommittee on Oversight
and Investigations
Committee on Commerce
House of Representatives

In our November 22, 1999 letter¹ to your office, we summarized the results of our work in response to your request that we (1) determine the extent of and reasons for the differences between the number of the National Institutes of Health (NIH) research inventions licensed under cooperative research and development agreements (CRADA) compared to inventions licensed under other intramural research projects and (2) review NIH's internal controls that ensure proper accountability for royalty income resulting from these licenses. While carrying out our work on these objectives, we identified deficiencies in NIH's internal controls over royalty income that is distributed to institutes and inventors. For fiscal year 1999, NIH reported \$45 million in royalty income from its licensees. As agreed with your office, we continued our work to review NIH's internal controls, and this report provides the results of that review.

Results in Brief

Although NIH has established policies and procedures for administering its royalty income, we identified deficiencies in internal controls that affect the monitoring of licensees and the completeness and accuracy of royalty income received. Specifically, with the exception of one licensee, the Office of Technology Transfer (OTT) did not follow up on the biennial audits of licensees' sales to ensure that licensees with sales that exceed \$2 million had been properly audited. OTT's follow-up on one licensee yielded

¹*Financial Management: National Institutes of Health Research Invention Licenses and Royalties* (GAO/AIMD-00-44R, November 1999).

previously uncollected royalty payments of \$9.2 million and the expectation that another \$1.2 million would be collected. Given the experience with this licensee, it would seem reasonable for OTT to obtain assurances that the net sales from these more lucrative licensees be routinely and timely audited. Also, OTT did not exercise its right to designate auditors to conduct reviews and verifications of semiannual royalty reports and royalty payments for the majority of its licensees. These biennial audits and verifications of semiannual royalty payments could provide OTT assurance that royalty income received from licensees is based on accurate sales amounts. We also found that OTT did not enforce its collection policies and procedures to ensure timely payment of royalty fees. As a result, institutes and inventors may not be receiving their share of royalty income in a timely manner.

In addition, NIH's systems and processes hampered proper management of royalty income. The systems maintained by the Office of Financial Management (OFM) and OTT that are used to account for royalty income were not integrated.² As a result, the monthly royalty income reconciliation process was labor-intensive and was not always performed in a timely manner.

Licensees are instructed to remit payments to a Treasury lockbox administered by a commercial bank. OFM, which receives payment information from the Treasury lockbox, did not record royalty income received from licensees in its general ledger in a timely manner. Rather, OFM records such receipts in a Treasury suspense account until it identifies the licensee, institute, and inventor. Delays in recording royalty income in its own general ledger increase the risk that financial and budgetary reports to Treasury will be inaccurate and may tend to delay distribution of funds. In its fiscal year 1999 financial audit report on internal controls, the independent public accountant (IPA) responsible for the financial statement audit of NIH noted a reportable condition related to posting of royalty income transactions. The IPA reported that NIH did not post royalty income to its general ledger in a timely manner. Timely posting

²Federal financial system requirements define an integrated financial system as one that coordinates a number of previously unconnected functions to improve overall efficiency and control. Characteristics of such a system include (1) standard data classifications for recording financial events, (2) common processes for processing similar transactions, (3) consistent internal controls over data entry, transaction processing, and reporting, and (4) a system design that eliminates unnecessary duplication of transaction entry.

of royalty income to its general ledger could help provide assurance that royalty income is properly accounted for and reported.

We are making recommendations to help NIH strengthen its internal controls over the administration of royalty income. In comments on a draft of this report, NIH agreed with four of our six recommendations and disagreed with two, stating that the areas in which we are making recommendations are areas where improvements can be, and are being, made.

Background

NIH, an operating division of the Department of Health and Human Services, is made up of 25 institutes and centers with a combined fiscal year 2000 appropriation of \$17.8 billion. One of NIH's primary missions is to promote new knowledge through basic and applied biomedical research that directly benefits public health. It performs biomedical research through both extramural and intramural projects. Extramural projects, which accounted for about \$13 billion in funding in fiscal year 1999, are carried out through grants and contracts with nonfederal organizations, such as universities and other nonprofit research organizations, and for-profit corporations. Intramural projects, which accounted for about \$1.5 billion in funding in fiscal year 1999, are primarily conducted within NIH laboratories.

Federal research performed under extramural and intramural projects can result in inventions. If the invention is developed under an extramural project, the contractor or grantee generally retains title to and profits from the invention, subject to certain terms and conditions. If the invention is developed under an intramural project, the federal agency normally retains title to the invention and can license it to others who may then commercialize it. The federal government receives royalty income from inventions it licenses. This royalty income can be in various forms including execution fees, minimum annual fees, patent fees, and earnings based on sales. These fees are negotiated with the licensees and are included in the licensing agreement.

Licensees pay a one-time execution fee to NIH for execution of the licensing agreement. The minimum annual fee is what the licensee pays to NIH for maintaining the license agreement, and the patent fees are paid for

patent filings.³ Earnings are based on net sales of the licensed product or licensed processes and are computed by the licensees based on an agreed-upon rate specified in the license agreement. For fiscal year 1999, NIH reported \$45 million in royalty receipts from its licensees. It currently has a reported 1,204 license agreements with approximately 516 licensees. Licensees' sales information is subject to a biennial audit by an independent auditor.⁴

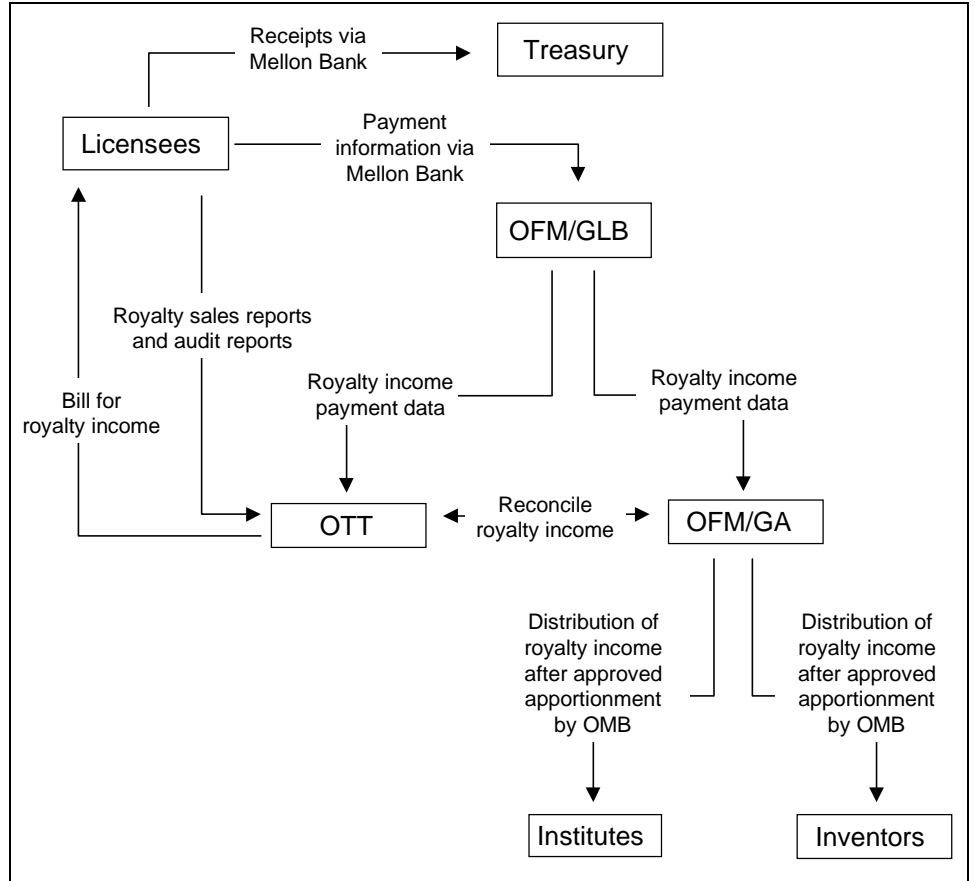
NIH management is responsible for establishing an internal control system to properly account for royalty income. In November 1999, we updated our *Standards for Internal Control in the Federal Government*. These standards, which are issued pursuant to the Federal Managers' Financial Integrity Act, provide the overall framework for establishing and maintaining internal control in the federal government.⁵ In implementing these standards, management is responsible for developing the detailed policies, procedures, and practices to fit their agency's operations and to ensure that they are built into and an integral part of operations. To comply with the Comptroller General's Standards, NIH needs to implement procedures for (1) monitoring licensees, (2) receiving, recording, and reconciling royalty income received, and (3) distributing royalty income to institutes and inventors. Primarily, two offices within NIH manage royalty income received from licensees: the Office of Technology Transfer (OTT) and the Office of Financial Management (OFM). Figure 1 depicts how royalty income is received, reconciled, and distributed.

³Patents are property rights authorized by the U.S. Constitution and statutes enacted pursuant thereto. An issued patent gives the owner the right to exclude others from making, using, selling, or importing the claimed invention.

⁴Beginning in fiscal year 1997 executed license agreements required licensees with sales that exceeded \$2 million to have a biennial audit performed. This requirement was not applicable to license agreements executed prior to 1997. License agreements also require licensees to submit semiannual sales reports to OTT.

⁵Under the Federal Managers' Financial Integrity Act of 1982, managers are responsible for ensuring that adequate systems of internal controls are developed and implemented.

Figure 1: Royalty Income Process



OTT is responsible for administering and maintaining the licensing agreements and for billing licensees for royalty income when it is due. OTT is also responsible for the oversight and monitoring of licensees that have entered into license agreements with NIH. OTT’s oversight includes the review of biennial audit reports and the enforcement of royalty collection policies and procedures. OFM, which comprises the General Ledger Branch (GLB) and the Government Accounts Section (GA), is responsible for receiving information on licensees’ payments and distributing royalty income to institutes and inventors. The GLB receives advices of royalty payments from licensees through a Treasury lockbox at Mellon Bank. The GA is responsible for reconciling royalty income with OTT monthly to ensure that (1) the amounts to be distributed to institutes and inventors agree with royalty income received from licensees and (2) payments are

made to the correct institute and inventor. The Federal Technology Transfer Act of 1986 (FTTA) provides for the distribution of royalty income received by federal agencies. To fulfill the act's requirements in this regard, NIH royalty policy requires OFM to distribute inventor royalty payments twice a year, in the early summer and early winter. Inventors' share of royalty income includes the first \$2,000 of royalties received under the license, 15 percent of receipts between \$2,000 and \$50,000, and 25 percent of receipts over \$50,000. An inventor may not receive more than \$150,000 of royalty receipts in a given year unless specifically approved by the President. Even if their employment is terminated with the government, inventors are still entitled to their share of royalty income. After the inventors have received their share of the royalty income, the remaining royalties are allocated to the institute from which the patents originated. However, before royalty income can be allocated to institutes, it must be apportioned by OMB.

Scope and Methodology

To determine the controls that NIH has in place to ensure proper accountability for royalty income, we obtained an understanding of the royalty receipt and disbursement process by interviewing officials in OTT, OFM, and two of NIH's largest institutes—the National Cancer Institute and the National Institute of Allergy and Infectious Diseases. To gain an understanding of license requirements, we reviewed the contents of license agreements. We reviewed and analyzed monthly reconciliations for June, September, and November 1999 to determine the accuracy of royalty receipts. To determine whether royalty receipts were properly accounted for and reported, we selected and tested a statistical sample of fiscal year 1999 royalty receipts from OTT's Invention Tracking System.⁶ We tracked the sample of receipts from the Invention Tracking System to the related license agreements. Because of the confidence level provided by the statistical sample, which showed no discrepancies, we randomly selected 10 different license agreements from OTT's files and tracked pertinent data from these agreements to the Invention Tracking System. We reviewed the audit work performed by the independent public accountant responsible for the fiscal year 1999 financial statement audit of NIH and reviewed the pertinent laws and regulations related to royalty income. We also reviewed NIH policies and procedures related to the collection of royalty income.

⁶The Invention Tracking System is used by NIH's OTT to maintain data on federal inventions and the licenses and royalties resulting from them.

We conducted our work from January 2000 through June 2000 in accordance with generally accepted government auditing standards. We requested comments on a draft of this report from the Acting Director of NIH or her designee. These comments are reprinted in appendix I.

NIH also provided technical comments, which we incorporated into this report where appropriate but have not included in the appendix.

Monitoring Controls Over Licensees Are Insufficient

OTT did not adequately monitor its licensees to ensure accurate payments of royalty fees because its monitoring controls over licensees were insufficient. Monitoring controls are key internal controls for ensuring that NIH receives accurate amounts of royalty income from licensees. The Comptroller General's *Standards for Internal Control in the Federal Government* states that internal controls should generally be designed to assure that ongoing monitoring occurs in the course of normal operations. The standards also state that ongoing monitoring activities include comparisons and reconciliations to identify inaccuracies or exceptions that alert management to any internal control problems. OTT's monitoring controls include biennial audits of licensees' sales information, semiannual verifications of royalty reports and royalty payments, and enforcement of collection policies and procedures. We found that OTT did not follow up on the biennial audits of licensees' sales and did not exercise its right to designate accountants and auditors to conduct reviews and verifications of licensees' semiannual royalty reports and royalty payments. In addition, OTT did not enforce its royalty collection policies and procedures to ensure that licensees made royalty payments in a timely manner and did not assess interest and penalties on delinquent licensees.

In 1997, OTT identified 14 licensees with annual sales over \$2 million and sent letters to them requesting that an audit be performed.⁷ The letters specified areas that the auditors should address during the audit and report on in the audit report to provide NIH a basis for determining if licensees submit accurate amounts of royalty income. These areas included determining (1) the amount of gross sales for each year covered by the

⁷The letters sent to the 14 licensees stated that OTT requires licensees to have compliance audits conducted of license agreements as a part of the company's annual audit by an independent audit firm. However, OTT officials told us that they viewed these audits as voluntary because the audit requirement was not applicable to license agreements executed prior to 1997.

audit, (2) the amount of funds owed to the federal government for each license agreement, and (3) whether the amounts owed the federal government had been paid and were reflected in the licensee's records.

Upon completion of the audits, the licensees were asked to submit the audit reports to OTT. However, OTT did not specify a time frame for submitting the audit reports but indicated that the audit reports should be submitted in a timely manner. In 1998, the 14 licensees submitted audit reports to OTT covering calendar years 1995 and 1996. According to OTT officials, while the licensees' independent public accountants (IPA) properly performed 4 of the 14 audits covering calendar years 1995 and 1996, the remaining 10 were not properly performed in accordance with the guidelines specified in OTT's letters. The IPAs did not disclose in the 10 audit reports the gross sales amount and related expenses used to arrive at net sales, which is the basis for calculating royalty fees.

In addition, OTT officials told us that 1 of the above 10 licensees submitted its audit report much later than others did. As a result, OTT compared the licensee's sales information to similar information reported to the Securities and Exchange Commission as an alternative means for determining if the licensee had reported accurate sales amounts.⁸ Based on this comparison, OTT found discrepancies and, in 1998, sent an auditor to review and verify the licensee's sales and royalties reports. As a result, in 1999 OTT recovered \$9.2 million in unpaid royalty fees from this licensee and is anticipating the collection of an additional \$1.2 million.

At the time of our review, the sales and royalty reports had not been verified for the remaining nine licenses for which OTT had questions about their audit reports. OTT officials indicated that although letters requesting an audit were sent to the 14 licensees, the audits were voluntary because the audit requirement was not included in license agreements executed prior to 1997. Therefore, according to OTT officials, it did not have a basis for requiring the remaining 9 licensees to have additional audit work performed. They told us that the institutes would have to finance those audit costs. Given the amount of royalty income collected from the 1 licensee in which follow-up was performed, it would appear to have been in the government's best interest to follow up on the nine audits.

⁸The Federal Securities Act of 1934 requires companies whose stock is publicly traded to include sales information in financial reports submitted to the Securities and Exchange Commission.

OTT is still facing the same problem today. Starting with license agreements executed in 1997, OTT requires the licensee to have an audit of sales and related royalties conducted by an independent auditor at least every 2 years if annual sales of the licensed product or the licensed processes exceeded \$2 million. Currently there are 13 licensees with annual sales over \$2 million. However, only 1 is required to have a biennial audit because the audit requirement is not applicable to license agreements executed prior to 1997. OTT did not separately contract for audits for the remaining 12 licensees and did not require audits for the licensees with annual sales that were \$2 million and under.

OTT personnel told us that its licensing specialists performed some monitoring of licensees' semiannual sales reports that were submitted to OTT. According to OTT, this monitoring included following up with licensees that had sales significantly lower or higher than those submitted on a prior semiannual sales report. In some instances, the follow-up resulted in the licensees submitting a corrected sales report. However, OTT could not provide supporting documentation of how it monitored licensees. Without better-defined processes and documentation of what OTT says it does, it cannot be assured that royalty receipts submitted by licensees are accurate and reliable.

In addition to the biennial audits, the license agreements require the licensee to submit a semiannual royalty report that shows the amount of the licensed products sold, the net sales, and the amount of royalty fees due. The license agreement further states that the licensee's records should be made available during normal business hours for inspection by an accountant or other designated auditor selected by OTT for the sole purpose of verifying reports and royalty payments. While licensees submitted the required semiannual sales and royalty reports, OTT had not exercised its right to have auditors review and verify these reports. Because the majority of the licensees were not required to have biennial audits, the semiannual reviews and verifications of sales information could be a compensating control. Further, the reviews and verifications of royalty reports and payments could help to ensure the accuracy of sales used to determine royalty fees and the receipt of proper amounts of royalty income from licensees.

In addition, OTT did not enforce its collection policy to ensure timely payment of royalty fees. According to OTT's collection policies and procedures, if a royalty payment is not received within 90 calendar days of the original due date, a letter should be sent to the licensee to terminate the

license agreement. Our test results showed that 1 licensee owing \$125,000 as of February 2000 in overdue royalty fees had not made payments to OTT since January 1998. However, OTT did not send the required termination letter to the licensee until January 2000—2 years after the payments became delinquent. At the time of our review, the licensee had made a payment of \$100,000 of the \$125,000 overdue royalty fee.

We identified 78 of the 1,204 license agreements in which the licensees were over 90 days delinquent in making royalty payments as of April 2000, which was the most recent data available at the time of our review. The delinquent royalty payments for these 78 license agreements, which cover 36 licensees, amounted to \$864,302. OTT allowed licensees to exceed the 90 days delinquency in certain instances where public health considerations were involved. For example, according to OTT officials, a licensee that has invented a drug for AIDS treatment would not be terminated and would be allowed to exceed the 90-day delinquency because of the impact AIDS has on public health and the urgent need for effective drugs to combat the disease.

Also, NIH did not assess interest and penalty fees on licensees that were delinquent in making their royalty payments. The licensing agreement states that NIH may assess interest and penalties on any overdue payment. We determined that delinquent debt was not referred to OFM. OTT plans to refer future delinquent debt to OFM to assess interest and penalties. The timely submission of royalty fees is an equity issue that has a direct impact on NIH inventors and institutes that should receive a distributed share of royalty income. If licensees do not submit royalty fees on a timely basis, inventors payments are also delayed. Further, the institutes do not receive their share of royalty income to support research laboratory operations and for payment of related administrative expenses.

An Integrated System Could Enhance Management of Royalty Income

According to the CFO Act, agencies should develop and maintain an integrated accounting and financial management system that complies with federal requirements and provides for complete, reliable, consistent, and timely information that is responsive to the financial information needs of the agency. An integrated financial system coordinates a number of functions to improve overall efficiency and control. Two key NIH offices that are responsible for reconciling royalty income records maintained separate, nonintegrated systems. As a result, the monthly royalty income reconciliation process was labor-intensive and was not always performed in a timely manner. OTT recently changed its plans to develop and

implement a new system to replace its current Invention Tracking System when available funds for the contract ran out. OTT now has plans to upgrade the Invention Tracking System. However, the planned upgrade would not facilitate the royalty income reconciliation process performed by offices in OTT and OFM.

OFM's, General Ledger Branch (see figure 1) receives information on licensees' payments and forwards separate copies of original royalty receipt documents to OTT and OFM's Government Accounts Section so that they can determine whether NIH received proper amounts. Because NIH does not have an integrated system to account for royalty income, each of the three offices maintains royalty income in separate systems. OTT maintains royalty income data in the Invention Tracking System, and the two OFM offices maintain royalty income data on separate Lotus spreadsheets. At the end of each month, personnel from these offices perform reconciliations of royalty income receipts recorded in each of their systems. Reconciliation procedures are a control necessary to ensure accurate reporting of royalty income received. At the same time, the clerical effort involved in entering the same data into different systems is not efficient and introduces the possibility of errors.

We found that OTT's royalty income records were not always promptly reconciled with OFM's records. Of the royalty reconciliations we reviewed, we found that the June 1999 royalty reconciliation was not completed until October 1999, 3 months after the end of the accounting period. OTT officials told us that the delay in the reconciliation process resulted from licensees (1) submitting checks without proper identification such as the license number and (2) making multiple payments with a single check. The Comptroller General's *Standards for Internal Control in the Federal Government* states that internal control activities help ensure that management's directives are carried out. These activities include approvals, authorizations, verifications, reconciliations, and maintenance of related records that provide evidence of execution of these activities as well as appropriate documentation. Performing monthly reconciliations of royalty income information within 30 days could provide assurance that reported royalty income is accurate and complete, available faster for use by the institutes, and distributed in a timely manner to inventors.

We also found that the reconciliations we reviewed were prepared and approved by the same individuals and lacked indication of supervisory review, which further increases the risk of inaccurate and incomplete royalty income. The Comptroller General's *Standards for Internal Control*

in the Federal Government states that key duties and responsibilities should be divided or segregated among different people to reduce the risk of error or fraud. This includes separating the responsibilities for authorizing transactions, processing and recording them, reviewing the transactions, and handling any related assets.

OTT and OFM could more efficiently record, retrieve, and reconcile royalty income data if the OTT and OFM systems were integrated and the data shared among those needing the information. In our November 1999 correspondence, we reported that OTT planned to replace its Invention Tracking System with a new system, the Technology Transfer Information Management System (TTIMS). In July 1997, OTT contracted for the development of TTIMS. However, after available funds for the contract ran out, OTT did not retain the contractor. According to OTT officials, after spending about \$414,000, OTT terminated the contractor because it did not produce an adequate system. OTT could not provide us with the analysis it said it performed as a basis for discontinuing TTIMS.

OTT now plans to upgrade the current Invention Tracking System. However, OTT could not tell us how the upgrade to the Invention Tracking System would improve the efficiency of its overall operations. The Clinger-Cohen Act requires agencies to establish a process to assess the value and risks of information technology investments, including specific quantitative and qualitative criteria for comparing and prioritizing alternative information technology projects. Only by comparing the costs, benefits, and risks of a full range of technical options can agencies ensure that the best approaches are selected.

Royalty Income Was Not Recorded Promptly in the General Ledger

OFM did not promptly record royalty income in its general ledger when it was received from licensees. Rather, royalty income was recorded outside of the general ledger on a Lotus spreadsheet. Recording transactions in the general ledger in a timely manner can facilitate accurate reporting to Treasury. The Comptroller General's *Standards for Internal Control in the Federal Government* states that transactions should be promptly recorded to maintain their relevance and value to management in controlling operations and making decisions.

When licensees make royalty payments, the funds are deposited in a Treasury lockbox. Treasury requires agencies to submit monthly cash collection and disbursement transaction reports that identify the appropriation account in which Treasury should record the funds.

However, OFM prepares the monthly cash collections and disbursement transaction reports and instructs Treasury to post its royalty income received to a suspense account. The Treasury suspense account is an account that maintains transactions that cannot be readily identified. Although Treasury allows agencies to record transactions in a suspense account, these agencies are expected to clear the account in a timely manner by transferring the receipts to the proper appropriation account. According to OFM personnel, it generally takes 2 to 4 months to research royalty income and for OFM and OTT to reconcile this income. After the royalty income research process and the reconciliations are complete, receipts are transferred out of Treasury's suspense account and also recorded in the NIH general ledger. However, we found that about \$50 million in royalty income had remained in the Treasury suspense account since December 1998 and was not transferred to the proper appropriation account until April 2000. In addition, only a portion of the \$50 million was recorded in the NIH general ledger in a timely manner. As a result, the royalty receipts in NIH's general ledger may not be complete and accurate, resulting in inaccurate reporting in NIH's financial statements and other external reports sent to the Office of Management and Budget (OMB) and the Treasury.

The IPA responsible for the fiscal year 1999 financial statement audit of NIH identified the same issue as an example in support of a reportable condition in its internal control report. The IPA reported that the financial accounting systems at NIH do not have the appropriate controls in place to ensure that transactions are posted to the general ledger in a timely manner. Specifically, the IPA reported that royalty receipts were not posted to the NIH general ledger in a timely manner.

Allotments Were Improperly Provided Before Apportionments Were Approved

NIH submitted its fiscal years 2000-2001 royalty income apportionment request to OMB on March 21, 2000, and the request was approved in April 2000.⁹ However, 3 months before OMB approved the apportionment

⁹NIH submits a 2-year apportionment request to OMB. Under the Federal Technology Transfer Act of 1986, as amended, an agency may generally retain royalties for 2 years after the fiscal year in which the royalties were received.

request, NIH sent advice of allotments to its institutes.¹⁰ The distribution of royalty income should not be made to NIH institutes until the royalty apportionment request is approved by OMB. We found that in January 2000, the NIH budget office provided one of the institutes an approved advice of allotment that gave it the authority to obligate royalty income funds from the first allotment for fiscal years 2000 and 2001. According to institute officials, based on this allotment, it obligated royalty income.

NIH budget office officials told us that they notified some of the institutes verbally and by electronic mail in March 2000 that they had prematurely issued advice of allotments in January 2000 in error. The officials also told us that they requested that the allotments not be disbursed until the fiscal year 2000 apportionment had been approved. We were not able to verify that notifications had been sent to the institutes because the NIH budget office officials could not provide support. Timely submission and approval of apportionment requests could ensure that the use of royalty income is properly authorized prior to issuance of allotments to institutes.

Conclusions

As a result of insufficient internal controls over its administration of royalty income, NIH cannot ensure that reported sales and related royalty amounts are reliable. In addition, by not adhering to collection policies and procedures, NIH may be foregoing royalty income due to it. Further, NIH's lack of an integrated computerized system to process royalty income transactions has hampered its ability to process and record royalty income in a timely and efficient manner. As a result, a significant amount of time and effort is spent on tasks such as reconciliations.

Recommendations

To strengthen controls over the royalty receipt process, we recommend that the Acting Director of NIH

- review and revise NIH policies and procedures for monitoring activities to include (1) the use of biennial audits for all licensees with sales over \$2 million, (2) periodic reviews of the accuracy of semiannual royalty sales reports, including those under \$2 million, and (3) specific due dates for the submission of biennial audit reports;

¹⁰An advice of allotment provides an institute the authority to obligate royalty funds.

- impose and collect interest and penalties on licensees delinquent in submitting royalty payments;
- discontinue the practice of recording royalty income in the Treasury suspense account when received—instead, record royalty income in the NIH general ledger when it is received;
- prepare timely royalty income reconciliations and ensure proper supervisory review and approval of these reconciliations;
- develop and implement a centralized database system that integrates data used by OFM and OTT to facilitate the reconciliation process; and
- ensure that royalty income apportionment requests are approved prior to issuance of advice of allotments to institutes.

Agency Comments and Our Evaluation

In written comments (see appendix I) on a draft of this report, NIH agreed in principle with four of our six recommendations and did not concur with two. NIH stated that our recommendations addressed current management weaknesses and that it was aware of and addressing many of these problems. It expressed disagreement with our overall observations and conclusions concerning the problems encountered and reported on during our review. NIH also said that, had we conducted a benchmark study of organizations that license their technologies, it would have surfaced as a leader in the level of sophistication of its monitoring activities.

First, regarding the scope of our evaluative work, we evaluated NIH's processes against commonly accepted business practices and expectations. As noted in our report, our overarching conclusion is that NIH systems, processes, and disciplines imposed internally and on its licensee community were not adequate to meet what would be considered reasonable expectations for achieving financial accountability as well as for fulfilling NIH's fiduciary role to its inventor community, which shares the royalty proceeds.

Regarding the two recommendations with which it did not concur, NIH tended to mischaracterize and misconstrue the thrust of our proposed managerial enhancements. NIH agreed that appropriate and timely monitoring activities are necessary but said it did not concur with particular aspects of our recommendation related to biennial audits, periodic reviews of the accuracy of semiannual sales reports, and specified due dates for submission of the biennial audit reports. However, in discussing its perception of what we were asking it to do, NIH's comments presumed a much more intensive effort than we had contemplated or which could be justified by the circumstances involved.

The intent of this recommendation was to help ensure that royalty income due to NIH is collected in a timely and efficient manner. Performing biennial audits for all licensees with sales over \$2 million and periodic reviews of the accuracy of semiannual sales reports are mechanisms to ensure that accurate amounts of royalty income are received. NIH expressed the view that it would not be cost-effective to audit sales data for all 1,200 licenses because for many licensees, the cost of the audit would exceed the royalty income owed. This was not our intent. An appropriate approach would entail evaluating the risk of understatement of sales in semiannual reports, selecting and reviewing those licensees with sales data that exhibit a risk of understatement, and sampling the remaining licensees for review. NIH also contends that OTT provided several letters as evidence of the outcome of its monitoring activities. We requested support as evidence of OTT's monitoring of semiannual sales reports throughout our review. However, this support has never been provided.

Further, specifying due dates for OTT to receive audit reports would help to ensure that NIH receives royalty income on a timely basis and that its institutes and inventors in turn receive their royalty income in a timely manner. As NIH stated in its comments, it is not practical to require a single due date for all licensees. We were not suggesting a single due date, but rather that NIH set a time frame for audit reports to be submitted to OTT—for example, a specified number of months after a licensee has met the \$2 million threshold or within a specified period after the close of the licensee's fiscal year. Merely asking that the audit reports be submitted timely is not specific enough to ensure consistent submission of audit reports from licensees.

NIH did not concur with our recommendation to discontinue the practice of recording royalty income in the Treasury suspense account when received and instead to record royalty income in its general ledger as received. In its comments, NIH stated that when licensees make payments, many do not provide sufficient data to allow proper recording of the receipts to the appropriate accounts in a timely manner. Specifically, it noted that it is obligated to acknowledge the receipt of the funds within its Treasury Agency Location Code by classifying the receipts in a suspense account until it can be properly classified to another specific account. We understand that the varying types of payments and the data or lack thereof accompanying licensees payments create accounting and recording problems, making resolution both time consuming and expensive. Therefore, it is incumbent upon NIH to change its expectations concerning the completeness and accuracy of licensees' submissions. It is reasonable

for NIH business practices and policies to reflect an expectation that any accounting and receipt questions be consistently resolved within 30 days.

NIH also said that if all receipts were recorded as royalty income, the potential for overstating income and budgetary resources would be high. We are not suggesting that all receipts be recorded as royalty income. NIH currently enters royalty receipts on Lotus spreadsheets but not in its accounting records until questions are resolved. Our point is that this practice means that receipt data is not being controlled by the accounting system and therefore poses a risk of lost data. Royalty receipts should be recorded in the general ledger when received, possibly in a suspense account there until resolved.

Related to royalty income reconciliations, NIH states that our report inaccurately portrays the reconciliation process as an internal control issue and that we do not present evidence or analysis to document the vulnerability. Reconciliations are a critical part of any entity's internal control activities. Reconciliation procedures are a control necessary to ensure accurate reporting of royalty income received. Also, while NIH said it was not aware of any instances where payments to inventors were delayed or missed because of a problem in the manner in which records were reconciled between OTT and OFM, officials told us that inventors and institutes cannot receive their share of royalty income until this process is complete.

We are sending copies of this report to Representative John D. Dingell, Ranking Minority Member, House Committee on Commerce; Representative Ron Klink, Ranking Minority Member, Subcommittee on Oversight and Investigations, House Committee on Commerce. We are also sending copies of this report to the Honorable Donna Shalala, Secretary of the Department of Health and Human Services; Dr. Ruth Kirschstein, the Acting Director of the National Institutes of Health; and the Honorable Jacob J. Lew, Director of the Office of Management and Budget. Copies will also be made available to others upon request. Please contact me at

(202) 512-4476 if you or your staff have any questions concerning this report. Key contributors to the assignment were Chinero Nwaigwe, Rosa Ricks Harris, Godwin Nwosu, and Debra Rucker.

Gloria L. Jarmon

Gloria L. Jarmon
Director, Health, Education, and Human Services
Accounting and Financial Management Division

Comments From the National Institutes of Health

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
<http://www.nih.gov>

JUL 11 2000

Ms. Gloria L. Jarmon
Director, Health, Education and Human Services Accounting
and Financial Management Division
U. S. General Accounting Office
Washington, D.C. 20548

Dear Ms. Jarmon:

Thank you for providing the NIH an opportunity to review and comment on the subject draft report. Our comments are enclosed.

The NIH concurs in principle with four of the report's recommendations and non-concurs with two recommendations. In general, the areas where GAO has made recommendations are areas where improvements can be, and are being made. Indeed, NIH has proactively incorporated program improvements in these areas. Thus, we are pleased that the GAO has agreed with our assessment of the importance of these activities. However, many of the assertions, generalizations, and conclusions presented in the report are not supported by findings and analyses and, therefore, we suggest that they be deleted before the report is finalized.

Should your staff have any questions, please call William Gillen, Office of Management Assessment, NIH, at (301) 496-2462.


Anthony L. Itteilag
Deputy Director for Management

Enclosure

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Comments of the National Institutes of Health on the General Accounting Office Draft Report “Financial Management: Improvements Needed in NIH’s Controls over Royalty Income” GAO/AIMD-00-210

General Comments

The National Institutes of Health (NIH) appreciates the opportunity to comment on the General Accounting Office’s (GAO) draft report. The NIH agrees fully or in principle with four of the recommendations included in the report and non-concurs with two recommendations. In general, the areas where GAO has made a recommendation are areas where improvements can be made. Indeed, NIH had already identified these as foci of activity prior to the GAO visit and has been working towards these goals. Thus, we are pleased that the GAO has agreed with our assessment of the importance of these activities. However, many of the assertions, generalizations, and conclusions presented in the report are not supported by findings and analyses, and we recommend that they be deleted before the report is finalized.

In the opening discussions with the reviewers, Office of Technology Transfer (OTT) staff shared the office’s determination that monitoring the progress and financial aspects of NIH licenses and royalty reconciliation were critical activities for OTT. In fact, the Director, OTT shared with GAO the office’s business plan in which these activities had already been singled out for special attention, including additional resources and staffing. As was pointed out to the reviewers, the plan was being implemented as the review was conducted.

Thus, the NIH is disappointed that the report does not provide any substantive additional insight into the findings and recommendations. The NIH had proactively identified the issues that the GAO report raises, and with which we concur, and actions had already been initiated.

The NIH also finds disappointing that the report does not, as requested by the Director, OTT, benchmark NIH license monitoring activities with other organizations, including federal laboratories, academic institutions, and even for profit organizations who license their technologies. While it is readily understood that all activities have room for improvement, it is important to note that the OTT monitoring operations under review are ahead of the state of the art in peer organizations. To our knowledge, no other federal agency or academic institution has a monitoring activity as sophisticated as the NIH operation. This has not been recognized or stated in the report.

To better perform current activities, the OTT specifically requested the reviewers to offer suggestions on methods to improve the current labor-intensive royalty reconciliation process between OTT and the Office of Financial Management (OFM). Again, we were disappointed that the report does not provide creative ideas that could be implemented at NIH; rather, it merely cites what NIH had noted for them: that the operation is labor intensive and a system should be devised to reduce that level of intensity. Again, the NIH has been proactively working on streamlining this activity. The recommendations provided by GAO were underway prior to the review.

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See comment 2.

We believe the report inaccurately portrays the reconciliation process as an internal control issue. The GAO report does not present evidence or analysis to document the vulnerability, and we are not aware of any instances where payments to inventors were delayed or missed due to a problem in the manner in which records were reconciled between the OTT and OFM. In fact, as stated in the response to recommendation 1, the report itself states that no discrepancies were found between the data system and the source documents. It is puzzling, therefore that the report characterizes these matters as internal control issues.

See comment 2.

With respect to the cover letter to Congress, NIH does not agree that there are deficiencies in the internal controls that affect the monitoring of licenses and the completeness and accuracy of royalty income received. While the assertion is made, the report provides no evidence or analysis to support such a statement. We, therefore, request that the statement be removed.

See comment 3.

Further, the letter inappropriately asserts that OTT licenses are not audited routinely and timely. We were concerned that the reviewers had misread the biennial audit requirement currently present in OTT licenses as bi-annual requirement for audits (see comments below). It is our position that the OTT is in compliance with its audit policy and that it carries out and will continue to carry out monitoring activities at a level far beyond that of other agencies and organizations licensing under the Bayh-Dole Act .

In summary, we believe that the cover letter and report have a number of inaccuracies and provide misleading information to Congress. The examples noted above, and additional ones identified below, document these inaccuracies.

GAO Recommendation

We recommend that the Acting Director of NIH:

1. *Review and revise its policies and procedures for monitoring activities to include (1) the use of bi-annual audits for all licensees with sales over \$2 million (2) periodic reviews of the accuracy of semi-annual royalty sales reports, including those under \$2 million and (3) specific due dates for the submission of bi-annual audit reports.*

NIH Comment

NIH agrees that appropriate and timely monitoring activities are necessary, but we non-concur with particular aspects of this recommendation for the following reasons.

See comment 3.

1. NIH has no licenses with bi-annual audit reporting requirements. Exclusive licenses entered into since 1995 are to have negotiated in the license a requirement for a licensee to have a special audit conducted by its auditors, at least once every two years (biennially), of sales and royalty income on NIH licensed technologies and to have the auditors send the report to the NIH. The audit is triggered when a licensee reaches product sales over \$2 million. At this time, only one licensee has reached this benchmark. It reached the benchmark in 1999 and has through the year 2000 to have the special audit conducted.

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See comment 4.

The report also refers to a one-time effort to ask the major royalty income providers to voluntarily conduct an audit of sales. The reports were to provide us with an indication of how firms and their auditors would respond to such a request. On the basis of the documents received, OTT found NIH owed one firm money for overpayment of royalties and indications that another firm's response may be questionable. The questionable response was referred to a special OTT contract auditor. That audit firm found what it believed were discrepancies that should result in the NIH being owed over \$9 million in royalties. After a review, discussion and attempts to negotiate with the licensee, the NIH issued a request for payment. The firm did so under protest and the case is now in litigation in federal court.

See comment 4.

We do not concur with the report's statement that it would appear to have been in the government's interest to follow up on the other voluntary audits. We believe that if a review of a required audit must be done, OTT will take the steps necessary to engage an auditor to conduct such an audit. Also see comment on 2 below.

See comment 2.

2. Of the 1200 active licenses at the NIH, all but 15-20 generate less than \$20,000 per year in earned royalty income. As was explained to the review team, the cost of having independent auditors confirm through a review of licensee records that the amounts submitted are accurate would cost in excess of \$20,000 per audit. This would mean that the cost of verification in almost every license would cost the government more money than it receives. Additionally, we do not believe that the auditing of every license every six months is necessary or reasonable especially since NIH licenses have terms that call for payments on a variety of schedules, including quarterly, semi annually, and annually. This type of action would be onerous on licensees, most of whom are small businesses, and would require in-depth assessment as to the value added if such a requirement were put in place.

When a payment is not in keeping with information contained in progress reports, public announcements on product sales, media information, etc., NIH strongly agrees that there is a need for a more in-depth review by OTT staff. It is our practice to recommend to the Institutes that audits should be conducted when OTT staff has determined that there is a strong basis for further review and incurring of audit costs. This is the basis of the monitoring program the OTT is implementing and the information was provided to the review team.

See comment 2.

We disagree with language on page 9 of the report regarding monitoring licensees' sales reports. NIH reviews each royalty sales report it receives. Specifically, the Royalties Administration and the Licensing Specialist assigned to the license review all reports. Contrary to what is stated in the report, OTT, in response to a review team special request, provided several letters as evidence of the outcome of OTT monitoring activities. We request that statement be removed from the report.

See comment 2.

Due to the cost reasons cited above and the due diligence carried out by NIH, we disagree with the statement that each report should be subjected to a review by independent auditors to confirm if the figures are accurate.

See comment 2.

3. We do not concur with the recommendation for specific due dates for all audit reports for the following reasons. First, the actual time when a benchmark has been met (reaching \$2 million in

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sales) differs on each license. Thus a single due date is impractical. Importantly, having a single date would allow those licensees that reach that milestone after the due date not to report until the next cycle, further delaying the receipt of information. Second, the licenses provide that the audit be conducted as part of the usual audit conducted on the firm. Thus, the actual date for the conduct of an audit varies from company to company. To require a special audit outside of the normal audit process would increase the cost to the company. In turn, this will reduce the amount of royalty income being received by inventors and laboratories since the cost of the audit is deducted from royalty income the government has earned under the license. NIH currently asks that the auditors, upon completion of their audit, submit audit reports directly to us. Monitoring staff are responsible for tracking the required audits.

GAO Recommendation

2. *Impose and collect interest and penalties on licensees delinquent in submitting royalty payments.*

NIH Comment

We concur. OTT tracks all licenses to ensure timely payment of amounts owed. However, OTT does not take precipitous action to terminate licenses when a payment is late. As stated in the report, there are instances where public health implications are a concern. However, it is incumbent upon our staff to review the circumstances, determine what actions, if any, can be taken to rectify the situation, and determine if the licensee is capable of bringing the technology to practical application. This can be a lengthy process; nevertheless, OTT has and will continue to take action to terminate licenses when such action is appropriate.

As the reviewers were informed, OTT has received authority to hire an additional staff person in the Royalties Administration Unit. The addition of this person, when the circumstances dictate, will permit us to process cases to the NIH Debt Collection Officer in a more timely manner. Only the NIH Debt Collection Officer, not the OTT, has the authority to impose interest and penalties.

GAO Recommendation

3. *Discontinue the practice of recording royalty income in the Treasury suspense account when it is received – instead, record royalty income in the NIH general ledger when it is received.*

NIH Comment

We non-concur with this recommendation. Often, when the NIH receives cash, there is insufficient associated data upon which to properly classify the receipts in a timely manner. We are obligated to acknowledge the receipt of the funds within our Treasury Agency Location Code (ALC) and do so by classifying the receipts in a suspense account until we can properly classify them to another specific account.

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See comment 2.

In order to process all receipts in a uniform manner, our internal processes require that all receipt funds be posted to this account. Those receipts are cleared as swiftly as possible. The clearing process requires that OFM move the funds from one specific Treasury account to another and that those transactions be posted concurrently and properly in the NIH central accounting system. Royalty receipts are identified and properly classified for posting at the time of reconciliation. If, as suggested, the NIH reported all receipts as royalty income, the potential for overstating income and budgetary resources would be high, and the overstatement could amount to millions of dollars. The NIH process of determining actual royalty funds prior to reporting income minimizes this potential overstatement. In the instant case, we did not concurrently and properly post all of the transactions. The NIH staffs involved in this process have been reminded of their responsibilities, and this situation should not recur.

GAO Recommendation

4. *Prepare timely royalty income reconciliations and ensure proper supervisory review and approval of these reconciliations.*

NIH Comment

See comment 2.

We concur that royalty income reconciliation should be prepared in a timely manner. Considering the current royalty process at the NIH, we believe the reconciliation is completed in a timely manner. The royalty collection process is complex due to the size of our operations. We had requested the reviewers to use GAO's expertise and experience to benchmark this matter; however, no benchmark or detailed analyses were conducted by the reviewers and the criteria for their statements on the timeliness are not based on any objective standard.

Now on p. 2.
See comment 2.

On page 2 of the Draft Report, the last line of the second paragraph states: "As a result, the monthly royalty income reconciliation process was labor-intensive and was not always performed in a timely manner." We concur the reconciliation process is labor-intensive. However, we do not concur the reconciliation was not always performed in a timely manner. As stated above, considering the current royalty process at the NIH, we believe the reconciliation is completed as swiftly as possible. Without any benchmarks for comparison, we recommend the sentence be changed to: "As a result, the monthly royalty income reconciliation process was labor-intensive."

Now on p. 11.
See comment 2.

On page 12 of the Draft Report, the last sentence of the first paragraph states: "Performing monthly reconciliation of royalty income information within 30 days could provide assurance that reported royalty income is accurate and complete, available faster for use by the institutes, and distributed timely to inventors." While we concur with the concept, considering the complexity of obtaining proper identification of payments made and assignment to the proper license, it is not feasible that this should be accomplished in a 30-day time period. Numerous occurrences contribute to this situation. For example: duplicate payments from the licensees; incorrect license number referenced on the payment; payments received which are not royalty payments; and lack of any identification of license or even licensee on payments. We do not believe that there is a valid objective basis for the 30-day recommendation, and, therefore, we suggest this sentence be deleted.

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See comment 5.

We generally concur with the second part of the recommendation regarding supervisory review and approval. However, through streamlining and reduction of supervisory layers, we have sought to delegate responsibility for many of the more routine processes to highly qualified staff members, and we are not convinced that much value would be added to having each and every reconciliation reviewed and approved by another supervisory layer. The OTT staff person who signs the document supervises the OTT Royalties Administration staff and the reconciliation process. We do not believe any further signatories are needed between the two offices. Nonetheless, we have initiated a process that requires all participating ICs to approve the final reconciliation of their royalty funds before any payouts are made. This will provide a further check on the completeness and accuracy of the lists of inventors and licenses.

GAO Recommendation

5. *Develop and implement a centralized database system that integrates data used by OFM and OTT to facilitate the reconciliation process.*

NIH Comment

We concur in principle. The NIH is developing a new business system that relies on the newest information technology to replace the current Administrative Data Base (ADB) with an integrated system to meet the business management needs of the agency. At this time, the Office of Information Technology, together with the OTT and OFM, is reviewing the systems to determine what enhancements might be possible for improving the automated integration of the data collected and reconciled by both organizations. In addition, the use of technical coordination support that is being considered for the development of the new OTT single source database will foster improved system integration between the two organizations and confirm that the Institutes receive full notification.

GAO Recommendation

6. *Ensure that royalty apportionment requests are approved prior to issuance of advice of allotments to institutes.*

NIH Comment

We concur with this recommendation. NIH did issue advice of allotments before the Official of Management and Budget approved the apportionment. The NIH funds control mechanisms, both manual and automated, generally work quite well, but in this instance, they did not. The responsible parties have been informed of this finding and corrective action taken.

GAO Comments

1. During a meeting with an OTT official, future plans for OTT's operations were discussed. However, OTT did not provide a written plan of its business activities for our review.
2. Discussed in "Agency Comments and Our Evaluation" section of this report.
3. This report has been revised to reflect that these audits are to be conducted every 2 years, namely, "biennially."
4. As stated in the report, it appears that it would have been in the government's best interest to follow up on other voluntary audits. Although a firm under one of the voluntary audits paid NIH \$9 million, NIH stated that the firm did so under protest and that the case is now in litigation in federal court. We do not believe that the threat of a lawsuit should be a factor in determining if an audit should be performed.
5. In its comments, NIH stated that because many of its routine processes have been delegated to highly qualified staff, it is not convinced that much value would be added to having reconciliations reviewed and approved by another supervisory layer. Contrary to NIH's comment that the OTT staff that signs the reconciliation supervises the staff that prepares the reconciliation, our review of NIH royalty income reconciliations for 3 months showed that the reconciliations were signed by the preparer without supervisory review and approval. Supervisory review and approval of royalty income reconciliations could offer additional assurance that royalty income is accurate and complete.

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