U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

EPA's Risk Assessment Division Has Not Fully Adhered to Its Quality Management Plan

Report No. 14-P-0350 **September 10, 2014**

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Abbreviations

EPA	U.S. Environmental Protection Agency
FY	Fiscal Year
IRIS	Integrated Risk Information System
OEI	Office of Environmental Information
OIG	Office of Inspector General
OPPT	Office of Pollution Prevention and Toxics
QAC	Quality Assurance Coordinator
QAM	Quality Assurance Manager
RAD	Risk Assessment Division
TSCA	Toxic Substances Control Act

Cover photo: Elements of the RAD Quality Management Plan. (EPA OIG image—colors chosen at random)

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U.S. Environmental Protection Agency
Office of Inspector General

14-P-0350
September 10, 2014

At a Glance

Why We Did This Review

Our objective was to determine to what extent the U.S. Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics' (OPPT's) Risk Assessment Division (RAD) uses and implements quality management policies during chemical risk assessments.

The goal of the quality management system is to provide a foundation to "ensure that environmental data are of sufficient quantity and quality to support the data's intended use." Each EPA office that collects, evaluates and uses environmental data is required to develop a Quality Management Plan. That plan defines an organization's quality-related policies, procedures, roles, responsibilities and authorities.

This report addresses the following EPA goal or cross-agency strategy:

- *Ensuring the safety of chemicals and preventing pollution.*

Send all inquiries to our public affairs office at (202) 566-2391 or visit www.epa.gov/oig.

The full report is at:
www.epa.gov/oig/reports/2014/20140910-14-P-0350.pdf

EPA's Risk Assessment Division Has Not Fully Adhered to Its Quality Management Plan

What We Found

RAD has adhered to some but not all aspects of its current Quality Management Plan. RAD has not fully implemented key aspects of its plan related to training, internal audits and plan revisions. Additionally, unlike other agency offices, RAD does not post its Quality Management Plan online as a good business practice.

Without a robust quality management system, RAD risks making environmental and human health policy decisions that rest on a faulty foundation.

RAD is not ensuring managers and staff take in-house formal quality assurance training. RAD, instead, relies on branch chiefs and project managers to informally train staff through mentoring. OPPT is aware of the need to provide formal quality assurance training to its staff. The Quality Assurance Manager acknowledged the quality assurance training gap and plans to develop specific quality assurance training. Additionally, RAD did not conduct a formal quality assurance training needs assessment.

The RAD Quality Assurance Coordinator has not conducted internal audits of quality assurance programs. Moreover, RAD has not revised its Quality Assurance Annual Report and Work Plan or Quality Management Plan when changes occurred to its program activities that involve major risk assessment responsibilities. Lastly, RAD does not post its Quality Management Plan on its Intranet, which can facilitate internal sharing and ease staff access. The EPA needs to have accurate, reliable and relevant Quality Management Plans because they are an essential part of valid and reliable decisions. Chemical risk assessments using high-quality data are critical to maintaining public trust in the EPA.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention develop formal quality assurance training, direct RAD to conduct internal quality assurance audits and training needs assessments, and ensure that relevant RAD Quality Management Plans are updated when changes to quality assurance activities occur. In addition, the Office of Chemical Safety and Pollution Prevention needs to provide RAD's Quality Management Plan on the OPPT Intranet and conduct a quality assurance analysis of OPPT to determine whether all divisions have fully implemented their quality management plans. The EPA agreed with our recommendations and has proposed acceptable corrective actions. All recommendations are resolved.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

September 10, 2014

MEMORANDUM

SUBJECT: EPA's Risk Assessment Division Has Not Fully Adhered to Its Quality Management Plan
Report No. 14-P-0350

FROM: Arthur A. Elkins Jr.

TO: Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The offices with primary jurisdiction over the issues evaluated in this report are the Office of Chemical Safety and Pollution Prevention's Office of Pollution Prevention and Toxics, and the Office of Pollution Prevention and Toxics' Risk Assessment Division.

Action Required

You are not required to provide a written response to this final report because you provided agreed-to corrective actions and planned completion dates for the report recommendations. The OIG may make periodic inquiries on your progress in implementing these corrective actions. Should you choose to provide a final response, we will post your response on the OIG's public website, along with our memorandum commenting on your response. You should provide your response as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended.

We will post this report to our website at http://www.epa.gov/oig.

Table of Contents

Appendices

Purpose

Our objective was to determine to what extent the U.S. Environmental Protection Agency's (EPA's) Office of Pollution Prevention and Toxics' (OPPT's) Risk Assessment Division (RAD) uses and implements quality management policies during chemical risk assessments.

Background

Since 1979, the EPA has required all organizations[1] supporting environmental programs to participate in the agencywide quality system. The EPA's Office of Environmental Information (OEI) is responsible for developing quality assurance and quality control requirements[2] and overseeing the agencywide quality system. The goal of the quality management system is to "ensure that environmental data. . . are of sufficient quantity and adequate quality to support the data's intended use."[3] A consistent quality management system, when implemented, will provide the EPA the needed technical practices and management to assure that the agency decisions are supported by adequate environmental data.

Each EPA office that collects, evaluates and uses environmental data is required to develop a Quality Management Plan. The Quality Management Plan defines an organization's quality-related policies, procedures, roles, responsibilities and authorities. According to the EPA Quality Manual for Environmental Programs,[4] the OEI reviews and approves an office's Quality Management Plan, which is then valid for 5 years.

To assess the effectiveness of the approved quality management plan, program offices are required to submit a Quality Assurance Annual Report and Work Plan to the OEI. The OEI also conducts periodic assessments of the EPA's environmental programs to determine the effectiveness of their mandatory quality systems and recommend corrective actions.

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[1] EPA Policy CIO 2105.0 (EPA Order 2105), *Policy and Program Requirements for the Mandatory Agency-Wide Quality System,* defines an organization as an office, region, national center or laboratory that collects or uses environmental data.

[2] Quality assurance is an integrated system of management activities to ensure high-quality processes and products. Quality control, in contrast, focuses on the quality of technical and operational activities. We focused on quality assurance and related management activities in this report.

[3] EPA Order 2105 provides minimum quality system requirements for EPA organizations that collect or use environmental data. EPA Policy CIO 2106.0, *EPA Quality Program Policy,* "provides the structure and procedures to ensure and enhance the effectiveness of the quality program and its application to agency products and services." In addition, the EPA issued its Information Quality Act guidelines in 2002.

[4] The *EPA Quality Manual for Environmental Programs* provides the minimum program requirements for implementing the mandatory Quality System defined in EPA CIO 2105-P-01-0.

OPPT and Its Quality Management Plan

OPPT manages programs under the Toxic Substances Control Act (TSCA). The objective of TSCA is to "allow the EPA to regulate new commercial chemicals before they enter the market, to regulate existing chemicals when they pose an unreasonable risk to human health or the environment, and to regulate their distribution and use."[5] OPPT gathers data to provide the EPA information that can be used and analyzed to reduce the risk of chemical exposure. OPPT helps to ensure that chemicals used and sold in the United States do not harm human health and the environment. OPPT has six divisions to address the production, importation, use and disposal of both existing and new chemicals (see figure 1).

Figure 1. OPPT organizational chart

Source: OPPT.

OPPT's Director is responsible for the overall quality of OPPT's programs, in accordance with their quality management plan. The OPPT Director delegates management of quality assurance activities to the Quality Assurance Manager (QAM). The QAM has full responsibility and authority to implement OPPT's quality assurance activities with respect to the agency's quality management systems. The QAM is the official point of contact for all quality assurance matters and is the liaison between OPPT and OEI. The QAM is responsible for reviewing and approving each OPPT division's Quality Management Plan and quality assurance project plans. Each OPPT Division Deputy Director works as the Quality Assurance Coordinator (QAC) and oversees the division's quality assurance activities.

OPPT began an office reorganization in the fall of 2013 which coincided with OPPT's 5-year Quality Management Plan renewal deadline. OPPT requested an extension to submit the renewed Quality Management Plans to OEI and OEI approved the extension. OEI may grant an extension if it recently conducted a quality systems assessment, and OEI had conducted a quality systems assessment

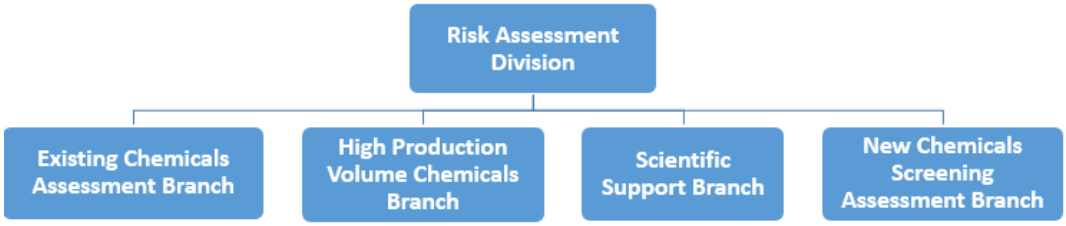
[5] 15 U.S.C. §2601.

of OPPT in November 2012. OEI's 2012 quality systems assessment found that OPPT's quality systems were in compliance with their Quality Management Plan. OPPT must submit an updated Quality Management Plan to OEI by September 2014. Although OPPT has its own Quality Management Plan, each of its six divisions are responsible for implementing its own divisional Quality Management Plan.

RAD and Its Quality Management Plan

RAD consists of four branch offices (see figure 2) and is responsible for numerous activities assessing the health and environmental hazards and risks of new and existing chemicals and microorganisms for both regulatory and non-regulatory programs. The division's responsibilities include assessing the hazards of high-production-volume chemicals. The main components of these assessments are reviewing and evaluating test data submitted under TSCA for environmental and health effects. RAD also manages the Structure-Activity Team, which is responsible for initial assessment of fate and effects of chemicals.

Figure 2. RAD organizational chart



Source: RAD.

According to RAD's Quality Management Plan, it uses numerous tools to ensure data quality.[6] RAD develops Quality Assurance Project Plans and uses standard operating procedures and other guidance documents to prepare work products and risk assessments. RAD uses external peer reviews, such as the agency's Science Advisory Board; journal article and paper peer reviews; and, occasionally, the Office of Pesticide Program's Science Advisory Panel. The RAD QAC is assigned the responsibility to assess quality assurance training needs and conducts annual internal audits of its quality assurance program. The branch chiefs are responsible for ensuring that needed training is scheduled, funded and taken. OEI guidance provides information on minor and major revisions. Minor revisions to the Quality Management Plan must be documented in the annual quality assurance report. Major revisions or reissuance of the Quality Management Plan are required when there is a significant mission change or major reorganizations. Similar to OPPT, RAD has committed to submitting an updated Quality Management Plan for approval to OEI by September 2014.

[6] The RAD "Quality Management Plan exists in the context of the OPPT Quality Management Plan," which is under the control of the OPPT QAM.

Responsible Offices

The offices responsible for the issues evaluated in this report are the Office of Chemical Safety and Pollution Prevention's OPPT and OPPT's RAD.

Scope and Methodology

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our results based upon our objectives. We conducted this audit from January to July 2014.

We reviewed relevant documents, including laws, regulations, policies and procedures. We focused on management activities listed in EPA Order 2105 and the EPA Quality Manual for Environmental Programs. We also reviewed quality guidance documents, including the current OPPT and RAD Quality Management Plans.[7]

Our review of the current RAD Quality Management Plan focused on quality assurance training, internal audits and Quality Management Plan revisions. We interviewed agency officials, including OEI's Director of Quality Staff, OPPT's Deputy Director of Programs, OPPT's QAM, RAD's Division Director and Deputy Division Director/QAC, and other RAD personnel. We reviewed the RAD's Quality Assurance Project Plans, standard operating procedures, and the fiscal years (FYs) 2009/2010, 2012/2013 and 2013/2014 annual quality assurance reports and work plans. We obtained information regarding quality assurance training and types of RAD work products. We reviewed quality management plans from the Office of Pesticide Programs and the Office of Research and Development. We also reviewed annual quality assurance reports from the Office of Resource Conservation and Recovery and the Office of Pesticide Program's Biological and Economic Analysis Division.

Results of Review

According to the RAD's Quality Management Plan, the division uses the elements shown in table 1 to ensure data quality. During our review, we found that RAD has adhered to some but not all aspects of its current Quality Management Plan. RAD did not fully implement key aspects of its Quality Management Plan related to training, internal audits and plan revisions. Additionally, we found that, unlike other agency offices business practices, RAD does not post its Quality Management Plan online.

[7] For both OPPT and RAD, the 2008 Quality Management Plan is the most current version.

Table 1: RAD adherence to quality assurance activities

Quality assurance requirement	Adherence
RAD QAC assigned.	Yes
Management review of quality assurance project plans and standard operating procedures.	Yes
Identification of quality assurance training needs.	No
Provide in-house quality assurance training.	No
Contribute to the OPPT annual report.	Yes
Revisions and updates to Quality Management Plan.	No
Yearly internal audits of divisional quality assurance program.	No

Source: OIG analysis of quality management plan requirements.

Quality Assurance Training

Within its Quality Management Plan, RAD lists "providing in-house formal training classes" as a training mechanism. Yet RAD is not ensuring managers and staff take in-house formal quality assurance training—a key aspect of its current Quality Management Plan. RAD training mechanisms include: attending scientific and professional society meetings and workshops, attending seminars and training classes offered by various software and vendors, and offering recertification classes and informal peer-to-peer training. The Office of Water offered quality assurance training in FY 2013 that only seven RAD staff members attended; however, although applicable to the environmental data RAD works with, the training was not RAD-specific.

RAD senior management stated that RAD does not have formal quality assurance training.[8] One of RAD's four branch chiefs commented that he could not remember taking any quality assurance training since becoming a branch chief. The RAD division director informed the Office of Inspector General (OIG) that their training process is informal. In FY 2012/2013, informal training was achieved through a technical discussion of topics presented to a team of peers. RAD also relies on branch chiefs and project managers to train staff through mentoring. However, without formal quality assurance training, RAD will be unable to ensure that the information passed from mentoring is consistent or the best quality assurance information is available. Additionally, without formal training in place, institutional knowledge can be lost with employee attrition.

[8] OEI does not provide a formal overall quality assurance training program.

OPPT is aware of the need to provide quality assurance training to its staff. The QAM acknowledged the quality assurance training gap and plans to develop specific quality assurance training for OPPT, which will include RAD. The QAM stated that there are plans to design training with other agency QAMs, which would potentially establish a more solid program for the entire OPPT quality assurance system. Additionally, a meeting was held in March 2014 with the EPA quality assurance community to discuss ways to better serve their respective program offices.

In addition to requiring quality assurance training, RAD's current Quality Management Plan states that the QAC is responsible for conducting formal quality assurance training needs assessments. Training needs assessments are necessary to ensure that quality assurance-related training needs are addressed and the resources are available to complete the training. However, according to OPPT's quality assurance annual reports (FYs 2009, 2012 and 2013), RAD did not conduct a formal quality assurance training needs assessment.

Internal Quality Assurance Audits

The RAD QAC has not conducted internal audits of their quality assurance programs. A quality audit is defined as "a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives."[9] As stated earlier, the role of the QAC is to ensure quality assurance of their division. According to the current RAD Quality Management Plan, the division's QAC is required to conduct annual internal quality assurance audits of their programs. According to OPPT's quality assurance annual reports (FYs 2009, 2012 and 2013), RAD did conduct routine reviews of work products by staff and the assigned management teams. RAD also had external peer reviews of scientific data. However, these activities do not qualify as annual internal quality audits by RAD QAC. Moreover, during interviews, RAD senior management acknowledged that their division has not conducted any internal quality assurance audits. Routine internal quality assurance audits help identify potential deficiencies in data quality and management controls.

Quality Management Plan Revisions

RAD has not revised its Quality Management Plan when changes occurred to its program activities, including major risk assessment responsibilities. The EPA Quality Manual for Environmental Programs requires that the Quality Management Plan be reviewed annually and updated or reissued as needed. Necessary updates include major revisions to program roles and responsibilities. The current RAD Quality Management Plan specified that they develop and prepare Integrated Risk Information System (IRIS) assessments. In contrast, RAD

[9] Defined by the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, May 2000.

stopped producing IRIS assessments in 2011 and a subsequent Federal Register notice announced the elimination of RAD's role in the IRIS preparation. However, the revisions to their quality assurance activities regarding IRIS assessments have not been documented in either the quality assurance annual report and work plan or a revised Quality Management Plan. In addition, the current RAD Quality Management Plan included information on the Chemical Assessment and Management Program, which is a program that ceased in 2009. Although this change was contained in the FY 2009 annual quality assurance report, it was a major shift in quality assurance activities for RAD and, therefore, should have resulted in a revision or reissuance of their Quality Management Plan in accordance with the EPA and RAD quality assurance guidance.

Quality Management Plan Accessibility

RAD does not post its Quality Management Plan on its Intranet. Posting the plan would increase transparency and enhance availability to the EPA staff. As a good business practice, we found that other agency offices make their quality management plans available to all by posting it on the EPA's Intranet. Quality management plans, annual quality assurance reports, internal audits, and revisions to the plans that are posted to an intranet can be easily found by managers and staff. For instance, the Office of Pesticide Programs has its Quality Management Plan online. Its Quality Management Plan includes training requirements for its QAM, quality assurance officers and contracting officer representatives. It goes further to list the specific quality assurance training that these individuals must take. The Office of Research and Development includes revisions or updates to its Quality Management Plan on the Office of Research and Development's Intranet.

Conclusions

The lack of adherence to several aspects of RAD's Quality Management Plan creates the risk that RAD's quality system cannot meet the EPA's quality management system's goal. Without a robust quality management system, RAD risks having environmental and human health policy decisions that rest on a faulty foundation. To enhance its quality management system, RAD needs to implement quality assurance training and conduct training needs assessments to ensure that managers and staff obtain relevant quality assurance knowledge. RAD's QAC needs to conduct annual independent reviews of the division's quality assurance processes to assure the quality of work products. The EPA needs to have accurate, reliable and relevant Quality Management Plans because they are an essential part of valid and reliable decisions. Chemical risk assessments using high-quality data are critical to maintaining public trust in the EPA.

Recommendations

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention:

1. Develop formal quality assurance training that enhances awareness and understanding of relevant quality management policies and requirements for managers and staff to prevent loss of institutional knowledge and comply with their Quality Management Plan.

2. Direct RAD's QAC to conduct annual internal quality assurance audits in accordance with RAD's Quality Management Plan.

3. Direct RAD to identify and document individual staff training needs to ensure that RAD addresses quality assurance-related training gaps.

4. Ensure that RAD's Quality Management Plan and/or OPPT's quality assurance annual report and work plan are updated accordingly when minor and major changes to RAD's quality assurance activities are made.

5. Provide internal online access to RAD's Quality Management Plan to increase staff accessibility to relevant quality assurance activities.

6. Conduct a quality assurance analysis of OPPT to determine whether all divisions have fully implemented their Quality Management Plans.

Agency Comments and OIG Evaluation

The agency agreed with our recommendations, and provided corrective actions and estimated completion dates that meet the intent of the recommendations. Based on the agency's written response, we have determined that the recommendations are resolved and open with corrective actions ongoing. One recommendation is closed due to being implemented prior to the final report issuance. No further response to this report is required. The agency's detailed response is in appendix A and our response to the agency is embedded in appendix A. The agency also provided technical comments on the draft report, which we have incorporated into our report as appropriate.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed-To Amount
1	8	Develop formal quality assurance training that enhances awareness and understanding of relevant quality management policies and requirements for managers and staff to prevent loss of institutional knowledge and comply with their Quality Management Plan.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	12/31/14		
2	8	Direct RAD's QAC to conduct annual internal quality assurance audits in accordance with RAD's Quality Management Plan.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/15		
3	8	Direct RAD to identify and document individual staff training needs to ensure that RAD addresses quality assurance-related training gaps.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/15		
4	8	Ensure that RAD's Quality Management Plan and/or OPPT's quality assurance annual report and work plan are updated accordingly when minor and major changes to RAD's quality assurance activities are made.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/15		
5	8	Provide internal online access to RAD's Quality Management Plan to increase staff accessibility to relevant quality assurance activities.	C	Assistant Administrator for Chemical Safety and Pollution Prevention	7/29/14		
6	8	Conduct a quality assurance analysis of OPPT to determine whether all divisions have fully implemented their Quality Management Plans.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/15		

[1] O = Recommendation is open with agreed-to corrective actions pending.
C = Recommendation is closed with all agreed-to actions completed.
U = Recommendation is unresolved with resolution efforts in progress.

Agency Response to Draft Report and OIG Comments

July 30, 2014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: Response to Office of Inspector General Draft Report No. OPE-FY14-0012 "EPA's Risk Assessment Division has Not Fully Adhered to Its Quality management Plan," dated June 30, 2014

FROM: James J. Jones
Assistant Administrator for Chemical Safety and Pollution Prevention

TO: Arthur A. Elkins, Jr.
Inspector General (OIG)

Thank you for the opportunity to respond to the subject audit report. This memorandum provides the Agency's response to OIG's recommendations, and identifies corrective actions the Agency will be taking in response (Attachment A). In addition, the Agency has suggested technical corrections to improve the accuracy of the report (Attachment B).

Every day the Office of Pollution Prevention and Toxics (OPPT) produces and uses scientific and technical work products that inform Agency decision making. We make approximately 1,000 new chemicals decisions a year based on assessments that are unchallenged by industry and other stakeholders. Our tools and models are used around the world for chemicals-related decision making. OPPT scientists play leading roles internationally in such bodies as the OECD to develop the next-generation of chemical assessment guidelines and risk assessment approaches. OPPT's Work Plan risk assessment program for existing chemicals is producing assessments that are subjected to independent, expert review that surpasses in rigor federal and Agency guidelines for peer review. It is notable that the external peer reviews of all the Work Plan assessments we have completed thus far have supported our overall assessment methodologies and conclusions. OPPT's record of strong and sound science is consistent with

OIG Response: The scope of our evaluation did not include a review of the quality of OPPT's scientific and technical work products.

the fact that your office's review of our quality system found no concerns with the quality of OPPT's scientific and technical work products.
The administrative recommendations that have resulted from your audit are very useful, and we look forward to implementing them. The report contains a total of six recommendations:

Recommendation 1. Develop formal quality training that enhances awareness and understanding of relevant quality management policies and requirements for managers and staff to prevent loss of institutional knowledge and comply with their quality management plan.

Recommendation 2. Direct RAD's QAC to conduct annual internal quality assurance audits in accordance with RAD's Quality Management Plan.

Recommendation 3. Direct RAD to identify and document individual staff training needs to ensure that RAD addresses quality assurance-related training gaps.

Recommendation 4. Ensure that RAD's Quality Management Plan and/or OPPT's quality assurance annual report and work plan updated accordingly when minor and major changes to RAD's quality assurance activities are made.

Recommendation 5. Provide internal online access to RAD's Quality Management Plan to increase staff accessibility to relevant quality assurance activities.

Recommendation 6. Conduct a quality assurance analysis of OPPT to determine whether all divisions have fully implemented their Quality Management Plans.

The Agency concurs with all of the report recommendations and will begin steps to implement the corrective actions identified in Attachment A.

We do take issue with one finding. The draft report states (p. 7) that OPPT's changes in program activities since 2009 have led to a major shift in quality assurance activities, and implies that its current Quality Management Plan is not accurate, reliable, or relevant. The final report should take care not to convey this implication. Our QMP is relevant to and supportive of all OPPT scientific and technical activities, including our new and existing chemical risk assessments.

While the policy goals and programmatic focus for conducting data reviews and evaluations within OPPT have changed over the past 5 years, the sources and types of data, the evaluation approaches and tools, and the QA/QC activities associated with using this data have not changed significantly or substantively. This is largely due to OPPT's adherence to Agency assessment guidelines and contract management processes and procedures. We did not make changes to the QMP because changes in program activities were explained in the Quality Assurance Annual Report and Work Plan (QAARWP), and the QA/QC activities did not change in any substantive way. Each QAARWP has a section for addressing changes to the QMP. In each of the QAARWPs for 2008-2013, OPPT noted that no changes to the QMP were warranted; the QAARWPs were submitted to and accepted by the Agency's Office of Environmental Information.

OIG Response: The OIG did not state that RAD's current QMP is not accurate, reliable or relevant. We specifically state that RAD has adhered to some but not all aspects of its current quality management plan. OEI's guidance was used to determine RAD's use and implementation of its QMP. Our review of OEI guidance and RAD's activities indicated that certain RAD program changes were major activities and thereby should have resulted in an updated QMP. OIG suggests that OPPT contact OEI to obtain more information or request updated guidance that further clarifies how to determine a major activity.

If you have questions or need further information about this response, please contact Deborah Hartman, OCSPP's Audit Liaison at (202) 564-1488.

Attachment A: Corrective Action Plan

EPA's Risk Assessment Division Has Not Fully Adhered to Its Quality Management Plan
Report No. OPE-FY14-0012 (June 30, 2014)

Recommendation	Corrective Action	Target Date
Recommendations to OCSPP Assistant Administrator		
1. Develop formal quality training that enhances awareness and understanding of relevant quality management policies and requirements for managers and staff to prevent loss of institutional knowledge and comply with their quality management plan.	OCSPP accepts the OIG recommendation. OPPT will develop a formal quality training program.	FY15; Q1
2. Direct RAD's QAC to conduct annual internal quality assurance audits in accordance with RAD's Quality Management Plan.	OCSPP accepts the OIG recommendation. The OPPT-RAD QAC will conduct internal quality assurance audits.	Annually, beginning in FY15.
3. Direct RAD to identify and document individual staff training needs to ensure that RAD addresses quality assurance-related training gaps.	OCSPP accepts the OIG recommendation. OPPT-RAD will identify and document Division staff training needs in the annual QA/AC report. Individual staff training needs will be addressed in Individual Development Plans	Annually, beginning in FY15.
4. Ensure that RAD's Quality Management Plan and/or OPPT's quality assurance annual report and work	OCSPP accepts the OIG recommendation. OPPT-RAD will more explicitly identify and	Annually, beginning in FY15 or when a major change in QA/QC activity occurs.

	plan updated accordingly when minor and major changes to RAD's quality assurance activities are made.	document, in the annual QA/QC report, when changes to quality assurance activities are made.	
5.	Provide internal online access to RAD's Quality Management Plan to increase staff accessibility to relevant quality assurance activities.	OCSPP accepts the OIG recommendation. OPPT has posted its QMP on the intranet.	Completed July 29, 2014 http://intranet.epa.gov/opptwork/quality-management/
6.	Conduct a quality assurance analysis of OPPT to determine whether all divisions have fully implemented their Quality Management Plans.	OCSPP accepts the OIG recommendation.	FY15

Appendix B

Distribution

Office of the Administrator
Assistant Administrator for Chemical Safety and Pollution Prevention
Agency Follow-Up Official (the CFO)
Agency Follow-Up Coordinator
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Deputy Assistant Administrator for Chemical Safety and Pollution Prevention
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