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Presidential Documents

Title 3—

The President

Proclamation 10645 of October 6, 2023

Fire Prevention Week, 2023

By the President of the United States of America

A Proclamation

During Fire Prevention Week, my Administration reaffirms our commitment to preventing fires before they happen and mitigating the damage when devastation strikes. We also honor our brave firefighters and first responders, who put their lives at risk to save others and help their communities rebuild from the rubble.

This year, we have already seen tens of thousands of wildfires burn over two million acres to the ground. And climate change will only intensify the threats that wildfires pose. Further, over one thousand Americans and dozens of firefighters have died in fires this year. Whether they are fires that start at home, in parks or neighborhoods, or in forests and the great outdoors, the devastation these fires cause mean far more than numbers can capture—they reflect lives lost; families heartbroken; natural resources wiped out; and homes, businesses, community centers, and so much more destroyed.

That is why my Investing in America Agenda includes the most significant climate investment in history. As part of that agenda, the Bipartisan Infrastructure Law is investing billions of dollars for enhanced drought resilience, early wildfire detection, and post-wildfire restoration and rehabilitation. And with historic funding for green manufacturing, clean energy development, and climate-smart agriculture, the Inflation Reduction Act is putting us on a path to cut America's carbon emissions by at least half by 2030.

My Administration is doing everything we can to make sure firefighters have the resources they need to do their jobs as safely, effectively, and efficiently as possible. I am proud to have increased the Federal firefighter minimum wage to $15 an hour—a critical first step in giving these heroes the pay, respect, and dignity they deserve. We have also created new programs to improve recruitment, retention, and professional opportunities for Federal firefighters. In addition, we have increased Federal funding for local fire departments to hire more firefighters and expanded Federal grant programs to pay for hundreds of emergency response vehicles and thousands of sets of turnout gear.

In times of tragedy, we so often find the most profound stories of hope and heroism. Across the country, the First Lady and I have been amazed by the courage and strength of those we have seen reestablishing their lives in the aftermath of devastating fires—neighbors helping neighbors, communities coming together, and people from all walks of life working with one another to rebuild what has been lost, making our Nation more resilient. We remain focused on the recovery and rebuilding efforts in Maui, where the First Lady and I visited in August to demonstrate our support for the community. To the people of Maui, who have shown such courage—this Nation stands with you.

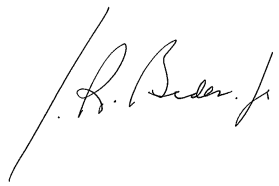
This week, we also encourage Americans to take the time to educate themselves on fire prevention and safety. This year's Fire Prevention Week theme—''Cooking safety starts with YOU. Pay attention to fire prevention''—emphasizes the simple actions we can all take to remain safe while preparing food. That includes: being alert while cooking and turning the stove off

if leaving the kitchen is necessary; keeping anything that can catch fire away from stovetops; turning pot handles toward the back of the stove; and keeping a lid nearby.

This Fire Prevention Week, let us honor those we have lost in these catastrophes, remain vigilant to prevent future fires from occurring, vow to support those who rush into danger to help us in times of need, and recommit to spreading awareness about the importance of fire safety.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 8 through October 14, 2023, as Fire Prevention Week. I call on all Americans to participate in this observance with appropriate programs and activities and by renewing their efforts to prevent fires and their tragic consequences.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of October, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2023–22663
Filed 10–11–23; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10646 of October 6, 2023

National School Lunch Week, 2023

By the President of the United States of America

A Proclamation

I have often said that children are the kite strings that keep our national ambitions aloft. During National School Lunch Week, we recognize that the health and well-being of children is a national priority and that every student should have access to healthy meals. We also reaffirm our support of the National School Lunch Program and all school nutrition professionals nationwide for the work they do to feed 30 million children each school day.

School lunches have long been a lifeline for so many students across our country. For all families, including those that qualify for free or reduced-price school lunch, parents have the peace of mind of knowing there is a healthy, balanced meal available to their children. And children, fueled by their school lunches, can more effectively focus and learn in the classroom. In fact, studies show that nutritious school lunches may increase academic performance and reduce the likelihood of childhood obesity. And we know these school lunches are especially important for lower-income children, children of color, and children living in rural areas or territories, since they are less likely to have access to food outlets that sell healthier foods.

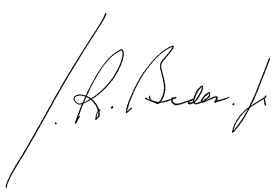
In order to build a stronger and healthier Nation, my Administration has made the well-being of American families and our children a priority. Our American Rescue Plan expanded the Child Tax Credit, which helped keep food on the table for millions of families during the pandemic, slashed child poverty by nearly 50 percent, and cut food insufficiency for families with children by more than 25 percent. My Administration also modernized the Thrifty Food Plan for the first time since 1975, making sure that the millions of families receiving Supplemental Nutrition Assistance Program benefits can afford a nutritious, practical, cost-effective diet. And last year, I convened the first White House Conference on Hunger, Nutrition, and Health in over 50 years, bringing together advocates, food companies, health care providers, and leaders from across the Government and Federal agencies. We also released a national strategy to end hunger and reduce diet-related diseases by 2030. This strategy includes the goal of expanding access to healthy, free school meals to 9 million more kids in the next decade, a major step toward free healthy school meals for every student.

We have already made significant progress. By making permanent the American Rescue Plan program that gives families money to buy groceries in the summer months when school is not in session, we are fulfilling our commitment to ensure each American child has a nutritious meal every day. We are also giving more schools the option to make healthy school meals available to all students at no cost to their families during the school year. And we are continuing to support schools so they can cook more meals from scratch and purchase more food from local farmers and ranchers. That means children will have healthier meals, and farmers and ranchers will be able to participate in reliable markets, strengthening rural economies. I also continue to call on the Congress to restore my enhanced Child Tax Credit, which helped millions of families afford healthy food at home.

In America, no child should ever go to bed hungry—without healthy food, our children cannot thrive. And no child's future should be determined by where they were born or their family's income. During National School Lunch Week, we recognize that helping our children fulfill their highest potential begins with access to healthy and nutritious meals at school. And we honor all the farmers, ranchers, teachers, school nutrition professionals, and staff who make these lunches possible and nourish the soul of America.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 8 through October 14, 2023, as National School Lunch Week. I call upon all Americans to recognize and commemorate all those who operate the National School Lunch Program with activities that raise awareness of the steadfast efforts in supporting the health and well-being of our Nation's children.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of October, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2023–22664
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Proclamation 10647 of October 6, 2023

German-American Day, 2023

By the President of the United States of America

A Proclamation

On German-American Day, we honor the over 40 million Americans who claim German heritage and the countless ways they have strengthened the diverse fabric of our Nation.

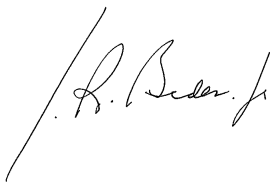
They have since the beginning. In 1683, 13 German families fled religious persecution at home and founded the first German settlement just outside of Philadelphia. Ever since, the story of German Americans has been inextricable from the story of America: German Americans fought for our freedom in the Revolutionary War, debates over the deliberations of the Continental Congress happened in German coffeehouses, a local German newspaper was the first to break the news that the Declaration of Independence had been signed, and so much more.

Today, German Americans continue to enrich our Nation's character and culture as leaders in every sector and community. They also form the cornerstone of our Nation's strong bonds with Germany and its people. As capable allies and close friends, the partnership between Germany and the United States is essential to our joint efforts to address global challenges—from tackling climate change and food insecurity to defending human rights and democracy. And together, we will continue to stand up for the values that unite us—freedom, liberty, and sovereignty—including standing with the brave people of Ukraine as they defend themselves against Russia's brutal aggression.

On this day—340 years after the first German settlement was founded on American shores—let us celebrate the incredible legacy of generations of German Americans and the unbreakable bonds of friendship between our two countries.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim October 6, 2023, as German-American Day. I urge all Americans to celebrate the rich and varied history of German Americans and remember the many contributions they have made to our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of October, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2023–22665
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Presidential Documents

Proclamation 10648 of October 6, 2023

Columbus Day, 2023

By the President of the United States of America

A Proclamation

Today, we celebrate all the Italian Americans, whose courage and character reflect and help define our Nation.

In 1891, 11 Italian Americans were murdered in one of the largest mass lynchings in our Nation's history. In the wake of this horrific attack, President Benjamin Harrison established Columbus Day in 1892. For so many people across our country, that first Columbus Day was a way to honor the lives that had been lost and to celebrate the hope, possibilities, and ingenuity Italian Americans have contributed to our country since before the birth of our republic.

More than a century later, we mark Columbus Day with that purpose—celebrating the heritage of Italian Americans, whose hands helped build our Nation and whose hearts have always carried faith in the American Dream. For many Italian Americans, the story of Christopher Columbus' voyage—from the Spanish port of Palos de la Frontera on behalf of Queen Isabella I and King Ferdinand II—remains a source of pride. It reflects the stories of trips across the Atlantic that so many Italian Americans grew up hearing at the dinner table, whether tales of ancestors who set sail on wooden boats across rough waters to begin new lives on our shores or grandparents who immigrated here with little more than hope in their hearts. These are stories of people leaving everything they knew and loved behind for the promise of opportunity in the United States.

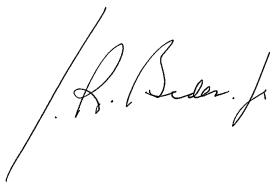
Today, we honor those stories told around the dinner table and celebrate what these hopeful Italian American newcomers brought to our Nation. Italian Americans are educators, service members, doctors, engineers, artists, Government officials, and leaders and innovators in every field. The Italian American community is also a source of strength for our Nation's enduring relationship with Italy—an essential NATO ally and partner in the European Union. Together, we are working to address the challenges of our time, especially supporting the people of Ukraine in defense of their freedom.

America was founded on an idea: that we are all created equal, endowed by our creator with certain inalienable rights, and deserve to be treated equally throughout our lives. Though we have never fully lived up to that idea, our aspirations have never let us walk away from it either. Today, we honor all the Italian Americans who never walked away from our fundamental creed and who, for generations, have helped realize the full promise of our Nation.

In commemoration of Christopher Columbus' historic voyage 531 years ago, the Congress, by joint resolution of April 30, 1934, and modified in 1968 (36 U.S.C. 107), as amended, has requested the President proclaim the second Monday of October of each year as ''Columbus Day.''

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim October 9, 2023, as Columbus Day. I direct that the flag of the United States be displayed on all public buildings on the appointed day in honor of our diverse history and all who have contributed to shaping this Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of October, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2023–22666
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Presidential Documents

Proclamation 10649 of October 6, 2023

Indigenous Peoples' Day, 2023

By the President of the United States of America

A Proclamation

On Indigenous Peoples' Day, we honor the perseverance and courage of Indigenous peoples, show our gratitude for the myriad contributions they have made to our world, and renew our commitment to respect Tribal sovereignty and self-determination.

The story of America's Indigenous peoples is a story of their resilience and survival; of their persistent commitment to their right to self-governance; and of their determination to preserve cultures, identities, and ways of life. Long before European explorers sailed to this continent, Native American and Alaska Native Nations made this land their home, some for thousands of years before the United States was founded. They built many Nations that created powerful, prosperous, and diverse cultures, and they developed knowledge and practices that still benefit us today.

But throughout our Nation's history, Indigenous peoples have faced violence and devastation that has tested their limits. For generations, it was the shameful policy of our Nation to remove Indigenous peoples from their homelands; force them to assimilate; and ban them from speaking their own languages, passing down ancient traditions, and performing sacred ceremonies. Countless lives were lost, precious lands were taken, and their way of life was forever changed. In spite of unimaginable loss and seemingly insurmountable odds, Indigenous peoples have persisted. They survived. And they continue to be an integral part of the fabric of the United States.

Today, Indigenous peoples are a beacon of resilience, strength, and perseverance as well as a source of incredible contributions. Indigenous peoples and Tribal Nations continue to practice their cultures, remember their heritages, and pass down their histories from generation to generation. They steward this country's lands and waters and grow crops that feed all of us. They serve in the United States military at a higher rate than any other ethnic group. They challenge all of us to celebrate the good, confront the bad, and tell the whole truth of our history. And as innovators, educators, engineers, scientists, artists, and leaders in every sector of society, Indigenous peoples contribute to our shared prosperity. Their diverse cultures and communities today are a testament to the unshakable and unbreakable commitment of many generations to preserve their cultures, identities, and rights to self-governance. That is why, despite centuries of devastation and turmoil, Tribal Nations continue to thrive and lead in countless ways.

When I came into office, I was determined to usher in a new era in the relationship between the Federal Government and Tribal Nations and to honor the solemn promises the United States made to fulfill our trust and treaty obligations to Tribal Nations. That work began by appointing Native Americans to lead on the frontlines of my Administration—from the first Native American Secretary of the Interior Deb Haaland and dozens of Senate-confirmed Native American officials to the over 80 Native American appointees serving across my Administration and in the Federal courts. I restored the White House Council on Native American Affairs to improve interagency coordination and decision-making as well as the White House

Tribal Nations Summit to bring together key members of my Administration and the leaders of hundreds of Tribal Nations.

Last year, I signed a new Presidential Memorandum that creates uniform standards for consultation between the Federal Government and Tribal Nations. And together, we are making historic investments in Indian Country. That includes $32 billion from the American Rescue Plan, the largest one-time direct investment in Indian Country in American history; more than $13 billion to rebuild infrastructure, the single largest investment in Indian Country infrastructure in history; and the biggest investment ever to combat the existential threat of climate change, including $700 million dedicated to climate change response in Native communities.

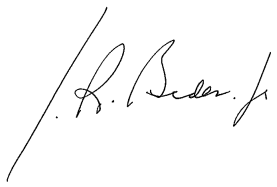
We are also working to improve public health and safety for Native Americans. That is why I signed an Executive Order that helps us respond more effectively to the epidemic of missing and murdered Indigenous peoples. And when we reauthorized the Violence Against Women Act last year, I was proud to include historic provisions that reaffirm Tribal sovereignty and restore Tribal jurisdiction. I have also requested a $9.1 billion infusion for Indian Health Services and asked the Congress to make that funding a mandatory part of the Federal budget for the first time in our history.

My Administration will also continue using all the authority available to it, including the Antiquities Act, to protect sacred Tribal lands. We have already restored protections for Bears Ears and Grand Staircase-Escalante in Utah and the Northeast Canyons and Seamounts National Monument in New England. I have declared new national monuments at the Camp Hale-Continental Divide in Colorado, Avi Kwa Ame in Nevada, and Baaj Nwaavjo I'tah Kukveni in Arizona to protect lands that are sacred to so many Tribes. My Administration has also signed at least 20 new co-stewardship agreements with Tribes, and we are working on many more.

As we celebrate Indigenous Peoples' Day, may we renew the enduring soul of our Nation-to-Nation relationships—a spirit of friendship, stewardship, and respect.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 9, 2023, as Indigenous Peoples' Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities. I also direct that the flag of the United States be displayed on all public buildings on the appointed day in honor of our diverse history and the Indigenous peoples who contribute to shaping this Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of October, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



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Presidential Documents

Proclamation 10650 of October 6, 2023

Leif Erikson Day, 2023

By the President of the United States of America

A Proclamation

It is believed that, roughly a millennium ago, Leif Erikson and his crew became the first Europeans to set foot in North America. These Norse explorers boldly charted new paths that would inspire adventurers for centuries to come. With bravery, optimism, and tireless effort, Leif Erikson embodied many of the same traits that future generations of Danes, Finns, Icelanders, Norwegians, and Swedes would weave into the fabric of America's story. This Leif Erikson Day, we join together to honor the heritage of our Nordic communities and celebrate all they have done to strengthen our country.

Throughout our Nation's history, countless Nordic immigrants have come to America—many with little more than the hope in their hearts. Motivated by the promise of possibilities and the search for the American Dream, these families packed up their lives on distant shores to build new homes here. Establishing communities across our Nation, Nordic Americans have contributed so much to our society. Nordic migrants helped lay our country's foundations by fighting for liberty in our Armed Forces; establishing churches, schools, and businesses; and playing essential roles in the labor movement. And as public servants, doctors, engineers, entrepreneurs, community leaders, and so much more, Nordic Americans continue to push our Nation ever forward, enriching every part of American life.

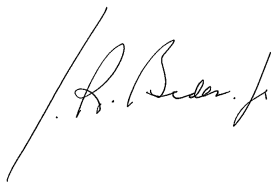
Today, my Administration also reaffirms our strong relations with Nordic nations and their people. Grounded in our shared values of democracy, freedom, and justice, America is working with our Nordic partners to take on our greatest challenges. We are collaborating to address the climate crisis by increasing opportunity and investments in emerging technologies. And we are working together to preserve a free and open Indo-Pacific and to provide security and humanitarian assistance to the people of Ukraine as they defend themselves against Russia's brutal invasion. In service of these missions, last year, the United States supported the ratification process for Finland to join NATO—culminating in the fastest ratification period in modern history. We continue to fully support Sweden's membership in our alliance. Our nations are stronger together, and we will continue working with these capable and committed partners.

This Leif Erikson Day, we celebrate the tremendous contributions of Nordic Americans to our Nation. Most of all, we rededicate ourselves to the American spirit of adventure embodied in Leif Erikson's journey roughly a millennium ago. Let us continue to pursue bravely principles of liberty, equality, and justice so all people in our country can achieve the American Dream.

To honor Leif Erikson, son of Iceland and grandson of Norway, and to celebrate Nordic-American heritage, the Congress, by joint resolution (Public Law 88–566) approved on September 2, 1964, has authorized the President of the United States to proclaim October 9th of each year as ''Leif Erikson Day.''

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim October 9, 2023, as Leif Erikson Day. I call upon all Americans to celebrate the contributions of Nordic Americans to our Nation with appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of October, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



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Rules and Regulations

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FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Part 2424

Negotiability Proceedings

Corrections

In Rule Document C1–2023–19269, appearing on page 69873 in the issue of Tuesday, October 10, 2023, make the following correction:

§ 2424.25 [Corrected]

■ 1. On page 69873, beginning in the first column, amendatory instruction 6 should read:

■ 6. On page 62458, in the first column, in the twenty-fourth line from the bottom, ''© *Content.*'' should read, ''(c) *Content.*''

[FR Doc. C2–2023–19269 Filed 10–11–23; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 2

RIN 0503–AA78

Delegations of Authority

AGENCY: Office of the Secretary, USDA.

ACTION: Final rule.

SUMMARY: This document revises the delegations of authority from the Secretary of Agriculture and general officers of the U.S. Department of Agriculture (USDA) to reflect changes and additions to the delegations as summarized below.

DATES: Effective October 12, 2023.

FOR FURTHER INFORMATION CONTACT: Melissa McClellan, Office of the General Counsel, (202) 720–5565, *melissa.mcclellan@usda.gov.*

SUPPLEMENTARY INFORMATION:

Overview of Changes

This rule amends the delegations of authority in 7 CFR part 2 to reflect changes to the organizational structure of the Office of Partnerships and Public Engagement (OPPE). This includes removing the delegations of authority by the Director, OPPE to the Director, Office of Advocacy and Outreach (OAO) at section 2.700, as OAO is no longer a separate entity within OPPE. In addition, this rule reflects the transfer of oversight of the 1994 Tribal Scholars Program from the Director of OPPE (section 2.38) to the Director of the Office of Tribal Relations (section 2.39) and the transfer of oversight of the Centers for Faith Based and Neighborhood Partnerships from the Director of OPPE to the Assistant Secretary for Congressional Relations (section 2.23).

This rule also amends the delegations of authority to reflect the transfer of responsibility for USDA's Controlled Unclassified Information Program from the Assistant Secretary for Administration (section 2.24) and the Executive Director of the Office of Homeland Security (section 2.95) to the Chief Information Officer (section 2.32). *See* Secretary's Memorandum 1077–006 (Nov. 2, 2022), available at *https://www.usda.gov/directives/sm-1077-006.*

Finally, this rule amends the delegations to the Under Secretary for Natural Resources and Environment (section 2.16) and the Chief of the Forest Service (section 2.60) to authorize the Forest Service's Law Enforcement and Investigations staff to enforce and investigate violations of the Lacey Act, 16 U.S.C. 3371–3378, involving timber and timber products. These delegations do not affect the existing delegations of authority under the Lacey Act to the Under Secretary for Marketing and Regulatory Programs and the Administrator of the Animal and Plant Health Inspection Service.

Classification

This rule relates to internal agency management. Accordingly, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. This rule also is exempt from the provisions of Executive Orders 12866 and 13771. This action is not a rule as defined by the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.,* or the Congressional Review Act, 5 U.S.C. 801 *et seq.,* and thus is exempt from the provisions of those acts. This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 2

Authority delegations (Government agencies).

Accordingly, as discussed in the preamble, 7 CFR part 2 is amended as follows:

PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 7 U.S.C. 6912(a)(1); 5 U.S.C. 301; Reorganization Plan No. 2 of 1953, 3 CFR 1949–1953 Comp., p. 1024.

Subpart C—Delegations of Authority to the Deputy Secretary, Under Secretaries, and Assistant Secretaries

■ 2. Amend § 2.20 by adding paragraph (a)(2)(xliii) to read as follows:

§ 2.20 Under Secretary for Natural Resources and Environment.

(a) * * *

(2) * * *

(xliii) Enforce and conduct investigations of violations of the Lacey Act, which prohibits importing or exporting any plant or plant product in interstate or foreign commerce in violation of any Federal, State, Tribal, or foreign law regulating plants or plant products (16 U.S.C. 3371–3378).

* * * * *

■ 3. Amend § 2.23 by adding paragraph (a)(2)(v) to read as follows:

§ 2.23 Assistant Secretary for Congressional Relations.

(a) * * *

(2) * * *

(v) Oversee the Center for Faith Based and Neighborhood Partnerships.

* * * * *

§ 2.24 [Amended]

■ 4. Amend § 2.24 by removing and reserving paragraph (a)(8)(xi).

Subpart D—Delegations of Authority to Other General Officers and Agency Heads

■ 5. Amend § 2.32 by adding paragraph (a)(14) to read as follows:

§ 2.32 Chief Information Officer.

(a) * * *

(14) Administer the Controlled Unclassified Information (CUI) Program for the Department pursuant to E.O. 13556, ''Controlled Unclassified Information'' (75 FR 68675, 3 CFR, 2011 Comp., p. 267) and 32 CFR part 2002.

* * * * *

§ 2.38 [Amended]

■ 6. Amend § 2.38 by removing and reserving paragraphs (a)(1)(xii) and (a)(4).

■ 7. Amend § 2.39 by adding paragraph (a)(9) to read as follows:

§ 2.39 Director, Office of Tribal Relations.

(a) * * *

(9) Administer the USDA/1994 Land Grant Institutions (Tribal Colleges) Programs.

* * * * *

Subpart J—Delegations of Authority by the Under Secretary for Natural Resources and Environment

■ 8. Amend § 2.60 by adding paragraph (a)(45) to read as follows:

§ 2.60 Chief, Forest Service.

(a) * * *

(45) Enforce and conduct investigations of violations of the Lacey Act, which prohibits importing or exporting any plant or plant product in interstate or foreign commerce in violation of any federal, state, Tribal, or foreign law regulating plants or plant products (16 U.S.C. 3371–3378).

* * * * *

Subpart P—Delegations of Authority by the Assistant Secretary for Administration

§ 2.95 [Amended]

■ 9. Amend § 2.95 by removing and reserving paragraph (b)(11).

Subpart V—Delegations of Authority by the Director, Office of Partnerships and Public Engagement

§ 2.700 [Removed and Reserved]

■ 10. Remove and reserve § 2.700.

The Secretary of Agriculture, Thomas J. Vilsack, having reviewed and approved this document, is delegating the authority to electronically sign this document to Mary Beth Schultz, Acting General Counsel, for purposes of publication in the **Federal Register**.

Mary Beth Schultz,

Acting General Counsel.

[FR Doc. 2023–22524 Filed 10–11–23; 8:45 am]

BILLING CODE 3410–90–P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 431

[EERE–2017–BT–STD–0048]

RIN 1904–AF27

Energy Conservation Program: Energy Conservation Standards for Dedicated Purpose Pool Pump Motors

Correction

In rule document 2023–20343, appearing on pages 66966 through 67041 in the issue of Thursday, September 28, 2023, make the following correction:

On page 66967, in Table I.1, in the fifth column, on the third line, ''September 28, 2025'' should read ''September 28, 2027''.

[FR Doc. C1–2023–20343 Filed 10–11–23; 8:45 am]

BILLING CODE 0099–10–D

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

RIN 3245–AH78

Debt Refinancing in the 504 Loan Program

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: SBA is adopting with changes the interim final rule published in the **Federal Register** on July 29, 2021. That interim final rule implemented section 328 of the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act, which modified the requirements for refinancing debt in the 504 Loan Program, as set forth in section 521(a) of title V of division E of the Consolidated Appropriations Act, 2016 and section 502(7) of the Small Business Investment Act of 1958. The modifications included: increasing the amount of existing indebtedness that may be refinanced for 504 debt refinancing involving expansions; and for 504 debt refinancing not involving expansions, removing two limitations on the program, reinstating an alternate job retention standard for the refinancing project, revising the definition of qualified debt, and removing the prohibition against Certified Development Companies (CDCs) participating in the Premier Certified Lenders Program using their delegated authority to make these loans.

DATES: The effective date of this final rule is November 13, 2023.

FOR FURTHER INFORMATION CONTACT: Gregorius Suryadi, Senior Financial and Loan Specialist, 504 Program Branch, Office of Financial Assistance, Small Business Administration, 409 3rd Street SW, Washington, DC 20416; telephone: (202) 205–6806; email: *gregorius.suryadi@sba.gov*.

SUPPLEMENTARY INFORMATION:

I. Background Information

The 504 Loan Program is an SBA financing program authorized under title V of the Small Business Investment Act of 1958, 15 U.S.C. 695 *et seq.* The core mission of the 504 Loan Program is to provide long-term financing to small businesses for the purchase or improvement of land, buildings, and major equipment, in an effort to facilitate the creation or retention of jobs and local economic development. Under the 504 Loan Program, loans are made to small business applicants by Certified Development Companies (''CDCs''), which are certified and regulated by SBA to promote economic development within their community. In general, a project in the 504 Loan Program (a ''504 Project'') includes: a loan obtained from a private sector lender with a senior lien covering at least 50 percent of the project cost; a loan obtained from a CDC (a ''504 Loan'') with a junior lien covering up to 40 percent of the total cost (backed by a 100 percent SBA-guaranteed debenture); and a contribution from the Borrower of at least 10 percent equity.

In addition, the 504 Loan Program may be used to refinance debt under two options authorized under section 502(7)(B) and (C) of the Small Business Investment Act of 1958. First, if a 504 Project involves the expansion of the small business, any amount of existing indebtedness that does not exceed 50 percent of the project cost of the expansion may be refinanced and added to the project's cost (Debt Refinancing with Expansion) under the conditions set forth in section 502(7)(B) and the implementing regulations. *See* 13 CFR 120.882(e) and (f). Second, debt refinancing is available for a 504 Project that does not involve the expansion of the small business under the requirements set forth in section 502(7)(C) and 13 CFR 120.882(g) (Debt Refinancing without Expansion).

Section 328(a) of the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act (Economic Aid Act), enacted December 27, 2020, Public Law 116–260, revised the conditions and requirements for refinancing debt in the 504 Loan Program as follows:

(1) With respect to Debt Refinancing with Expansion, 13 CFR 120.882(e), the Economic Aid Act increased the amount of existing indebtedness that may be refinanced as part of a 504 Project from not more than 50 percent of the project cost of the expansion to not more than 100 percent of the project cost;

(2) With respect to Debt Refinancing without Expansion, 13 CFR 120.882(g), the Economic Aid Act:

(a) Eliminated the condition that this program shall only be in effect in any fiscal year during which the cost to the Federal Government of making guarantees under 13 CFR 120.882(g) and under the 504 Loan Program is zero;

(b) Eliminated the requirement that a CDC limit its financing under the 504 Loan Program so that, during any Federal fiscal year, new financings under 13 CFR 120.882(g) do not exceed 50% of the dollars the CDC loaned under the 504 Loan Program, including under 13 CFR 120.882(g), during the previous fiscal year, unless otherwise waived;

(c) Eliminated the prohibition against Premier Certified Lender Program (PCLP) CDCs using delegated authority to approve loan applications for Debt Refinancing without Expansion;

(d) Reinstated an alternate job retention standard that was previously removed from the Debt Refinancing without Expansion Program by section 521 of division E of the Consolidated Appropriations Act, 2016 (2016 Consolidated Appropriations Act), enacted on December 18, 2015, Public Law 114–113;

(e) Revised the definition of ''qualified debt'' to mean debt that was incurred not less than six months before the date of application instead of two years before the date of application;

(f) Removed from the definition of ''qualified debt'' condition that the debt not be subject to a guarantee by a Federal agency; and

(g) Eliminated from the definition of ''qualified debt'' the requirement that the borrower be current on all payments for not less than one year before the date of the application for refinancing.

As described in the section-by-section analysis below, SBA is issuing this final rule to adopt the previously published interim final rule and to conform the current rules to the requirements of the Economic Aid Act.

II. Section-by-Section Analysis of Comments and Changes

On July 29, 2021, SBA published in the **Federal Register** an interim final rule implementing section 328(a) of the Economic Aid Act. 86 FR 40775. Although effective immediately, the interim final rule included a request for comments seeking input from the public. The comment period for the interim final rule was open from July 29, 2021, until October 8, 2021. SBA received 79 comments of which many were duplicative. Of the unique comments received, two were from national trade associations, 68 were from Certified Development Companies, one (1) was from a bank, one (1) from a private industry, and four (4) from individuals. This section includes a description of the comments received and is organized by the rules being revised. SBA received comments from a national trade association and 63 CDCs recommending changes beyond the scope of this rule that will not be addressed in this final rule.

III. Section-by-Section Analysis

Section 120.882(e). In the interim final rule SBA revised this provision by increasing the amount of existing indebtedness that may be refinanced to no more than 100 percent of the project cost (from 50 percent of the project cost) to conform with the amendments to section 502(7)(B) of the Small Business Investment Act made by section 328(a)(2)(A) of the Economic Aid Act. SBA did not receive any comments on this change and is adopting this change as set forth in the interim final rule.

Section 120.882(g)(3). In the interim final rule SBA removed the requirement that the approval of a Refinancing Project is subject to the requirement that the cost to the Federal Government of making guarantees under 13 CFR 120.882(g) and under the 504 Loan Program is zero during the fiscal year in which the guarantee is made in accordance with section 328(a)(1) of the Economic Aid Act, which repealed this statutory requirement set forth in the 2016 Consolidated Appropriations Act.

In its place SBA inserted a provision that set forth the conditions and requirements that apply to the refinancing of a loan that is subject to a guarantee by a Federal agency or department. As indicated above, the Economic Aid Act removed the prohibition against refinancing a loan that is subject to a guarantee by a Federal agency or department. Although these loans may now be refinanced if the refinancing project does not involve expansion, the loan must comply with the following conditions and requirements:

(1) for an existing 504 loan, either both the Third Party Loan and the 504 loan must be refinanced, or the Third Party Loan must have been paid in full; and

(2) for an existing 7(a) loan, the CDC must verify in writing that the present lender is either unwilling or unable to modify the current payment schedule. In addition, in the case of same institution debt, if the Third Party Lender or the CDC affiliate as authorized under 13 CFR 120.820 is the 7(a) lender, the loan will be eligible for 504 refinancing only if the lender is unable to modify the terms of the existing loan because a secondary market investor will not agree to modified terms.

(3) the refinancing of any federally-guaranteed loan must provide a substantial benefit to the borrower. ''Substantial benefit'' means that the portion of the new installment amount attributable to the debt being refinanced must be at least 10 percent less than the existing installment amount(s). Prepayment penalties (including any subsidy recoupment fee), financing fees, and other financing costs must be added to the amount being refinanced in calculating the percentage reduction in the new installment payment. The portion of the new installment amount attributable to Eligible Business Expenses will not need to be included in this calculation. The rule allows the Director, Office of Financial Assistance (D/FA) or designee, to approve an exception to the 10 percent reduction requirement for good cause and does not allow PCLP CDCs to use their delegated authority to approve a loan requiring this exception.

SBA received 66 comments on this rule change, of which 50 supported the rule change with modifications. There were no comments opposing the rule change.

A national trade association and its member CDCs requested that SBA not include in regulation any conditions or requirements that restrict or limit the ability to refinance a loan that is subject to a guarantee by a Federal agency or department as no such conditions or restriction exists in statute or in the Economic Aid Act (EAA) update.

The national trade association and its member CDCs also recommended that SBA remove the requirement that CDCs obtain written verification of the existing 7(a) lender's inability or unwillingness to modify the current payment schedule as a requirement to allowing the refinance of an existing 7(a) loan. The national trade association

asked that the ability to refinance an existing 7(a) loan be unfettered and guided by what is in the best interest of the borrower.

Another national trade association proposed safeguards of increasing the substantial benefit requirement for both 7(a) and 504 programs, which include, but are not limited to, the SBA issuing specific guidance on the underwriting for both programs. In addition, to protect the borrower from paying additional and significant fees, the national trade association recommended the SBA limit fees for new 504 loans. SBA feels that increasing the substantial benefit requirement as requested in a rising interest rate environment would not be in the best interest of the small business borrower.

Based on the public comments received, SBA is revising this rule to remove the requirement that CDCs and 7(a) lenders be given the opportunity to modify existing debt. Instead, SBA is transferring the burden of contacting the CDC or 7(a) lender whose debt is being refinanced from the borrower to the CDC that will be packaging the 504 loan for the borrower. The revised rule requires the CDC to notify in writing (by email or letter) the existing CDC or 7(a) lender to advise them in advance when a government guaranteed loan is being refinanced.

Section 120.882(g)(11). In the interim final rule SBA removed the section that states PCLP CDCs may not use delegated authority to approve refinancing under 13 CFR 120.882(g), in accordance with section 328(a) of the Economic Aid Act, which removed this statutory prohibition. In its place, the interim final rule stated that PCLP CDCs may not approve the refinancing of same institution debt under their delegated authority and must submit the loan to SBA for approval. This requirement is consistent with SBA's long-standing policy of prohibiting its participating lenders from using their delegated authority to approve the financing of same institution debt due to the potential conflict of interest and the risk of the 504 loan proceeds being used to shift to SBA a potential loss from the existing debt. SBA did not receive any comments on this change and is adopting this change as set forth in the interim final rule.

Section 120.882(g)(15). In the interim final rule SBA redesignated paragraph (g)(15), Definitions, as paragraph (g)(16), and added a new paragraph (g)(15) to set forth the alternate job retention standard that was reinstated by section 328(a) of the Economic Aid Act. Under this alternate job retention standard, for a Refinancing Project under 13 CFR 120.882(g) the debt does not need to meet the job creation or other economic development objectives set forth in 13 CFR 120.861 or 120.862, provided that the 504 loan does not exceed the product obtained by multiplying the number of employees of the borrower by $75,000. On May 11, 2023, SBA published in the **Federal Register** a notice announcing an increase to the job creation or retention standards for the 504 Loan Program to reflect increases in the Consumer Price Index (CPI) for All Urban Consumers. 88 FR 30379. This included increasing the amount per Job Opportunity that a 504 Loan Project must create or retain from $75,000 to $90,000. Accordingly, the amount set forth in 13 CFR 120.882(g)(15) is adjusted from $75,000 to $90,000.

The alternate job retention standard provides that the number of employees of a borrower is equal to the sum of:

(1) the number of full-time employees of the borrower on the date on which the borrower applies for a loan under this subparagraph; and

(2) the product obtained by multiplying:

(a) the number of part-time employees of the borrower on the date on which the borrower applies for a loan under this subparagraph, by

(b) the quotient obtained by dividing the average number of hours each part-time employee of the borrower works each week by 40.

An example of how this standard is calculated is included in the text of the rule.

SBA did not receive any comments on this adjustment. The final rule adopts the interim final rule with one change, namely an increase in the amount per Job Opportunity that a 504 Loan Project must create from $75,000 to $90,000 as per SBA's announcement in the **Federal Register** on May 11, 2023.

Section 120.882(g)(16). As stated above, SBA redesignated paragraph (g)(15), Definitions, as paragraph (g)(16) and made five changes to the definition of ''Qualified debt''. First, paragraph (i) of the definition of ''Qualified debt'' (redesignated as paragraph (A)) previously required that the debt must not have been incurred less than two years before the date of the application for refinancing. However, section 328(a) of the Economic Aid Act shortened this period to six months before the date of the application for refinancing. Accordingly, SBA revised this paragraph by replacing two years with six months.

Second, paragraph (i) of the definition of ''Qualified debt'' (redesignated as paragraph (A)) previously allowed a loan that was refinanced within the two years before the date of application (the most recent loan) to be deemed incurred not less than two years before the date of the application provided that the effect of the most recent loan was to extend the maturity date without advancing any additional proceeds. With the minimum age of the qualified debt shortened from two years to six months, SBA believed that it was no longer necessary to address this situation and therefore SBA removed the second and third sentences of paragraph (i) (redesignated as paragraph (A)).

Third, paragraph (ii) of the definition of ''Qualified debt'' previously excluded debt that was subject to a guarantee by a Federal agency or department. As stated above, section 328(a) of the Economic Aid Act removed this statutory exclusion and SBA consequently removed this paragraph and renumbered the remaining paragraphs accordingly. The conditions and requirements that apply to the refinancing of a loan that is subject to a Federal guarantee are set forth in paragraph (g)(3).

Fourth, paragraph (vi) of the definition of ''Qualified debt'' previously excluded a Third Party Loan that is part of an existing 504 Project. However, under the new paragraph (g)(3), an existing 504 loan may be refinanced when both the Third Party Loan and the 504 loan are being refinanced. Accordingly, SBA revised this paragraph, which was redesignated as paragraph (E), to incorporate this exception to the general prohibition against a qualified debt including a Third Party Loan.

Fifth, paragraph (vii) of the definition of ''Qualified debt'' previously reflected the statutory requirement that, for the debt to qualify for refinancing, the applicant had to be current on all payments due for not less than one year preceding the date of application. Because section 328(a) of the Economic Aid Act removed this requirement from section 502(7)(C) of the Small Business Investment Act, SBA removed this paragraph from the regulations. In accordance with prudent lending standards, SBA expects CDCs to consider whether the applicant is current on all payments due, and the applicant's history of delinquency, in its credit analysis. SBA did not receive any comments on these specific revisions and is adopting the revisions as set forth in the interim final rule.

SBA did however receive comments from a national trade association and its member CDCs requesting that SBA lower the Qualified debt definition's standard of ''substantially all (85% or

more)'' to a ''majority'' standard of 51% or more to increase access to and utilization of 504 debt refinancing. SBA agrees that a decrease to the ''substantially all'' standard would increase refinancing opportunities for small businesses. Neither the Small Business Act nor the Small Business Investment Act define or test for ''substantially all.'' The 85% ''substantially all'' standard in paragraph (g) was established with regulations implementing section 1122 of the Small Business Jobs Act of 2010. 76 FR 9213. SBA is modifying the ''substantially all'' definition to 75% from 85% with the remainder being adjusted to 25% from 15%. SBA has determined that ''substantially all'' is not 51%.

Finally, the phrase ''Same institution debt'' was previously used with Debt Refinancing without Expansion only in reference to the Third Party Loan, *see* 13 CFR 120.882(g)(13), and, thus, the definition of ''same institution debt'' referenced only the Third Party Lender. With the requirement in 13 CFR 120.882(g)(11) that PCLP CDCs cannot use their delegated authority to approve the refinancing of same institution debt in the Debt Refinancing without Expansion program, SBA revised the definition of ''Same institution debt'' to also mean the debt of the CDC (or its affiliates) that is providing funds for the refinancing. SBA did not receive any comments on this change and is adopting this change as set forth in the interim final rule.

Section 120.883(e). SBA currently allows certain administrative costs that are not part of Project costs to be paid with the proceeds of the 504 loan and the Debenture. 13 CFR 120.882. This includes CDC Closing Fees up to a maximum of $2,500. 13 CFR 120.882(e).

Since the publication of the interim final rule SBA conducted a series of roundtable discussions with CDCs and lenders at annual and regional events. In alignment with the adjustment with jobs created/retained due to the CPI, SBA received multiple comments during the regional roundtables for an inflation adjustment also to update § 120.883, Eligible administrative costs for 504 loans, in paragraph (e) which currently limits of the amount of CDC closing fees allowed to be included in 504 financing portion of a project to be capped at $2,500. In alignment with these changes and in an attempt to keep the limit of CDC closing costs relevant to administrative costs, SBA is proposing an increase to the legal fees. According to the public comments, this cap does not reflect current administrative costs and creates a burden on the borrower to pay for closing expenses from its own account. In the final rule, SBA increases the amount from $2,500 to $10,000.

Compliance With Executive Orders 12866, 12988, 13132, and 13563, the Congressional Review Act (5 U.S.C. 801–808), Paperwork Reduction Act (44 U.S.C., Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Orders 12866 and 13563

The Office of Management and Budget (OMB) has determined that this rule constitutes a ''significant regulatory action'' for purposes of Executive Orders 12866 and 13563. SBA, however, is proceeding under the emergency provision at Executive Order 12866, section 6(a)(3)(D), based on the need to move expeditiously to mitigate the current conditions arising from the COVID–19 pandemic.

As shown in Table 1 below, during the five-year period spanning fiscal year (FY) 2018 and FY 2022, a total of 38,022 504 loans were approved for a total gross approval amount as of September 30, 2022, of $32,965,182,830. In addition, during this five-year period, SBA approved 247 debt refinance with expansion loans on average per year with an average annual dollar volume of $309,165,400, and approved 451 debt refinance without expansion loans on average per year with an average annual dollar volume of $469,596. The Economic Aid Act passage increased the debt refinance with expansion from 50 percent of a project to 100 percent of a project. Prior to this change, of the debt refinance with expansion loans, only 16 refinanced a debt that equaled 50 percent of the expansion costs; if these borrowers had been able to refinance 100 percent of the expansion costs instead of 50 percent, and assuming that all these borrowers did so, these borrowers would have been able to borrow $15 million more over five years, or about $3 million more annually. Since the passage of the Economic Aid Act, and the issuance of the interim final rule, there have been 746 504 loan refinancing with expansion projects approved for a total of $1,030,563,000 approved. This legislative change has expanded the access to capital to small business for expansion projects that also need debt refinancing.

TABLE 1—504 LOAN ACTIVITY FY 2018–FY 2022

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Total Number of 504 Loans	5,874	6,099	7,119	9,676	9,254	3,844
Total Dollar Volume of 504 Loans Approved	$4,753,644,000	$4,958,552,000	$5,826,885,000	$8,218,105,540	$9,207,996,290	$3,533,163,000
Number of 504 Debt Refi With Expansion	181	181	236	301	336	109
Dollar Volume of 504 Debt Refi With Expansion	$212,098,000	$192,968,000	$296,392,000	$389,801,000	$454,568,000	$186,194,000
Number of 504 Debt Refi Without Expansion	181	166	386	693	829	249
Dollar Volume of 504 Debt Refi Without Expansion	$154,062,000	$154,842,000	$370,160,000	$709,020,000	$959,897,000	$270,151,000

TABLE 2—504 LOAN ACTIVITY BY DEFINED COHORT AUGUST 2018–JULY 2023

	Aug' 18–Jul' 19	Aug' 19–Jul' 20	Aug' 20–Jul' 21	Aug' 21–Jul' 22	Aug' 22–Jul' 23
Total Number of 504 Loans	6,153	6,836	9,572	9,392	6,253
Total Dollar Volume of 504 Loans Approved	$5,063,078,000	$5,575,249,000	$7,934,192,540	$9,248,887,290	$6,624,952,000
Number of 504 Debt Refi With Expansion	183	243	295	332	183
Dollar Volume of 504 Debt Refi With Expansion	$191,786,000	$309,027,000	$362,039,000	$446,975,000	$305,619,000
Number of 504 Debt Refi Without Expansion	160	302	66	934	388
Dollar Volume of 504 Debt Refi Without Expansion	$157,880,000	$295,396,000	$601,831,000	$1,057,386,000	$432,638,000

Data as of 9/15/2023, total dollar volume is lifetime gross approval amount including increases.

This rule was necessary to implement the Economic Aid Act and provide economic relief to small businesses adversely impacted by COVID–19. SBA anticipates that finalizing these changes to the 504 debt refinancing programs will continue to result in benefits to

small businesses by providing greater flexibility to restructure debt.

To assess the impact of the interim final rule, SBA evaluated 504 loan activity (including the number of loans and dollar volume of both debt refinance with and without expansion) between August 2018 and July 2023. Because the interim final rule was published on July 29, 2021, with immediate effectiveness, the first full month during which the modifications to 504 debt refinancing were available was August 2021, with August 2021 through July 2022 being the first 12-month period during which the modifications to 504 debt refinancing were available to 504 applicants. SBA divided the data into five cohorts of 12 months each, with the first cohort beginning in August 2018 and the last cohort beginning August 2023. See Table 2.

As an appropriate baseline for evaluation of the impacts of the interim final rule that would be made permanent in this rule, SBA considers the state of 504 lending for debt refinance with expansion and without expansion before July 2021. SBA examines the 12-month periods from August 1, 2018, through July 31, 2019, to the period from August 1, 2022, to July 31, 2023, noting that external influences from the pandemic and from the payments made on behalf of borrowers by SBA under section 1112 of the Coronavirus Aid Recovery, and Economic Security Act (Section 1112 Payments) that ended in September 2021 occurred. The Section 1112 Payments required SBA to make principal and interest payments on 504 loans for certain periods of time depending on the when the 504 loan was approved, which would have made a 504 loan an attractive option for small businesses and consequently would have increased 504 loan volume. Further, interest rates on 504 loans in these two periods differ, from a range of approximately 4.0 to 5.0 percent in the earlier period to rates up to 7.0 percent in the later period, as do rates on alternatives to 504 loans. These changes mean that lending total volume comparisons may not be appropriate for assessment of impact. Because the major changes in the interim final rule were the increases in the amounts of existing indebtedness that may be refinanced for both 504 debt involving expansions and 504 debt not involving expansions, SBA examined the percentages of 504 lending that were for these two types of debt refinancing. The chart below shows these percentages for five August-July cohorts.

	2018–19 %	2019–20 %	2020–21 %	2021–22 %	2022–23 %
Dollar Volume of 504 Debt Refi with Expansion as Percentage of Dollar Volume of Total 504 Loans	3.79	5.54	4.56	4.83	4.61
Dollar Volume of 504 Debt Refi without Expansion as Percentage of Dollar Volume of Total 504 Loans	3.12	5.30	7.59	11.43	6.53

As indicated in the chart, the percentages of 504 debt refinancing loans with and without expansion are in the recent period returning to the levels seen prior to the publication of the interim final rule in July 2021. For debt refinancing without expansion, the August 2020–July 2021 period was elevated and the August 2021–July 2022 cohort was an outlier, but the next 12 months settled to a percentage that at a level consistent with the periods before the interim final rule and not indicative of a significant impact. These two cohorts with higher percentages were during the pandemic and were covered, at least in part, by Section 1112 Payments. The 12-month percentages of 504 debt refinancing with expansion did not vary widely.

The interim final rule increased the amounts on 504 debt refinancing with and without expansion. Aggregate 504 lending over the period in question ranged from approximately $5 billion to almost $9.25 billion, with total 504 lending in the latest 12-month cohort at about $6.6 billion. Even in the unlikely scenario of the interim final rule as the sole cause of an increase in total 504 lending from the low volume in the examined period of $5 billion (in 2018–19) to the latest 12-month total of $6.6 billion, the incremental impact, as indicated by changes in the percentage of total lending accounted for by each, is under $100 million.

Congressional Review Act

OMB's Office of Information and Regulatory Affairs has determined that this rule is not a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), 5 U.S.C. 804(2). Per the above cost benefit analysis, the annual effect on the economy is less than $100 million.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have preemptive effect or retroactive effect.

Executive Order 13132

This rule does not have federalism implications as defined in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive order. As such it does not warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

In order to implement the Act, SBA determined that it was necessary to modify SBA Form 1244, *Application for Section 504 Loans,* which is currently approved under OMB Control Number 3245–0071, to conform the form to the revised requirements for debt refinancing loans. The changes did not add any new burdens for the respondents, rather, in some instances, the revisions will result in reduced burden as applicants and CDCs no longer have to submit certain information.

(a) The information collection previously required PCLP CDCs to process all applications for debt refinancing without expansion through the Sacramento Loan Processing Center (SLPC) and not through the PCLP CDC's delegated authority. As discussed above, this requirement was removed by the Economic Aid Act and, accordingly, SBA removed the requirement from the information collection when the interim final rule (IFR) was released in 2021. The final rule would result in no further changes. This revision did not change the information the PCLP CDC is required to collect, only how the application is processed. In addition, consistent with the changes made by the

IFR, SBA added two questions to clarify that, for debt refinancing without expansion, PCLP CDCs must process applications through the SLPC when the application involves the refinancing of same institution debt or, in cases involving the refinancing of federally-guaranteed debt, the CDC is requesting an exception to the requirement that the new installment payment be at least 10% less than the existing installment amount. No further changes are necessary.

(b) With respect to the question regarding whether the Applicant creates or retains the required number of jobs per debenture amount, an option has been added for the Applicant to indicate whether the project is eligible under the 504 debt refinance alternate job standard reinstated by the Economic Aid Act.

(c) Of the exhibits that are required, Exhibit 20 required that if the debt had been refinanced within two years of the date of application, non-PCLP CDCs had to submit with the application (and PCLP CDCs had to retain in the loan file) copies of the current debt and lien instruments as well as copies of the debt and lien instruments for the debt that was replaced by the current debt. With the minimum age of the qualified debt shortened from two years to six months by the Economic Aid Act, SBA revised the form to remove the requirement that these debt and lien instruments be included as part of Exhibit 20.

In addition to the changes resulting from this rule, SBA made the following technical corrections and clarifying changes to Form 1244: (1) SBA corrected the description of which exhibits the CDC must retain and which the CDC must submit with the loan application; (2) SBA added a separate entry to facilitate disclosure of the use of refinancing proceeds involving land purchases only (the previous format of ''Land/Building'' did not clearly indicate how information is to be reported); and (3) under the list of economic development objectives met by the project, SBA added references to ''base closures'' and ''minority-owned business''.

Regulatory Flexibility Act, 5 U.S.C. 601–612

When an agency issues a rulemaking, the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires the agency to ''prepare and make available for public comment an initial regulatory analysis'' which will ''describe the impact of the proposed rule on small entities.'' Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The changes in the final rule are a codification of new legislation and will involve changes to regulations at 13 CFR 120.882, however there will be no changes to SBA Form 1244, and the burden hours to the small business concern and the Certified Development Company will remain the same. There are no anticipated additional compliance costs. Furthermore, SBA does not anticipate that any changes to the Eligible Project costs for 504 loans regulations would have a significant impact to a substantial number of small businesses. This is because only a small percentage of each year's 504 loans involve debt refinancing without expansion. Each loan represents a unique small business borrower because these borrowers are only eligible to refinance their debt once in a fiscal year with the 504 Loan Program, and therefore do not have multiple 504 debt refinancing without expansion loans in any given year. Based on the average number of 504 loans from FY 2021–2023, only 13% involved debt refinancing without expansion. Specifically, in FY 2021, out of 9,676 loans, 693 loans or 7% were for debt refinancing without expansion. In FY 2022, this figure was 829 out of 9,254 or 9% 504 loans, while in FY 2023, 1,005 out of 4,451 or 23% of 504 loans were for debt refinancing without expansion. While the percentage of the 504 loan portfolio involving debt refinancing without expansion increased by 20% from FY 2021 to 2023, this increase was due in part to the Section 1112 Payments, and in part to a rapidly increasing interest rate environment. The Section 1112 Payments have sunset and SBA anticipates some adjustment due to the continued interest rate increases planned by the Federal Reserve. Because Section 1112 Payments have sunset, SBA believes that the 504 debt refinancing without expansion volume will return to the pre-section 1112 level of less than 10% of small entities. As such, SBA concludes that the rule will not impact a substantial number of small entities.

While the economic implications of the final rule are small and the data do not reveal a significant economic impact on a substantial number of small entities, SBA anticipates a refinancing growth rate more in alignment with pre-pandemic levels, with some adjustment to the economic impact because the final rule will expand program eligibility. SBA analyzed potential growth scenarios of up to 30% growth in the 504 loan program, and even using this impact model (actual growth has never exceeded 15% in any prior fiscal year) the total of 504 debt refinance without expansion projects as a percentage of either number of loans or dollar volume of loans is not estimated to exceed 16% of the overall portfolio. When this percentage is applied to the estimated number of loans (small businesses impacted), this would result in less than 1,100 small businesses impacted. SBA estimates that the average monthly savings for small businesses that refinance their existing loans through the 504 loan program would be between $7,000 to $8,300 per month, with a total estimated savings over the life of the loan of between $180,000 to $205,000. SBA determined this estimate based on the historical average of a 504 debt refinancing without expansion loan averaging $1,000,000 for each small business applicant. SBA used the 504 July 2023 interest rates to calculate both the monthly and total loan savings to each small business concern. The lower end of the $180,000 to $205,000 range reflects the economic impact if a small business concern refinanced for 20 years, while the higher end reflects the economic impact of a small business concern refinanced for 25 years. Small business concerns do not use 10 year 504 loans for debt refinancing without expansion, as their goal is to lower their payments by not only taking advantage of the 504 loan program's fixed interest rate, but also the longer 20 and 25-year loan terms available.

For the reasons stated above, SBA certifies that this action would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 13 CFR Part 120

Loan programs-business, Reporting and recordkeeping requirements, Small businesses.

Accordingly, the interim rule amending 13 CFR part 120, which was published at 86 FR 40775 on July 29, 2021, is adopted as final with the following changes:

PART 120—BUSINESS LOANS

■ 1. The authority citation for part 120 is revised to read as follows:

Authority: 15 U.S.C. 634(b) (6), (b) (7), (b) (14), (h), and note, 636(a), (h) and (m), 650, 687(f), 696(3) and (7), and 697(a) and (e); sec. 521, Pub. L. 114–113, 129 Stat. 2242; sec. 328(a), Pub. L. 116–260, 134 Stat. 1182.

■ 2. Amend § 120.882 as follows:

■ a. Revise paragraphs (g)(3) and (15); and

■ b. In paragraph (g)(16), in paragraph (B) of the definition of *Qualified debt,* remove ''85%'', ''120.131 and 120.870(b)'', and ''120.131(b)'' and add in their places ''75%'', ''§§ 120.131 and 120.870(b)'', and ''§ 120.131(b)'', respectively.

The revisions read as follows:

§ 120.882 Eligible Project costs for 504 loans.

* * * * *

(g) * * *

(3) A loan that is subject to a guarantee by a Federal agency or department may be refinanced under the following conditions and requirements:

(i) An existing 504 loan may be refinanced if both the Third Party Loan and the 504 Loan are being refinanced or the Third Party Loan has been paid in full. If the 504 Loan being refinanced received approval through another CDC, the CDC working on the current refinancing must provide advance notice to the other CDC in writing (by email or letter).

(ii) An existing 7(a) loan may be refinanced if the CDC notifies the 7(a) lender in advance in writing (by email or letter).

(iii) The refinancing will provide a substantial benefit to the borrower. For purposes of this paragraph (g)(3)(iii), ''substantial benefit'' means that the portion of the new installment amount attributable to the debt being refinanced must be at least 10 percent less than the existing installment amount(s). Prepayment penalties (including subsidy recoupment fees), financing fees, and other financing costs must be added to the amount being refinanced in calculating the percentage reduction in the new installment payment, but the portion of the new installment amount attributable to Eligible Business Expenses (as described in paragraph (g)(6)(ii) of this section) is not included in this calculation. Exceptions to the 10 percent reduction requirement may be approved by the Director, Office of Financial Assistance (D/FA) or designee for good cause. PCLP CDCs may not use their delegated authority to approve a loan requiring the exception in this paragraph (g)(3)(iii).

* * * * *

(15) Notwithstanding § 120.860, a debt may be refinanced under this paragraph (g) if it does not meet the job creation or other economic development objectives set forth in § 120.861 or § 120.862. In such case, the 504 loan may not exceed the product obtained by multiplying the number of employees of the Borrower by $90,000. The number of employees of the Borrower is equal to the sum of:

(i) The number of full-time employees of the Borrower on the date of the application; and

(ii) The product obtained by multiplying:

(A) The number of part-time employees of the Borrower on the date of the application; by

(B) The quotient obtained by dividing the average number of hours each part-time employee of the Borrower works each week by 40.

Example 1 to paragraph (g)(15): 30 full-time employees and 35 part-time employees working 20 hours per week is calculated as follows: $30 + (35 \times (20/40)) = 47.5$. The maximum amount of the 504 loan would be 47.5 multiplied by $90,000, or $4,275,000.

* * * * *

■ 3. Amend § 120.883 by revising paragraph (e) to read as follows:

§ 120.883 Eligible administrative costs for 504 loans.

* * * * *

(e) CDC Closing Fee (see § 120.971(a)(2)) up to a maximum of $10,000; and

* * * * *

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2023–22169 Filed 10–11–23; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF JUSTICE

28 CFR Part 68

[EOIR Docket No. 022–0010; AG Order No. 5812–2023]

RIN 1125–AB28

Office of the Chief Administrative Hearing Officer, Review Procedures

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: Interim final rule; request for comment.

SUMMARY: The Department of Justice (''Department'') is revising its regulations to provide that the Attorney General may, in his discretion, review decisions and orders of Administrative Law Judges (''ALJs'') in the Office of the Chief Administrative Hearing Officer (''OCAHO'') in cases arising under section 274B of the Immigration and Nationality Act (''INA'' or ''the Act''). This revision will ensure that the adjudicatory process for section 274B cases is consistent with the Supreme Court's decision in the 2021 case *United States* v. *Arthrex, Inc.,* and will align that process with similar processes for discretionary review of decisions by ALJs in OCAHO and throughout the Executive Branch. It will not limit or alter parties' right to seek judicial review of adverse decisions.

DATES:

Effective date: This rule is effective October 12, 2023.

Comments: Electronic comments must be submitted and written comments must be postmarked or otherwise indicate a shipping date on or before December 11, 2023.

ADDRESSES: If you wish to provide comment regarding this rulemaking, you must submit comments, identified by the agency name and reference RIN 1125–AB28 or EOIR Docket No. 022–0010, by one of the two methods below.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the website's instructions for submitting comments. The electronic Federal Docket Management System (FDMS) at *https://www.regulations.gov* will accept electronic comments until 11:59 p.m. Eastern Time on December 11, 2023.
- *Mail:* Paper comments that duplicate an electronic submission are unnecessary. If you wish to submit a paper comment in lieu of electronic submission, please direct the mail/shipment to: Raechel Horowitz, Chief, Immigration Law Division, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 1800, Falls Church, VA 22041. To ensure proper handling, please reference the agency name and RIN 1125–AB28 or EOIR Docket No. 022–0010 on your correspondence. Mailed items must be postmarked or otherwise indicate a shipping date on or before the submission deadline.

FOR FURTHER INFORMATION CONTACT: Raechel Horowitz, Chief, Immigration Law Division, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 1800, Falls Church, VA 22041, telephone (703) 305–0289 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this interim final rule (''IFR'') via one of the methods and by the deadline stated above. The Department also invites comments that relate to the economic, environmental, or federalism effects that might result from this IFR. Comments that will provide the most assistance to the

Department in developing these procedures will reference a specific portion of the IFR; explain the reason for any recommended change; and include data, information, or authority that supports such recommended change.

Please note that all comments received are considered part of the public record and made available for public inspection at *https://www.regulations.gov.* Such information includes personally identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personally identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONALLY IDENTIFYING INFORMATION'' in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You also must prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *https://www.regulations.gov.*

Personally identifying information located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. The Department may withhold from public viewing information provided in comments that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.* To inspect the agency's public docket file in person, you must make an appointment with the agency. Please see the **FOR FURTHER INFORMATION CONTACT** section of this document for agency contact information.

II. Background

A. Office of the Chief Administrative Hearing Officer (''OCAHO''): Organization and Authority

OCAHO is a component of the Department's Executive Office for Immigration Review (''EOIR''). *See* 8 CFR 1003.0(a). Administrative Law Judges (''ALJs'') in OCAHO have jurisdiction to decide cases arising under sections 274A, 274B, and 274C of the Immigration and Nationality Act (''INA''), 8 U.S.C. 1324a, 1324b, and 1324c, and the procedures for such cases are set forth at 28 CFR part 68. Under these statutes and regulations, OCAHO ALJs conduct hearings, administer oaths, compel the production of documents and appearance of witnesses, issue subpoenas, and issue decisions and orders. 28 CFR 68.28(a); *see also* INA 274A(e), 274B(f), (g), and 274C(d), 8 U.S.C. 1324a(e), 1324b(f), (g), 1324c(d); *accord* 5 U.S.C. 556(c) (outlining general authorities of administrative agency ALJs). OCAHO is headed by a Chief Administrative Hearing Officer (''CAHO''), who exercises administrative supervision over the ALJs and other staff assigned to OCAHO and reviews certain decisions and orders issued by the ALJs. *See generally* 28 CFR 68.2 (delineating the authorities of the CAHO).

The INA provides instruction regarding the finality of and available appellate procedures for OCAHO ALJ orders under sections 274A, 274B, and 274C of the Act, 8 U.S.C. 1324a, 1324b, and 1324c.[1] Specifically, in cases arising under sections 274A and 274C of the Act, 8 U.S.C. 1324a and 1324c, the Act provides that final orders issued by OCAHO ALJs are subject to administrative appellate review by both ''an official delegated by regulation to exercise review authority'' and the Attorney General. *See* INA 274A(e)(7), 274C(d)(4), 8 U.S.C. 1324a(e)(7), 1324c(d)(4).[2] OCAHO's regulations in turn provide specific procedures for this review. *See* 28 CFR 68.54 through 68.55. However, in cases arising under section 274B of the Act, 8 U.S.C. 1324b, the statute provides that the ALJ's order ''shall be final'' unless appealed to the appropriate United States court of appeals. INA 274B(g)(1), (i), 8 U.S.C. 1324b(g)(1), (i). OCAHO's current regulations provide that the ALJ's final order in a case under section 274B of the Act, 8 U.S.C. 1324b, is the final agency order and is not subject to further review within the Department. *See* 28 CFR 68.52(g). Consistent with that regulation, OCAHO has previously concluded that ALJ orders under section 274B of the Act, 8 U.S.C. 1324b, are not subject to further administrative review, including by the Attorney General. *See A.S.* v. *Amazon Web Servs. Inc.,* 14 OCAHO no. 1381h, 2 (2021); *Wong-Opasi* v. *Sundquist,* 8 OCAHO no. 1051, 799, 799 (2000).

B. Concerns With Current Regulations Interpreting Section 274B of the Act, 8 U.S.C. 1324b

The Supreme Court's decision in *United States* v. *Arthrex, Inc.,* 141 S. Ct. 1970 (2021), has spurred a reevaluation of OCAHO's current regulatory framework that permits OCAHO ALJs to issue final orders not subject to further agency review in cases arising out of alleged violations of section 274B of the Act, 8 U.S.C. 1324b.

The Appointments Clause of the Constitution sets out the manner in which ''Officers of the United States'' who exercise significant governmental authority must be appointed. U.S. Const. art. II, sec. 2, cl. 2; *Buckley* v. *Valeo,* 424 U.S. 1, 126 & n.162, 141 (1976). Principal officers must be appointed by the President, by and with the advice and consent of the Senate, but inferior officers may be appointed by the President alone, the head of an executive department, or a court of law. U.S. Const. art. II, sec. 2, cl. 2; *see also Buckley,* 424 U.S. at 132. OCAHO ALJs are appointed by the Attorney General, *see* 28 U.S.C. 509, 510; 5 U.S.C. 3105, consistent with one of the methods permitted by the Constitution for the appointment of inferior officers, *see Buckley,* 424 U.S. at 132.

In *Arthrex,* the Court considered an adjudicatory framework where a statute expressly precluded a principal officer from directly reviewing the decisions of certain inferior officers—administrative patent judges (''APJs'')—and those APJs further had restrictions on their removal from office. *See Arthrex,* 141 S. Ct. at 1977–78, 1981–82, 1985. The Court explained that ''[a]n inferior officer must be 'directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate.' '' *Id.* at 1980 (quoting *Edmond* v. *United States,* 520 U.S. 651, 663 (1997)). The Court further explained that such unreviewable adjudicatory authority would conflict with the role of inferior officers, which inherently involves being subject to the direction

[1] Section 274A, 8 U.S.C. 1324a, relates to the unlawful employment of noncitizens, including making unlawful the employment of unauthorized noncitizens. Section 274B, 8 U.S.C. 1324b, sets forth requirements and procedures for investigating and conducting hearings related to unfair immigration-related employment practices, specifically discrimination based on national origin or citizenship status. Section 274C, 8 U.S.C. 1324c, establishes the penalties for document fraud when seeking immigration-related benefits or satisfying certain requirements of the INA.

[2] This appellate review authority has been delegated by regulation to the CAHO. *See* 28 CFR 0.118, 68.2, 68.54.

and supervision of others, either through higher-level review of the adjudicators' decisions or the ability to remove adjudicators from their positions at will. *See generally id.* at 1981–82. To remedy the constitutional concerns, the Court held that the statutory provision limiting or foreclosing review of APJ final decisions was unenforceable insofar as it prevented the Director of the United States Patent and Trademark Office (''USPTO'')—who is appointed by the President with the advice and consent of the Senate and therefore is ''a politically accountable officer'' as described in *Arthrex, id.* at 1982—from reviewing APJ decisions. *See id.* at 1986–87.

The Department has examined its current regulation governing cases arising under section 274B of the Act, 8 U.S.C. 1324b, in light of the principles outlined in *Arthrex.* The statutory framework under section 274B of the Act, 8 U.S.C. 1324b, does not expressly state that a principal officer may review an OCAHO ALJ's decision in cases arising under that provision and describes an OCAHO ALJ's order as final unless appealed to a federal circuit court, INA 274B(g)(1), 8 U.S.C. 1324(g)(1). Unlike the statutory framework in *Arthrex,* however, there is no statutory provision in section 274B of the Act, 8 U.S.C. 1324b, expressly limiting further review by a single principal officer. *Compare* 35 U.S.C. 6(c) (providing that decisions ''shall be heard by at least 3 members of the Patent Trial and Appeal Board'' and that ''[o]nly the Patent Trial and Appeal Board may grant rehearings'').

The Department's current regulation provides that, in cases arising under section 274B of the Act, 8 U.S.C. 1324b, an ALJ's decision ''becomes the final agency order on the date the order is issued'' and does not expressly provide for administrative review. 28 CFR 68.52(g). This regulation could be read to prevent further review by the Attorney General, which would make it comparable to the statutory scheme in *Arthrex* that prevented further review by the USPTO Director. *See id.; cf. Amazon Web Servs.,* 14 OCAHO no. 1381h at 2 n.4.

C. Interpreting INA 274B, 8 U.S.C. 1324b, in Light of Arthrex

Following the Supreme Court's decision in *Arthrex,* the Department has considered whether the current regulation setting out procedures for OCAHO ALJ decisions under section 274B of the Act, 8 U.S.C. 1324b, is the best implementation of the statute. The Department concludes that another reading of section 274B of the Act, 8 U.S.C. 1324b—one that expressly accounts for review of ALJ decisions by the Attorney General—is the better understanding of the law. This reading is also more consistent with the Administrative Procedure Act's (APA) general framework, which acknowledges a default rule of agency review of ALJ decisions. Specifically, the APA provides that after an ALJ makes an initial decision, ''that decision then becomes the final decision of the agency without further proceedings *unless there is an appeal to, or review on motion of, the agency* within time provided by rule.'' 5 U.S.C. 557(b) (emphasis added). This default rule of review supports the conclusion that the phrase ''shall be final'' in section 274B(g)(1) of the Act, 8 U.S.C. 1324b(g)(1), is best understood to mean that the ALJ's initial decision under section 274B of the Act, 8 U.S.C. 1324b, is the final agency action for purposes of seeking judicial review unless the decision is further reviewed by the Attorney General. This conclusion is further bolstered when read in conjunction with general principles of administrative law, the well-settled meaning of the word ''final'' in this context, the Executive Branch's practice in related areas, and the constitutional requirements of the Appointments Clause, each discussed in further detail below.

Specifically, this understanding of section 274B of the Act, 8 U.S.C. 1324b, is most consonant with general administrative law principles. As the Office of Legal Counsel has previously explained, ''[u]nder the APA, 'final agency action' is generally understood to mean that action which is necessary and sufficient for judicial review.'' *Secretary of Education Review of Administrative Law Judge Decisions,* 15 Op. O.L.C., 8, 10 (1991) (''*Secretary of Education*''). An ''extensive body of precedent'' establishes that an ''agency's decision need not be its last word on a subject to be considered 'final agency action,' '' and that an ''agency action can be 'final' for purposes of the APA, and thus for purposes of judicial review, even though it is subject to reconsideration on appeal to a higher authority within the agency.'' *Id.* at 10–11. And where ''Congress employs a term of art with a well-established meaning, it is generally presumed in the absence of evidence to the contrary to have intended that meaning to apply.'' *Id.* at 11. Section 274B of the Act, 8 U.S.C. 1324b, is thus ''most naturally read'' to indicate that an ALJ's decision shall be considered final agency action for purposes of sufficiency for judicial review under 5 U.S.C. 704, not as ''preclud[ing] further review of an ALJ's decision'' by the Attorney General. *Id.*

Indeed, throughout the Executive Branch, including in other Department components that utilize ALJs, ALJs render ''initial decisions,'' sometimes called ''recommended decisions,'' in certain cases that the agency can review further or, if there is no appeal or referral, become final agency decisions. *See, e.g.,* 21 CFR 1316.64 through 1316.67 (providing a process through which the Administrator of the Drug Enforcement Administration reviews recommended decisions of ALJs before they are published as final decisions); 27 CFR 555.79 (providing a process for the Director of the Bureau of Alcohol, Tobacco, Firearms, and Explosives to review initial decisions of ALJs in license and permit proceedings, after which the initial decision becomes final unless modified or reversed by the Director, but also noting that initial decisions may be appealed directly to the federal court of appeals); *see also* 28 CFR 68.52(g) (providing that ALJ orders in cases under sections 274A and 274C of the Act, 8 U.S.C. 1324a and 1324c, become final agency orders 60 days after issuance unless the orders are modified or vacated by the CAHO or referred to the Attorney General for review). Thus, a structure in which ALJ decisions are not subject to further review within the Executive Branch is an anomaly rather than the standard.

In addition to the above conclusion that this reading of the term ''final agency action'' is most consonant with general administrative law practices, the analysis in *Secretary of Education* provides further support for this interpretation as a mechanism for avoiding potential constitutional issues that would arise with a contrary reading of section 274B(g)(1) of the Act, 8 U.S.C. 1324b(g)(1). That opinion explained that a statutory provision providing that an ALJ's decision ''shall be considered to be a final agency action'' was best read to mean that the decision could be a final agency action for purposes of seeking judicial review, not that the Secretary of Education was foreclosed from exercising the agency head's customary role of reviewing the decisions of subordinates. 15 Op. O.L.C. at 12–13. The opinion noted that ''[i]f the Act were construed to forbid the Secretary's review of an ALJ decision, there would be presented serious constitutional questions relating to the ALJ's appointments and the lack of presidential control over their activities.'' *Id.* at 13.

Relatedly, ensuring that the Attorney General has the opportunity to review ALJ decisions is informed by the remedy that the Supreme Court prescribed in *Arthrex.* There, the Court held that pursuant to severability principles, ''the structure of the PTO and the governing constitutional principles chart a clear course: Decisions by APJs must be subject to review by the Director,'' a politically accountable officer. *Arthrex,* 141 S. Ct. at 1986. Here too, allowing the Attorney General to ''review[ ] the decisions of the [ALJs] on his own,'' *id.* at 1987, would be most consistent with the Appointments Clause.

Given the general principles of administrative law, the well-settled meaning of the word ''final'' in this context, the fact that head-of-agency review of ALJ decisions is the APA norm, and possible constitutional concerns with granting ALJs final decision-making authority not subject to further agency review, the Department declines to read the statute as precluding Attorney General review.

D. Purpose of the IFR

Consequently, the Department concludes that section 274B(g)(1) of the Act, 8 U.S.C. 1324b(g)(1), should not be read to preclude all further administrative review of an ALJ's decision. The typical understanding of the word ''final'' in Administrative Procedure Act cases, the fact that head-of-agency review of ALJ decisions is the APA norm, and possible constitutional avoidance concerns make this IFR's new provisions implementing procedures related to section 274B of the Act, 8 U.S.C. 1324b, including section 274B(g)(1) of the Act, 8 U.S.C. 1324b(g)(1), most appropriate to ensure a constitutionally sound review procedure for claims arising under this section.[3] Further, OCAHO cases arising under section 274A and 274C of the Act, 8 U.S.C. 1324a and 1324c, are already subject to possible review by the Attorney General. *See* 28 CFR 68.55.

[3] Additional authority for this IFR is found in 28 U.S.C. 509, which provides that ''[a]ll functions of other officers of the Department of Justice and all functions of agencies and employees of the Department of Justice are vested in the Attorney General,'' except for functions ''vested by [the APA] in administrative law judges'' and other exceptions not relevant here. The exclusion of ALJ functions in 28 U.S.C. 509 does not affect the Attorney General's authority to promulgate an appeal or referral procedure for cases heard by ALJs and review such cases pursuant to that regulation because when reviewing an ALJ decision, the Attorney General would be exercising a function generally vested in agency heads under the APA, 5 U.S.C. 557(b), and not the functions of ALJs themselves.

Accordingly, to effectuate the Department's new interpretation and avoid potential constitutional issues raised by the *Arthrex* decision, the Department is amending relevant parts of 28 CFR part 68 to provide the opportunity for Attorney General review of ALJ decisions in cases arising under section 274B of the Act, 8 U.S.C. 1324b, consistent with longstanding existing practices used in cases under sections 274A and 274C of the Act, 8 U.S.C. 1324a and 1324c.

III. Summary of Changes

The Department is amending OCAHO's rules of practice and procedure to implement a review procedure for ALJ decisions in cases arising under section 274B of the Act, 8 U.S.C. 1324b, that aligns with the agency review procedures set forth in the APA, is consistent with general administrative law principles, and is constitutionally sound. These changes will provide the Attorney General with an opportunity to review all OCAHO ALJ final orders consistent with the Attorney General's position as the head of the Department with responsibility for oversight of inferior officers at the Department. The decision whether to review an OCAHO ALJ decision would be within the sole discretion of the Attorney General, and no party will have the right to seek or request such review.

First, consistent with the overall intent of this IFR to ensure the opportunity for Attorney General review of ALJ decisions in cases under section 274B of the Act, 8 U.S.C. 1324b, this IFR amends the definitions of ''entry'' and ''final agency order'' in 28 CFR 68.2. With respect to the definition of ''entry,'' this IFR removes the separate definition of ''entry'' for cases arising under section 274B(i)(1) of the Act, 8 U.S.C. 1324b(i)(1). *See* 28 CFR 68.2 (2023) (defining the word ''entry'' to mean ''the date the Administrative Law Judge, Chief Administrative Hearing Officer, or the Attorney General signs the order'' and, as used in section 274B(i)(1) of the INA, to mean ''the date the Administrative Law Judge signs the order[.]''). Thus, pursuant to this IFR, the regulation provides a singular definition for ''entry'' that applies to cases arising under sections 274A, 274B, and 274C of the Act, 8 U.S.C. 1324a, 1324b, and 1324c. Regarding the definition of ''final agency order,'' this IFR adds a reference to section 274B of the Act, 8 U.S.C. 1324b, in addition to the existing references to sections 274A and 274C of the Act, 8 U.S.C. 1324a and 1324c, to the first sentence of the definition and removes a separate definition of the term ''final agency order'' exclusive to cases arising under section 274B of the Act, 8 U.S.C. 1324b. *See* 28 CFR 68.2 (2023) (stating that ''[i]n cases arising under section 274B of the INA, an Administrative Law Judge's final order is also the final agency order''). Further, this IFR makes conforming amendments in paragraph (g) of 28 CFR 68.52 regarding what constitutes the final agency order in cases under section 274B of the Act, 8 U.S.C. 1324b. Specifically, the IFR adds that in cases arising under 274B of the Act, 8 U.S.C. 1324b, the Administrative Law Judge's order becomes the final agency order sixty (60) days after the date of entry of the Administrative Law Judge's order, unless the order is referred to the Attorney General pursuant to 28 CFR 68.55.

Second, the IFR amends 28 CFR 68.55 to specify the procedures for Attorney General review of ALJ decisions and orders in cases arising under section 274B of the Act, 8 U.S.C. 1324b, including by providing a time frame for referral of such cases.

Third, the IFR amends 28 CFR 68.57 regarding the procedures for seeking judicial review of a final agency order in cases arising under section 274B of the Act, 8 U.S.C. 1324b, to include final agency orders issued under 28 CFR 68.55(d). *See* 28 CFR 68.55(d) (2023) (describing the final agency order in cases referred to the Attorney General for review). The IFR also makes non-substantive edits to 28 CFR 68.56 to include cross-references to relevant regulatory provisions and parallel the structure of revised 28 CFR 68.57.

Finally, the IFR also revises the authority citation for 28 CFR part 68 to include citations to 28 U.S.C. 509 (''Functions of the Attorney General''), 28 U.S.C. 510 (''Delegation of Authority''), and 5 U.S.C. 557(b) to ensure clarity regarding the basis for the Attorney General's authority to review OCAHO cases.

IV. Regulatory Requirements

A. Administrative Procedure Act

The Department has determined that this rule is not subject to the general requirements of notice and comment and a 30-day delay in the effective date. The requirements of 5 U.S.C. 553 do not apply to these regulatory changes because this IFR is a rule of ''agency organization, procedure, or practice.'' 5 U.S.C. 553(b)(A). This IFR, as with prior OCAHO procedural rulemakings, pertains solely to agency procedures and practices regarding the processing of cases before OCAHO and does not diminish or reduce any substantive

rights possessed by parties utilizing those practices and procedures. *See, e.g.,* Rules of Practice and Procedure for Administrative Hearings Before Administrative Law Judges in Cases Involving Allegations of Unlawful Employment of Aliens and Unfair Immigration-Related Employment Practices, 56 FR 50049, 50052 (Oct. 3, 1991); Rules of Practice and Procedure for Administrative Hearings Before Administrative Law Judges in Cases Involving Allegations of Unlawful Employment of Aliens, Unfair Immigration-Related Employment Practices, and Document Fraud, 64 FR 7076, 7072 (Feb. 12, 1999). Although the Department has determined that this IFR is not subject to the general requirements of notice and comment and a 30-day delay in the effective date, it is nevertheless promulgating this rule as an IFR, providing the public with the opportunity for post-promulgation comment.

B. Regulatory Flexibility Act

The Department has reviewed this regulation in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and has determined that this IFR will not have a significant economic impact on a substantial number of small entities. Further, a regulatory flexibility analysis is not required when the agency is not required to publish a general notice of proposed rulemaking, as is the case here. 5 U.S.C. 604(a) (''When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking . . . the agency shall prepare a final regulatory flexibility analysis.''); *see also* 5 U.S.C. 601(2) (defining a rule for purposes of the Regulatory Flexibility Act ''as any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b)'').

C. Unfunded Mandates Reform Act of 1995

This IFR will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1532(a).

D. Congressional Review Act

This IFR is not a major rule as defined by section 804 of the Congressional Review Act. See 5 U.S.C. 804(2). Moreover, this action is a rule of agency organization that does not substantially affect the rights or obligations of non-agency parties. Accordingly, it is not a ''rule'' as that term is used in 5 U.S.C. 804(3). Therefore, the reports to Congress and the Government Accountability Office specified by 5 U.S.C. 801 are not required.

E. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Executive Order 14094 (Modernizing Regulatory Review)

Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Sept. 30, 1993), Executive Order 13563, Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011), and Executive Order 14094, Modernizing Regulatory Review, 88 FR 21879 (Apr. 6, 2023), direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). Executive Order 13563 also emphasizes the importance of using the best available methods to quantify costs and benefits, and of reducing costs, harmonizing rules, and promoting flexibility.

Because this IFR is limited to agency organization, management, or personnel matters, it is not subject to review by the Office of Management and Budget pursuant to section 3(d)(3) of Executive Order 12866. Further, because this IFR is one of internal organization, management, or personnel, it is not subject to the requirements of Executive Order 13563.

F. Executive Order 13132 (Federalism)

This IFR will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, Federalism, 64 FR 43225, 43257–58 (Aug. 4, 1999), it is determined that this IFR does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

G. Executive Order 12988 (Civil Justice Reform)

This IFR meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, 61 FR 4729, 4730–32 (Feb. 5, 1996).

H. Paperwork Reduction Act

This IFR does not propose new or revisions to existing ''collection[s] of information'' as that term is defined under the Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (May 22, 1995), codified at 44 U.S.C. 3501 *et seq.,* and its implementing regulations, 5 CFR part 1320. *See* 44 U.S.C. 3502(3).

List of Subjects in 28 CFR Part 68

Administrative practice and procedure, Aliens, Citizenship and naturalization, Civil Rights, Employment, Equal employment opportunity, Immigration.

Accordingly, for the reasons set forth in the preamble and by the authority vested in me as Attorney General by law, part 68 of title 28 of the Code of Federal Regulations is amended as follows:

PART 68—RULES OF PRACTICE AND PROCEDURE FOR ADMINISTRATIVE HEARINGS BEFORE ADMINISTRATIVE LAW JUDGES IN CASES INVOLVING ALLEGATIONS OF UNLAWFUL EMPLOYMENT OF ALIENS, UNFAIR IMMIGRATION-RELATED EMPLOYMENT PRACTICES, AND DOCUMENT FRAUD

■ 1. The authority citation for part 68 is revised to read as follows:

Authority: 5 U.S.C. 301, 554, 557(b); 8 U.S.C. 1103, 1324a, 1324b, and 1324c; 28 U.S.C. 509, 510, and 2461 note.

■ 2. Amend § 68.2 by revising the definitions of ''Entry'' and ''Final agency order'' to read as follows:

§ 68.2 Definitions.

* * * * *

Entry means the date the Administrative Law Judge, the Chief Administrative Hearing Officer, or the Attorney General signs the order;

Final agency order is an Administrative Law Judge's final order, in cases arising under sections 274A, 274B, and 274C of the INA, that has not been modified, vacated, or remanded by the Chief Administrative Hearing Officer pursuant to § 68.54, referred to the Attorney General for review pursuant to § 68.55(a) or accepted by the Attorney General for review pursuant to § 68.55(b)(3). Alternatively, if the Chief Administrative Hearing Officer modifies or vacates the final order pursuant to § 68.54, the modification or vacatur becomes the final agency order if it has not been referred to the Attorney General for review pursuant to § 68.55(a) or accepted by the Attorney General for review pursuant to

§ 68.55(b)(3). If the Attorney General enters an order that modifies or vacates either the Chief Administrative Hearing Officer's or the Administrative Law Judge's order, the Attorney General's order is the final agency order.

* * * * *

■ 3. Amend § 68.52 by revising paragraph (g) to read as follows:

§ 68.52 Final order of the Administrative Law Judge.

* * * * *

(g) *Final agency order.* In a case arising under section 274A, 274B, or 274C of the INA, the Administrative Law Judge's order becomes the final agency order sixty (60) days after the date of entry of the Administrative Law Judge's order, unless:

(1) In a case arising under section 274A or 274C of the INA, the Chief Administrative Hearing Officer modifies, vacates, or remands the Administrative Law Judge's final order pursuant to § 68.54; or

(2) In a case arising under section 274A, 274B, or 274C of the INA, the order is referred to the Attorney General pursuant to § 68.55.

■ 4. Amend § 68.55 by revising the section heading, paragraph (a), and the first sentence of paragraph (c) introductory text to read as follows:

§ 68.55 Referral of cases arising under section 274A, 274B, or 274C to the Attorney General for review.

(a) *Referral of cases by direction of the Attorney General.* The Chief Administrative Hearing Officer shall promptly refer to the Attorney General for review any final order in cases arising under section 274A, 274B, or 274C of the INA if the Attorney General so directs the Chief Administrative Hearing Officer. For cases arising under section 274A and 274C, the Attorney General may so direct the Chief Administrative Hearing Officer within no more than thirty (30) days of the entry of a final order by the Chief Administrative Hearing Officer modifying or vacating an Administrative Law Judge's final order, or within no more than sixty (60) days of the entry of an Administrative Law Judge's final order, if the Chief Administrative Hearing Officer does not modify or vacate the Administrative Law Judge's final order. For cases arising under section 274B, the Attorney General may so direct the Chief Administrative Hearing Officer within no more than sixty (60) days of the entry of a final order by the Administrative Law Judge. When a final order is referred to the Attorney General in accordance with this paragraph (a), the Chief Administrative Hearing Officer shall give the Administrative Law Judge and all parties a copy of the referral.

* * * * *

(c) * * * When a final order of an Administrative Law Judge or the Chief Administrative Hearing Officer is referred to the Attorney General pursuant to paragraph (a) of this section, or a referral is accepted in accordance with paragraph (b)(3) of this section, the Attorney General shall review the final order in accordance with the provisions of this section. * * *

* * * * *

■ 5. Amend § 68.56 by revising the first sentence to read as follows:

§ 68.56 Judicial review of a final agency order in cases arising under section 274A or 274C.

In cases arising under section 274A or 274C of the INA, a person or entity adversely affected by a final agency order issued under § 68.52(c) or (e), § 68.54(e), or § 68.55(d) may file, within forty-five (45) days after the date of the final agency order, a petition in the United States Court of Appeals for the appropriate circuit for review of the final agency order. * * *

■ 6. Revise § 68.57 to read as follows:

§ 68.57 Judicial review of a final agency order in cases arising under section 274B.

In cases arising under section 274B of the INA, any person aggrieved by a final agency order issued under § 68.52(d) or § 68.55(d) may, within sixty (60) days after entry of the order, seek review of the final agency order in the United States Court of Appeals for the circuit in which the violation is alleged to have occurred or in which the employer resides or transacts business. If a final agency order is not appealed, the Special Counsel (or, if the Special Counsel fails to act, the person filing the charge, other than the Department of Homeland Security) may file a petition in the United States District Court for the district in which the violation that is the subject of the final agency order is alleged to have occurred, or in which the respondent resides or transacts business, requesting that the order be enforced.

Merrick B. Garland,

Attorney General.

[FR Doc. 2023–22206 Filed 10–11–23; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2023–0113]

RIN 1625–AA09

Drawbridge Operation Regulation; Cheboygan River at Cheboygan, MI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is altering the operating schedule that governs the US 23 Highway Bridge, mile 0.92, across the Cheboygan River—Part of the Inland Route, at Cheboygan, Michigan. The Cheboygan County Road Commission requested we extend the winter advance notice for the bridge.

DATES: This rule is effective November 13, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type the docket number USCG–2023–0113 in the ''SEARCH'' box and click ''SEARCH''. In the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email *Lee.D.Soule@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
IGLD85 International Great Lakes Datum of 1985
MDNR Michigan Department of Natural Resources
MDOT Michigan Department of Transportation
OMB Office of Management and Budget
LWD Low Water Datum based on IGLD85
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On April 5, 2023, the Coast Guard published an NPRM titled Drawbridge Operation Regulation; Cheboygan River at Cheboygan, MI in the **Federal Register** (88 FR 20082) and posted it on *Regulations.gov* for 60-days to seek your comments on whether the Coast Guard should consider modifying the current operating schedule to the US 23

Highway Bridge, mile 0.92, across the Cheboygan River—Part of the Inland Route. No comments were received during the NPRM.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499.

The Cheboygan County Road Commission requested we extend the winter advance notice for the bridge due to ice coverage which continues beyond the period requiring advance notice as set forth in the prior rule.

IV. Discussion of Comments, Changes and the Final Rule

The Coast Guard provided a comment period of 60 days and no comments were received.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the ability that vessels can still transit the bridge given advanced notice.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V. A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and DHS Delegation No. 00170.1, Revision No. 01.3.

■ 2. Revise § 117.627 to read as follows:

§ 117.627 Cheboygan River

The draw of the US 23 highway bridge, mile 0.9 at Cheboygan shall operate as follows:

(a) From May 1 through November 31—

(1) Between the hours of 7 a.m. and 11 p.m., the draw need only open from three minutes before to three minutes after the quarter-hour and three-quarter hour.

(2) Between the hours of 11 p.m. and 7 a.m., no drawtender is required to be at the bridge and the bridge need not open unless a request to open the draw

is given at least 2-hours in advance of a vessels intended time of passage through the draw.

(b) From December 1 through April 31, no drawtender is required to be at the bridge and the bridge need not open unless a request to open the draw is given at least 12-hours in advance of a vessels intended time of passage through the draw.

(c) At all times, the draw shall open as soon as possible for the passage of vessels if carrying public safety or public utility vehicles and persons to or from the island.

(d) The owner of the bridge shall provide and keep in good legible condition two board gauges painted white with black figures not less than six inches high to indicate the vertical clearance under the closed draw at all water levels. The gauges shall be placed on the bridge so that they are plainly visible to operators of vessels approaching the bridge either up or downstream.

Jonathan Hickey,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2023–22556 Filed 10–11–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0838]

RIN 1625–AA00

Safety Zone; Saint Thomas, USVI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 0.25 nautical miles radius around the Motor Vessel (M/V) BONNIE G grounded near the coast of Saint Thomas, U.S.V.I. This action is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the M/V BONNIE G grounding. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port San Juan.

DATES: This temporary final rule is effective without actual notice from October 12, 2023 through October 20, 2023. For the purposes of enforcement, actual notice will be used from October 6, 2023 until October 12, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0838 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Commander Carlos M. Ortega-Perez, Waterways Management Division Chief, U.S. Coast Guard; telephone 787–729–2380, email *Carlos.M.Ortega-Perez@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this TFR because doing so would be impracticable. The M/V BONNIE G grounded near the coast of Saint Thomas, U.S.V.I, and immediate action is needed to respond to the potential safety hazards associated with the emergency response and salvage operations. It is impracticable to publish an NPRM because we must establish this safety zone by October 6, 2023.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the emergency response and salvage operations.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port San Juan (COTP) has determined that there are potential hazards associated with the response and salvage operations regarding the M/V BONNIE G grounding. There will be a safety concern for anyone within a 0.25 nautical miles radius around the M/V BONNIE G grounded near the coast of Saint Thomas, U.S.V.I. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during response and salvage operations.

IV. Discussion of the Rule

This rule establishes a safety zone on certain waters of the Caribbean Sea off the coast of Saint Thomas, U.S.V.I. The safety zone will be enforced from October 6, 2023 through October 20, 2023. The safety zone will cover all navigable waters within 0.25 nautical miles radius of 18°19′27″ N 64°58′25″ W, the current location of the M/V BONNIE G. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the Owning company of the vessel completes their salvage plan.

No person or vessel will be permitted to enter, transit through, anchor in, or remain within the safety zone without first obtaining permission from the COTP or a designated representative. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted by the COTP or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP or a designated representative. The Coast Guard will provide notice of the safety zone by Broadcast Notice to Mariners, and/or by on-scene designated representatives.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on following reasons: (1) the temporary safety zone will only be enforced for 15 consecutive days and may be removed earlier if the response and salvage operations are completed prior October 20, 2023; (2) although persons and vessels may not enter, transit through, anchor in, or remain within the safety zone without authorization from the COTP or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the areas during the enforcement period if authorized by the COTP or a designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal Government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a .25 nautical mile perimeter safety zone, lasting the duration of response and salvage operations or a maximum of 15 consecutive days and thus limited in scope. This zone will prohibit entry while in effect. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T07–0838 to read as follows:

§ 165.T07–0838 Safety Zone; Saint Thomas, U.S.V.I.

(a) *Location.* The following area is a safety zone: All waters of the Caribbean Sea off the coast of Saint Thomas, U.S.V.I, from surface to bottom, that are within a 0.25 nautical mile radius of 18°19′27″ N 64°58′25″ W, the current location of the M/V BONNIE G, from surface to bottom.

(b) *Definitions.* As used in this section, the term ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) San Juan in the enforcement of the safety zone.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering,

transiting through, anchoring in, or remaining within the regulated area unless authorized by the COTP San Juan or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the COTP San Juan by telephone at (787) 289–2041, or a designated representative via VHF–FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP San Juan or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners via VHF–FM channel 16, or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 6 a.m. until 6 p.m. on October 6, 2023, through October 20, 2023.

Dated: October 6, 2023.

José E. Díaz,

Captain, U.S. Coast Guard, Captain of the Port San Juan.

[FR Doc. 2023–22595 Filed 10–11–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2022–0007; FRL–9344–02–OAR]

RIN 2060–AV63

Reference Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere (Chemiluminescence Method)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing an update to the current ozone absorption cross-section to the recommended consensus-based cross-section value of $1.1329x10^{-17}$ cm^2 $molecule^{-1}$ or 304.39 atm^{-1} cm^{-1}, with an uncertainty of 0.94 atm^{-1} cm^{-1}. The new value is 1.2% lower than the current value of 308 atm^{-1} cm^{-1} and reduces the uncertainty in the value to 0.31%. The adoption of this updated ozone absorption cross-section could result in increases in measured ozone concentrations but given the existing sources of potential variability in monitoring data, it is unlikely that there will be any consistent measurable and predictable effect on reported data. The EPA is also updating the dates of publication for two references associated with the updated cross-section value, adding a new reference, and making a technical correction to move three figures inadvertently placed in section 6.0 *References* to a new section 7.0 *Figures.*

DATES: This final rule is effective on November 13, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2022–0007. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Joann Rice, Office of Air Quality Planning and Standards, Air Quality Assessment Division, Ambient Air Monitoring Group (C304–06), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–3372; email address: *rice.joann@epa.gov.*

SUPPLEMENTARY INFORMATION:

Organization of this document. The information in this preamble is organized as follows:

Table of Contents

I. Background

In 1961, the ozone absorption cross-section was measured to be 1.1476 $x10^{-17}$ cm^2 $molecule^{-1}$ or 308.3 $atmosphere\ (atm)^{-1}$ $centimeter\ (cm)^{-1}$ with a reported relative standard uncertainty of 1.4% (Hearn, 1961).[1] In the 1980s, the National Institute of Standards and Technology (NIST), in collaboration with the EPA, developed the Standard Reference Photometer (SRP), which is the international standard for the measurement of ozone. The SRP is based on ultraviolet (UV) photometry and uses this cross-section value as the reference value for UV ozone measurements. To establish and maintain traceability, the readings of an ozone analyzer are compared to a NIST-made ozone SRP through a hierarchy of standards. Efforts to improve the accuracy of the ozone absorption cross-section have continued over several years during which rigorous assessment of the bias and uncertainty in the value became a high priority.

The Gas Analysis Working Group of the Consultive Committee for Metrology in Chemistry and Biology (CCQM–GAWG) of the Bureau of Weights and Measures in France (BIPM) convened a task group in 2016 to review all published measurements of the ozone cross-section since 1950. This task group was also charged with recommending a consensus-based cross-section value and associated uncertainty for adoption in measurements of ozone concentrations by standard UV photometric instruments, including the SRP. (Hodges et al., 2019).[2]

After publication in Hodges et al., 2019, the CCQM–GAWG[3] convened an international group of stakeholders in October 2020 to discuss adopting and implementing a globally coordinated change in the cross-section value for surface ozone monitoring. This group, representing several international and national metrology institutes, NIST, and environmental agencies including EPA, agreed to adopt and implement the new cross-section value as it represents a more accurate value with less

[1] Hearn A.G. (1961). Absorption of ozone in ultra-violet and visible regions of spectrum, *Proc. Phys. Soc. 78 932,* DOI: 10.1088/0370–1328/78/5/340.

[2] Hodges, J.T., Viallon, J., Brewer, P.J., Drouin, B.J., Gorshelev, V., Janssen, C., Lee, S., Possolo, A., Smith, M.A.H., Walden, and Wielgosz, R.I. (2019). Recommendation of a consensus value of the ozone absorption cross-section at 253.65 nm based on a literature review, Metrologia, 56, 034001. *https://doi.org/10.1088/1681-7575/ab0bdd.*

[3] *https://www.bipm.org/en/committees/cc/ccqm/wg/ccqm-gawg-ozone-tg.*

uncertainty and is an advancement and improvement in the UV photometer measurement method.

40 CFR part 50, appendix D, ''Reference Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere,'' currently provides EPA's ozone calibration procedure with a stated value of 308 ± 4 atm^{-1} cm^{-1}. This final action updates the ozone absorption cross-section to align with the BIPM CCQM–GAWG's updated international cross-section value of 304.39 atm^{-1} cm^{-1} with an uncertainty of 0.94 atm^{-1} cm^{-1} at standard temperature and pressure of 0 °C and 1 atmosphere. The EPA agrees that the new cross-section value results in an improvement in the accuracy of surface ozone monitoring measurements by reducing uncertainty and is finalizing the change in appendix D of part 50 to this more accurate consensus value.

The updated value reduces the uncertainty to 0.31% from the current 1.4%. The value is also 1.2% lower than the current value of 308 atmosphere atm^{-1} cm^{-1}, a change that could result in increases in measured ozone concentrations. However, there are several factors that EPA believes make it unlikely that this change will have a measurable, predictable influence on any particular set of ozone monitoring data.

Design values, the metric used to compare ambient ozone concentrations measured at a monitor to the National Ambient Air Quality Standard (NAAQS) to determine compliance, are determined using the data reporting, data handling, and computation procedures provided in 40 CFR part 50, appendix U, ''Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone.''

Multiple factors can contribute to variability in monitoring data and ultimately design values, including, but not limited to, the precision of the monitoring method, the acceptance criteria for Standard Reference Photometer (SRP) calibration and verification, the acceptance criterion for bench and field standards used to calibrate ozone monitors in the field, how agencies perform calibration and adjust analyzer response, the precision and bias acceptance criteria in EPA's Quality Assurance (QA) Handbook,[4] data handling and computation procedures in Appendix U, and meteorology.

The inherent precision (variability) of the measurements from analyzers used to measure ozone is about ±1 ppb, or ±0.001 ppm. The variability in the measurement in either the positive or negative direction should be considered relative to the change in monitoring data due to the new cross-section value.

When the new cross-section value is implemented, all SRPs maintained by BIPM, NIST, and the EPA will be updated to incorporate the new value. The update will be achieved through software/firmware modification and will not require any hardware changes. The EPA is planning to update all Agency's SRPs simultaneously, instead of through a phased approach, to minimize disruption of the SRP network. To establish and maintain traceability, the readings of an ozone analyzer are compared through a hierarchy of standards to a NIST ozone SRP. The process of using NIST-traceable standards to verify the ozone concentrations is implemented for all regulatory network ozone analyzers used for comparison to the NAAQS. There are 12 SRPs within the EPA's network: three at EPA's Office of Research and Development (ORD) and nine at various EPA Regional offices and the California Air Resources Board (CARB). One of ORD's SRPs is sent to NIST to be re-verified against the NIST SRP annually. That SRP serves as the reference for the two other ORD SRPs. Each SRP in the U.S. is re-verified against one of ORD's three SRPs annually. Under normal verification operations, implementing the ozone standards traceability process for the entire SRP network could take 2 or more years starting from when the SRP software/firmware is updated. During this time, the implementation progress and monitoring data collected with the new cross-section will need to be tracked.

The acceptance criteria used in comparing the SRPs (Level 1 standards) to each other is a slope of 1.00 ± 0.01 (or 1%) and an intercept 0.00 ± 1 ppb. Field and bench standards (Level 2 standard) used to calibrate ozone analyzers in the field have acceptance criteria for the slope of 1.00 ± 0.03 (or 3%) and an intercept of 0 ± 3 ppb. The 1.2% change in cross-section value is well within the 3% acceptance for Level 2 standards.

The goal for annual measurement uncertainty for ozone in 40 CFR part 58, ''Ambient Air Quality Surveillance,'' is an upper 90 percent confidence limit for the coefficient of variation of 7% for precision and for bias an upper 95 percent confidence limit of 7%. Bias and precision estimates are determined using data obtained from the comparison of the ozone analyzer response to one-point Quality Control (QC) checks using a Level 2 calibration standard. The 1.2% change in cross-section value is well within the bias and precision goal of 7%. Data reported to the EPA's Air Quality System by state, local, and tribal monitoring agencies is used to assess bias and precision. The 2021 national average precision for all ozone analyzers in the U.S. is 2.3% and the national average bias is 1.6%.[5] The 1.2% change is, therefore, within the national precision and less than the national bias.

The QA Handbook, Volume II, Appendix D Validation Template[6] also specifies critical criteria for monitoring organizations to maintain the integrity and evaluate the quality of the data collected by the analyzer. The critical criteria are a one-point QC check (every 14 days at a minimum) < ±7.1% difference or < ±1.5 ppb difference, whichever is greater; zero drift < ± 3.1 ppb (over a 24-hour period) or < ±5.1 ppb (>24 hours and up to 14 days); and span check drift over a 14-day period of < ±7.1%. Any change to monitoring data due to the new cross-section is also well within the 7.1% acceptance criteria. Monitoring organizations may manually adjust the analyzer response while others may institute automated adjustment through use of a data acquisition or data handling system. Automated adjustments to the ozone analyzer data are not recommended because the monitoring agency may not know if the standard being used for monitor comparison, or the analyzer, has degraded or drifted.

Ozone analyzers are calibrated or verified every 182 days if one-point zero and span checks are performed every 14 days, and every 365 days if one-point zero and span checks are done daily. The acceptance criteria for multi-point calibration are all points < ±2.1% or ≤ ±1.5 ppb difference of the best fit straight line, whichever is greater, and a slope of 1 ± 0.05 or 5%. The 1.2% change is also well within this acceptance criteria for ozone monitor calibration.

Ozone design values are computed as the 3-year average of the annual 4th highest daily maximum 8-hour value

[4] Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, EPA–454/B–17–001, Jan. 2017, available at: *https://www.epa.gov/sites/default/files/2020-10/documents/final_handbook_document_1_17.pdf.*

[5] Data obtained on 9/1/2022 from EPA's Ozone Data Quality Dashboard: *https://sti-r-shiny.shinyapps.io/ozone_dashboard/.*

[6] Appendix D, Measurement Quality Objectives and Validation Templates: *https://www.epa.gov/sites/default/files/2020-10/documents/app_d_validation_template_version_03_2017_for_amtic_rev_1.pdf.*

measured at each monitoring site. Appendix U provides for three levels of truncation for the hourly, daily 8-hour maximum, and design value calculations. Hourly averaged ozone monitoring data are to be reported in ppm to the third decimal place, with additional digits to the right truncated (*e.g.,* 0.070 ppm). In assessing how and if the updated cross-section value may affect ozone design values, it is important to note that other factors, including meteorology, can also influence design values. The effects of meteorology on hourly ozone concentrations can contribute to an increase or decrease in design values for a site because formation of ozone is heavily dependent on meteorological conditions. Interannual meteorological variations are known to affect daily and seasonal average ozone concentrations. Therefore, while we do not have reason to believe this proposal will significantly increase design values, meteorology would be a confounding factor in determining the effect on 3-year design values.

Taking these factors into consideration, the EPA believes it is unlikely that the cross-section change will have a measurable, predictable influence on any given ozone design value or monitoring data set.

Because the EPA believes that adoption of the new cross-section will improve the accuracy of measured ozone values and is unlikely to have a measurable, predictable influence on any given monitor or design value, the EPA is finalizing its proposal to revise the current ozone absorption cross-section to the recommended international consensus-based cross-section value of 304.39 atm^{-1} cm^{-1}, with an uncertainty of 0.94 atm^{-1} cm^{-1}.

Ozone analyzers are traceable to a NIST standard reference UV-based photometer with a specified ozone UV absorption cross-section value. The absorption cross-section value stated this appendix (304.39 atm^{-1} cm^{-1} ± 0.94 atm^{-1} cm^{-1}) will be implemented January 1, 2025, with an additional year for state, local, and tribal monitoring agencies to complete implementation, to January 1, 2026. Until January 1, 2025, the previous ozone absorption cross-section value (308 ± 4 atm^{-1} cm^{-1}) will be used. After January 1, 2025, both cross-section values, 304.39 ± 0.94 atm^{-1} cm^{-1} and 308 ± 4 atm^{-1} cm^{-1}, may be used. After January 1, 2026, only the cross-section value of 304.39 ± 0.94 atm^{-1} cm^{-1} may be used. EPA recognizes the challenges, complexity, and time it will take to develop guidance and complete implementation of the updated cross-section value and is, therefore, delaying the proposed implementation start date of January 1, 2024, until January 1, 2025, with an additional year (to January 1, 2026) to complete implementation.

The EPA is including an additional published reference for the research done to support the cross-section change in 40 CFR part 50, appendix D, section 6.0 *References:* Hodges, J.T., Viallon, J., Brewer, P.J., Drouin, B.J., Gorshelev, V., Janssen, C., Lee, S., Possolo, A., Smith, M.A.H., Walden, and Wielgosz, R.I., ''Recommendation of a consensus value of the ozone absorption cross-section at 253.65 nm based on a literature review,'' Metrologia, 56 (2019) 034001, *https://doi.org/10.1088/1681-7575/ab0bdd.* The EPA is also changing the publication dates of two existing references associated with the updated cross-section value in 40 CFR part 50, appendix D, section 6.0 *References.*

Comments on the Proposed Rule

On February 24, 2023, the EPA proposed to update the current ozone absorption cross-section (88 FR 11835) and solicited comment on the proposed update. The EPA received two comments by the close of the public comment period on March 27, 2023. One commenter expressed concern that the proposed target date of January 1, 2024, provides insufficient time to implement the new cross-section value and noted that monitoring equipment that is no longer supported by manufacturers would require monitoring agencies to purchase new ozone monitoring equipment.

In further consideration of global implementation of the updated cross-section value, the international task group leading implementation and the EPA recognize the challenges, complexity, and time it will take to implement the updated value and are accordingly delaying the implementation start date from January 2024 until January 2025 with an additional year (to January 2026) to complete implementation. Regarding the assertion that some monitoring agencies will be required to purchase new equipment, existing equipment will be adjusted by firmware updates if available. Where firmware updates are not available for certain monitors, those monitors may instead be calibrated against ozone transfer standards, which are calibrated directly back to a Standard Reference Photometer (SRP) using the updated cross-section value. Therefore, the purchase of new equipment should not be required.

A second comment on the proposed cross-section value assumed that the percentage increase in monitoring data would be 0.00086 ppm at the current level of the standard (0.070 ppm). The commenter noted that, if that increase had been applied to the health studies upon which the current NAAQS is based, ''a NAAQS closer to 71 ppb very well could have been chosen based on the monitoring data.'' The commenter also noted that under the current ozone reconsideration, the Clean Air Science Advisory Committee (CASAC) and EPA ''must'' consider the ozone cross-section change on monitoring data and health effect studies and, if not considered, the NAAQS may be ''artificially lowered'' or more stringent.

The EPA disagrees that this change will make the NAAQS ozone standard more stringent. As described in the proposed action, at the current level of the standard (0.070 ppm), 0.00086 ppm is within the current precision of the measurement method which is +/- 0.001 ppm. Moreover, when viewed in conjunction with the current monitor calibration acceptance criteria [7], the use of truncation conventions for the ozone hourly, daily 8-hour maximum, and design value calculations, and other unpredictable factors, EPA disagrees with the commenter's suggestion that the change will result in any consistent measurable and predictable effect on reported data. This inherent measurement variability is already included in the measurements that have been and are being used in health effects research studies related to the ozone NAAQS. The CASAC is aware of this action, which is required to bring the U.S. into alignment with international monitoring standards.

No other comments were received. The EPA is finalizing this action as proposed.

II. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined by Executive Order 12866, as amended by

[7] See *QA Handbook, Vol. II, App. D, Measurement Quality Objectives and Validation Templates,* available at *https://www.epa.gov/sites/default/files/2020-10/documents/app_d_validation_template_version_03_2017_for_amtic_rev_1.pdf.*

Executive Order 14094 and was, therefore, not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action revises the ozone absorption cross-section and revise and amend relevant references. It does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden on the small entities subject to the rule. This action updates the ozone absorption cross-section value for surface ozone monitoring under 40 CFR part 50, and we anticipate that there will be minimal costs associated with this change. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments, or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This action updates a reference measurement principle and calibration procedure for the measurement of ambient ozone under 40 CFR part 50. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking involves technical standards. The EPA used voluntary consensus standards in the preparation of this measurement principle and procedure; it is the benchmark against which all ambient ozone monitoring methods are compared. This action is simply updating the reference measurement principle in light of updated information.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, Feb.16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color) and low-income populations.

The EPA believes that this type of action does not concern human health or environmental conditions and, therefore, cannot be evaluated with respect to potentially disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. This regulatory action is an update to a previously promulgated analytical method and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each house of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Ozone.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, the EPA amends title 40, chapter I of the Code of Federal Regulations as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

■ 1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 2. Amend appendix D to part 50 by:
■ a. Revising sections 2.2, 4.1 and 4.5.3.10;
■ b. Revising references 13. and 14. in section 6.0;
■ c. Removing figures 1., 2., and 3. in section 6.0;
■ d. Adding reference 15 in section 6.0; and
■ e. Adding section ''7.0 *Figures.*''.

The revisions and addition read as follows:

Appendix D to Part 50—Reference Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere (Chemiluminescence Method)

* * * * *

2.0 *Measurement Principle.*

* * * * *

2.2 The measurement system is calibrated by referencing the instrumental chemiluminescence measurements to certified O_3 standard concentrations generated in a dynamic flow system and assayed by ultraviolet (UV) photometry to be traceable to a National Institute of Standards and Technology (NIST) standard reference photometer for O_3 (see section 4, Calibration Procedure, below) with a specified ozone absorption cross-section value. The absorption cross-section value stated in section 4.1 and section 4.5.3.10 of this appendix (304.39 atm^{-1} $cm^{-1} \pm 0.94$ atm^{-1} cm^{-1}) will be implemented January 1, 2025, with an additional year to complete implementation (January 1, 2026). Until January 1, 2025, the previous ozone absorption cross-section value, 308 ± 4

atm^{-1} cm^{-1}, will be used. After January 1, 2025, both cross-section values, 304.39 ± 0.94 atm^{-1} cm^{-1} and 308 ± 4 atm^{-1} cm^{-1}, may be used. After January 1, 2026, only the cross-section value of 304.39 ± 0.94 atm^{-1} cm^{-1} may be used.

* * * * *

4.0 *Calibration Procedure.*

4.1 *Principle.* The calibration procedure is based on the photometric assay of O_3 concentrations in a dynamic flow system. The concentration of O_3 in an absorption cell is determined from a measurement of the amount of 254 nm light absorbed by the sample. This determination requires knowledge of (1) the absorption coefficient (α) of O_3 at 254 nm, (2) the optical path length (l) through the sample, (3) the transmittance of the sample at a nominal wavelength of 254 nm, and (4) the temperature (T) and pressure (P) of the sample. The transmittance is defined as the ratio I/I_0, where I is the intensity of light which passes through the cell and is sensed by the detector when the cell contains an O_3 sample, and I_0 is the intensity of light which passes through the cell and is sensed by the detector when the cell contains zero air. It is assumed that all conditions of the system, except for the contents of the absorption cell, are identical during measurement of I and I_0. The quantities defined above are related by the Beer-Lambert absorption law,

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$$\text{Transmitance} = \frac{I}{I_0} = e^{-\alpha c l} \quad (1)$$

Where:

α = absorption coefficient of O_3 at 254 nm = 304.39 atm^{-1} cm^{-1}, with an uncertainty of 0.94 atm^{-1} cm^{-1} at 0 °C and 1 atm. [1, 2, 3, 4, 5, 6, 7, 15]

c = O_3 concentration in atmospheres, and

l = optical path length in cm.

A stable O_3 generator is used to produce O_3 concentrations over the required calibration concentration range. Each O_3 concentration is determined from the measurement of the transmittance (I/I_0) of the sample at 254 nm with a photometer of path length l and calculated from the equation,

$$c(\text{atm}) = -\frac{1}{\alpha l}\left(\ln\frac{I}{I_0}\right) \quad (2a)$$

or

$$c(\text{ppm}) = -\frac{10^6}{\alpha l}\left(\ln\frac{I}{I_0}\right). \quad (2b)$$

The calculated O_3 concentrations must be corrected for O_3 losses, which may occur in the photometer, and for the temperature and pressure of the sample.

* * * * *

4.5 *Procedure.*

* * * * *

4.5.3.10. Calculate the O_3 concentration from equation 4. An average of several determinations will provide better precision.

$$[O_3]_{OUT} = \left(\frac{-1}{\alpha l}\ln\frac{I}{I_0}\right)\left(\frac{T}{273}\right)\left(\frac{760}{P}\right)\times\frac{10^6}{L} \quad (4)$$

Where:

$[O_3]_{OUT}$ = O_3 concentration, ppm

α = absorption coefficient of O_3 at 254 nm = 304.39 atm^{-1} cm^{-1} at 0 °C and 1 atm

l = optical path length, cm

T = sample temperature, K

P = sample pressure, torr

L = correction factor for O_3 losses from 4.5.2.5 = (1 − fraction of O_3 lost).

Note: Some commercial photometers may automatically evaluate all or part of equation 4. It is the operator's responsibility to verify that all of the information required for equation 4 is obtained, either automatically by the photometer or manually. For ''automatic'' photometers which evaluate the first term of equation 4 based on a linear approximation, a manual correction may be required, particularly at higher O3 levels. See the photometer instruction manual and Reference 13 for guidance.

* * * * *

6.0 *References.*

* * * * *

13. Technical Assistance Document for the Calibration of Ambient Ozone Monitors, EPA publication number EPA–454/B–22–003, January 2023.

14. QA Handbook for Air Pollution Measurement Systems—Volume II. Ambient Air Quality Monitoring Program. EPA–454/B–17–001, January 2017.

15. Hodges, J.T., Viallon, J., Brewer, P.J., Drouin, B.J., Gorshelev, V., Janssen, C., Lee, S., Possolo, A., Smith, M.A.H., Walden, and Wielgosz, R.I., Recommendation of a consensus value of the ozone absorption cross-section at 253.65 nm based on a literature review, *Metrologia,* 56 (2019) 034001. [Available at *https://doi.org/10.1088/1681-7575/ab0bdd*.]

7.0 *Figures.*

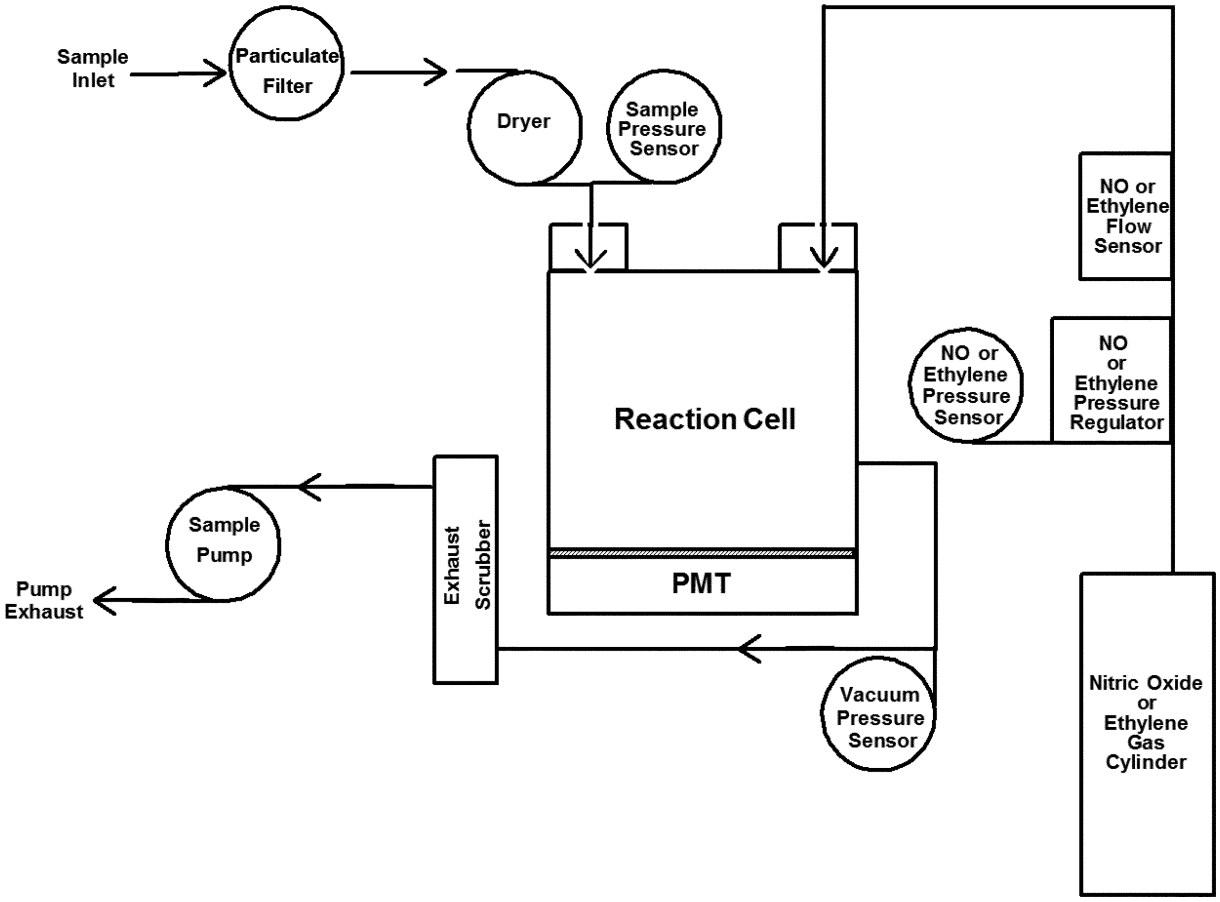

Figure 1. Gas-phase chemiluminescence analyzer schematic diagram, where PMT means photomultiplier tube.

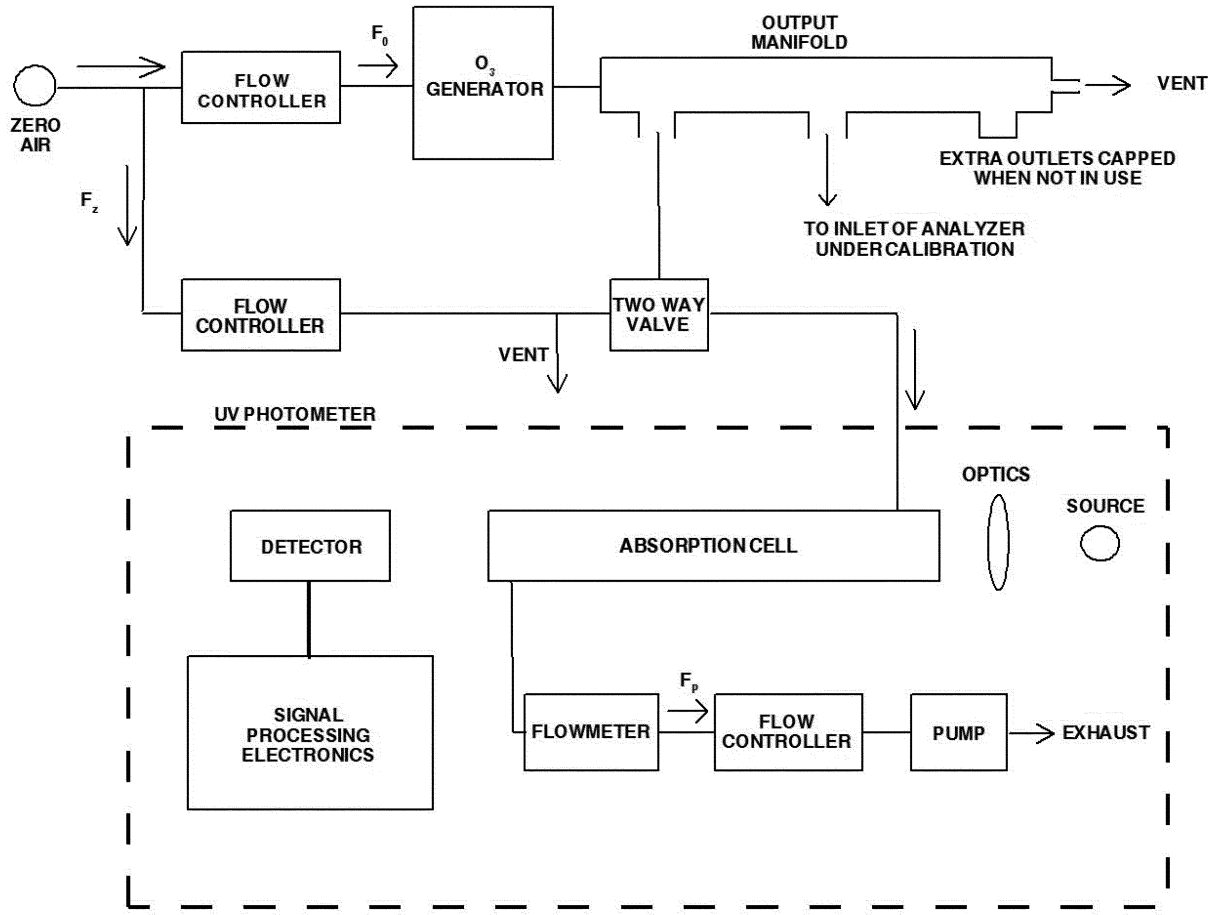

Figure 2. Schematic diagram of a typical UV photometric calibration system.

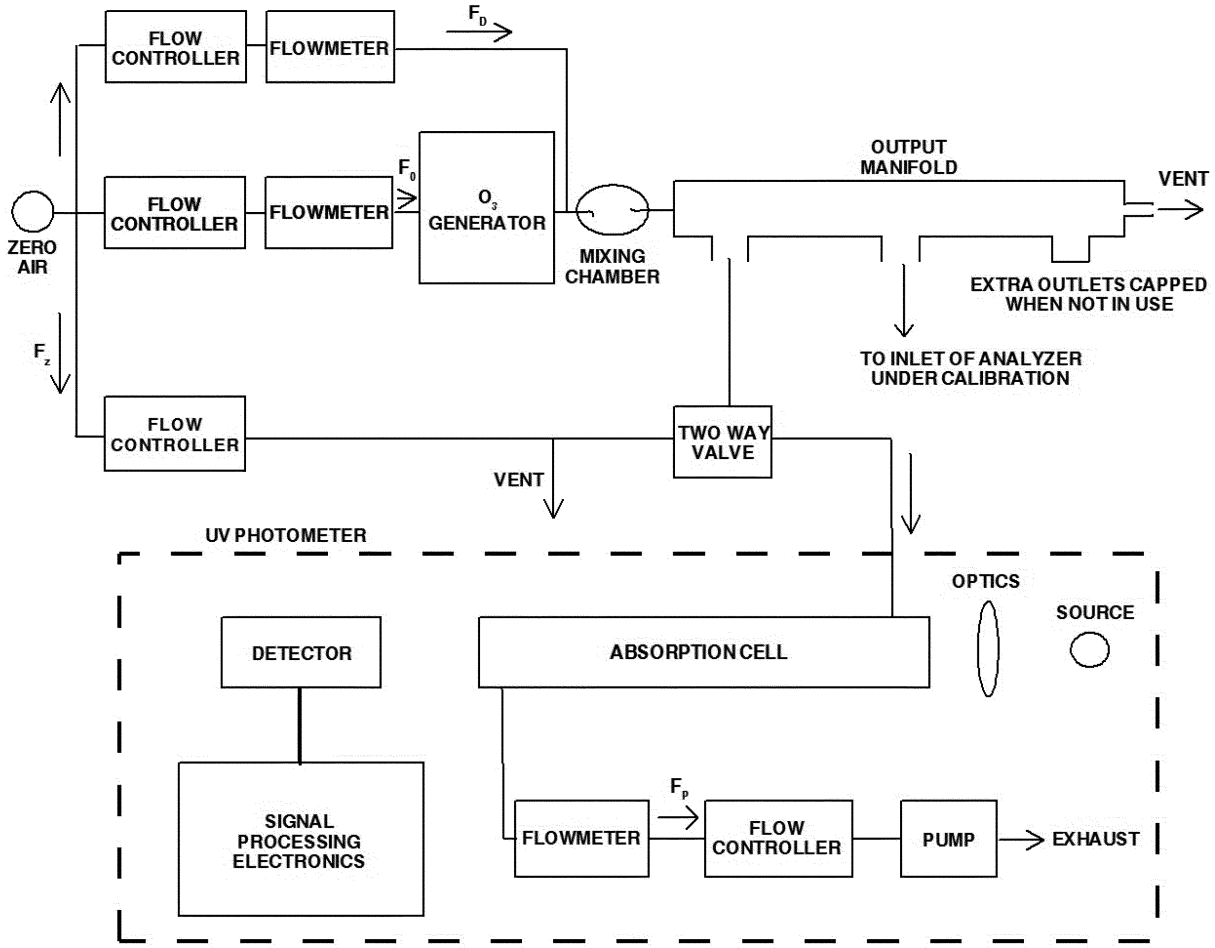

Figure 3. Schematic diagram of a typical UV photometric calibration system (Option 1).

[FR Doc. 2023–22531 Filed 10–11–23; 8:45 am]

BILLING CODE 6560–50–C

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 1090

[EPA–HQ–OAR–2023–0289; FRL 10290–01–OAR]

RIN 2060–AV87

Reformulated Gasoline Covered Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this final action, the Environmental Protection Agency (EPA) is amending its reformulated gasoline (RFG) regulations to reflect the reclassification of several ozone nonattainment areas as Severe for the 2008 ozone national ambient air quality standard (NAAQS). The subject areas are the Dallas-Fort Worth, TX area (Dallas), the Denver-Boulder-Greeley-Fort Collins-Loveland, CO area (Denver), and the Eastern Kern County, CA area (Eastern Kern). The reclassification of the Dallas and Denver areas as Severe for the 2008 ozone NAAQS was effective on November 7, 2022, and results in the prohibition of the sale of conventional gasoline throughout the entire nonattainment area under the Clean Air Act (CAA) eon November 7, 2023. Similarly, the reclassification of the Eastern Kern area was effective on July 7, 2021, and the Federal RFG requirement applied to the area on July 7, 2022.

DATES: This final rule is effective November 13, 2023.

FOR FURTHER INFORMATION CONTACT: Mark Coryell, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, MI 48105; email address: *coryell.mark@epa.gov* or Rudy Kapichak, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, MI 48105; email address: *kapichak.rudolph@epa.gov.*

SUPPLEMENTARY INFORMATION: The contents of this preamble are listed in the following outline:

I. General Information

A. Does this action apply to me?

Entities potentially affected by this final action are fuel producers and distributors who do business in the Dallas-Fort Worth, TX area, the Denver-Boulder-Greeley-Fort Collins-Loveland, CO area, and the Eastern Kern County, CA area.

Examples of potentially regulated entities	NAICS [1] codes
Petroleum refineries	324110 424710
Gasoline Marketers and Distributors	424720
Gasoline Retail Stations	457110 457120

[1] North American Industry Classification System.

Examples of potentially regulated entities	NAICS [1] codes
Gasoline Transporters	484220 484230

The above table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. The table lists the types of entities of which EPA is aware that potentially could be affected by this final action. Other types of entities not listed on the table could also be affected. To determine whether your organization could be affected by this final action, you should carefully examine the regulations in 40 CFR part 1090. If you have questions regarding the applicability of this action to a particular entity, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. How can I get copies of this document and other related information?

EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2023–0289. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *www.regulations.gov.*

II. Action

In this final action, the Environmental Protection Agency (EPA) is amending its reformulated gasoline (RFG) regulations at 40 CFR 1090.285(b) and (c) to reflect the reclassification of several ozone nonattainment areas as Severe for the 2008 ozone national ambient air quality standard. The subject areas are the Dallas-Fort Worth, TX area, the Denver-Boulder-Greeley-Fort Collins-Loveland, CO area, and the Eastern Kern County, CA area. The reclassification of the Dallas and Denver areas was effective on November 7, 2022, and results in the prohibition of the sale of conventional gasoline throughout the entire nonattainment area under CAA section 211(k)(10)(D) and section 211(k)(5) effective 1 year after the effective date of the reclassification, which is November 7, 2023.[2] Similarly, the reclassification of the Eastern Kern area was effective on July 7, 2021, and the Federal RFG requirement applied to the area on July 7, 2022.[3]

III. Background

The CAA prohibits the sale of conventional gasoline in any ozone nonattainment area that is reclassified as Severe and requires that Federal RFG must instead be sold. The prohibition on the sale of conventional gasoline takes effect 1 year after the effective date of the reclassification (see CAA section 211(k)(10)(D)). For areas that are reclassified as Severe for the 2008 ozone NAAQS, States would not promulgate State fuel rules for implementing Federal RFG because the CAA requirements would be implemented as written. Air agencies are thus not required to submit a State Implementation Plan (SIP) revision addressing Federal RFG requirements. Areas already subject to Federal RFG requirements are listed in 40 CFR 1090.285(a)–(d). Federal RFG is already sold in four counties in the Dallas area because Texas opted those counties into RFG under CAA section 211(k)(6)(A). The reclassification of the Dallas area as Severe for the 2008 ozone NAAQS results in Federal RFG being required in all 10 counties in the nonattainment area for the 2008 ozone NAAQS.[4] The sale of Federal RFG is a new requirement for the Denver area as Federal RFG is not currently required to be sold in any part of the Denver 2008 ozone NAAQS nonattainment area.[5] With respect to Eastern Kern, California law requires the sale of California Phase 3 RFG (CaRFG3) throughout the State, and EPA has exempted gasoline meeting the CaRFG3 regulations from the requirements that would otherwise apply under the Federal RFG regulations.[6] We granted this exemption because we found that gasoline complying with the CaRFG3 regulations provides emissions benefits equivalent to Federal RFG regulations and because California's compliance and enforcement program is sufficiently rigorous to assure that the standards are met.[7] Thus, reclassification of Eastern Kern to Severe does not impact the continued applicability of California's regulations that require the sale of CaRFG3 in the Eastern Kern area. Should California's regulations no longer apply in the future, EPA's RFG regulations would apply in keeping with CAA requirements.

IV. Public Participation

EPA is issuing this final action without prior notice and comment. The rulemaking procedures provided in CAA section 307(d) do not apply when the Agency for good cause finds that notice-and-comment procedures are impracticable, unnecessary, or contrary to the public interest pursuant to section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B). This is a ministerial action that amends 40 CFR 1090.285(b) and (c) to reflect that the Dallas, Denver, and Eastern Kern ozone nonattainment areas have been reclassified as Severe for the 2008 ozone NAAQS and that CAA section 211(k)(10)(D) requires that such reclassified areas become Federal RFG covered areas 1 year after the effective date of their reclassification. For this reason, EPA finds that notice-and-comment procedures under CAA section 307(d)(1) are unnecessary.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose any information collection burden under the PRA, because it does not contain any information collection activities.

[2] *See* 87 FR 60926, October 7, 2022.

[3] *See* 86 FR 30204, June 7, 2021.

[4] Six counties in the Dallas area are subject to a SIP-approved requirement to provide gasoline to retailers and wholesale purchaser consumers with a maximum RVP of 7.8 psi per gallon from June 1 through September 15. The six counties are Ellis, Johnson, Kaufman, Parker, Rockwall and Wise. Beginning with the 2024 summer season (June 1 through September 15 for retailers and wholesale purchaser consumers, and May 1 through September 15 for all other persons) gasoline sold in these six counties in the Dallas area will be required to comply with the more stringent Federal RFG RVP per gallon cap of 7.4 psi. *See* 40 CFR 1090.215(a)(3).

[5] The Denver area is subject to the Federal requirement to sell gasoline with a maximum RVP of 7.8 psi per gallon during the summer season (June 1 through September 15 for retailers and wholesale purchaser consumers, and May 1 through September 15 for all other persons). *See* 40 CFR 1090.215(a)(2). Beginning with the 2024 summer season, gasoline sold in the Denver area will be required to comply with the more stringent Federal RFG RVP per gallon cap of 7.4 psi. *See* 40 CFR 1090.215(a)(3).

[6] *See* 40 CFR 1090.625. See also 85 FR 78412 at 78430, footnote 70 (December 4, 2020).

[7] 70 FR 75914 (December 21, 2005).

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA. The RFA applies only to rules subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to notice-and-comment requirements because the Agency has invoked the APA ''good cause'' exemption under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This final rule does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action amends the reformulated gasoline (RFG) regulations at 40 CFR 1090.285(b) and (c) to reflect the reclassification of several ozone nonattainment areas as Severe for the 2008 ozone NAAQS, which results in the prohibition of the sale of conventional gasoline throughout the entire nonattainment area under CAA section 211(k)(10)(D) and section 211(k)(5) effective 1 year after the effective date of the reclassification.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications, as specified in Executive Order 13175. This final rule affects only those refiners, importers or blenders of gasoline that chose to produce or import gasoline that meets Federal RFG program requirements for sale in the Dallas, Denver, and Kern County areas and gasoline distributers and retail stations in those areas. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. EPA has no reason to believe that this action will disproportionately affect children since the RFG program results in lower emissions of ozone precursors in the Dallas, Denver, and Kern County areas.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rule does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

The EPA believes that the requirement to sell RFG is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples. This requirement in the areas referenced in this action will result in area-wide emission reductions for ozone precursors and provide clean air benefits. Therefore, disproportionately high and adverse human health or environmental effects on minority or low-income populations are not an anticipated result.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice-and-comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in section IV, including the basis for that finding.

VI. Legal Authority and Statutory Provisions

The statutory authority for this action is granted to EPA by sections 211(k) and 301(a) of the Clean Air Act, as amended; 42 U.S.C. 7545(h) and 7601(a).

List of Subjects in 40 CFR Part 1090

Environmental protection, Administrative practice and procedures, Air pollution control, Fuel additives, Gasoline, Motor vehicle and motor vehicle engines, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 1090 as follows:

PART 1090—REGULATION OF FUELS, FUEL ADDITIVES, AND REGULATED BLENDSTOCKS

■ 1. The authority citation for part 1090 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7522–7525, 7541, 7542, 7543, 7545, 7547, 7550, and 7601.

■ 2. Amend § 1090.285:

■ a. In table 2 to paragraph (b) by adding entries for ''Eastern Kern County, ''Dallas'', and ''Denver-Boulder-Greeley-Ft. Collins-Loveland'' to the end of the table and adding footnotes 5 through 7 in numerical order; and

■ b. In table 3 to paragraph (c) by removing the entry ''Dallas-Fort Worth''.

The additions read as follows:

§ 1090.285 RFG covered areas.

* * * * *

(b) * * *

TABLE 2 TO PARAGRAPH (b)—ADDITIONAL RFG COVERED AREAS UNDER 42 U.S.C. 7545(k)(10)(D)

Area designation	State or district	Counties	Independent cities
* *	*	* * *	*
Eastern Kern County	California	Kern County[5].	
Dallas	Texas	Collin, Dallas, Denton, Ellis, Johnson, Kaufman, Parker, Rockwall, Tarrant, Wise.	
Denver-Boulder-Greeley-Ft. Collins-Loveland.	Colorado	Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, Jefferson, Larimer County,[6] Weld County[7].	
* *	*	* * *	*

[5] That portion of the county (with the exception of that portion in Hydrologic Unit Number 18090205 the Indian Wells Valley) east and south of a line described as follows: Beginning at the Kern-Los Angeles County boundary and running north and east along the northwest boundary of the Rancho La Liebre Land Grant to the point of intersection with the range line common to Range 16 West and Range 17 West, San Bernardino Base and Meridian; north along the range line to the point of intersection with the Rancho El Tejon Land Grant boundary; then southeast, northeast, and northwest along the boundary of the Rancho El Tejon Grant to the northwest corner of Section 3, Township 11 North, Range 17 West; then west 1.2 miles; then north to the Rancho El Tejon Land Grant boundary; then northwest along the Rancho El Tejon line to the southeast corner of Section 34, Township 32 South, Range 30 East, Mount Diablo Base and Meridian; then north to the northwest corner of Section 35, Township 31 South, Range 30 East; then northeast along the boundary of the Rancho El Tejon Land Grant to the southwest corner of Section 18, Township 31 South, Range 31 East; then east to the southeast corner of Section 13, Township 31 South, Range 31 East; then north along the range line common to Range 31 East and Range 32 East, Mount Diablo Base and Meridian, to the northwest corner of Section 6, Township 29 South, Range 32 East; then east to the southwest corner of Section 31, Township 28 South, Range 32 East; then north along the range line common to Range 31 East and Range 32 East to the northwest corner of Section 6, Township 28 South, Range 32 East, then west to the southeast corner of Section 36, Township 27 South, Range 31 East, then north along the range line common to Range 31 East and Range 32 East to the Kern-Tulare County boundary.

[6] That portion of the county that lies south of a line described as follows: Beginning at a point on Larimer County's eastern boundary and Weld County's western boundary intersected by latitude 40 degrees, 42 minutes, and 47.1 seconds north, proceed west to a point defined by the intersection of latitude 40 degrees, 42 minutes, 47.1 seconds north and longitude 105 degrees, 29 minutes, and 40.0 seconds west, proceeding south on longitude 105 degrees, 29 minutes, 40.0 seconds west to the intersection with latitude 40 degrees, 33 minutes and 17.4 seconds north, proceeding west on latitude 40 degrees, 33 minutes, 17.4 seconds north until this line intersects Larimer County's western boundary and Grand County's eastern boundary.

[7] That portion of the county that lies south of a line described as follows: Beginning at a point on Weld County's eastern boundary and Logan County's western boundary intersected by latitude 40 degrees, 42 minutes, 47.1 seconds north, proceeding west on latitude 40 degrees, 42 minutes, 47.1 seconds north until this line intersects Weld County's western boundary and Larimer County's eastern boundary.

* * * * *

[FR Doc. 2023–22532 Filed 10–11–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 220919–0193; RTID 0648–XD387]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries; Closure of the General Category October Through November Fishery for 2023

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the General category fishery for large medium and giant (*i.e.,* measuring 73 inches (185 cm) curved fork length or greater) Atlantic bluefin tuna (BFT) for the remainder of the October through November time period. This action applies to Atlantic Tunas General category (commercial) permitted vessels and highly migratory species (HMS) Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT. This action also waives the previously-scheduled restricted-fishing days (RFDs) for the remainder of the October through November time period. With the RFDs waived during the closure, fishermen aboard General category permitted vessels and HMS Charter/Headboat permitted vessels may tag and release BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs. On December 1, 2023, the fishery will reopen automatically.

DATES: Effective 11:30 p.m., local time, October 9, 2023, through November 30, 2023.

FOR FURTHER INFORMATION CONTACT: Lisa Crawford, *lisa.crawford@noaa.gov,* 301–427–8503; or Larry Redd, Jr., *larry.redd@noaa.gov,* 301–427–8503.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

As described in § 635.27(a), the current baseline U.S. BFT quota is 1,316.14 metric tons (mt) (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). The current baseline quota for the General category is 710.7 mt. The General category baseline quota is suballocated to different time periods. Relevant to this action, the baseline subquota for the October through November time period is 92.4 mt. Effective September 28, 2023, NMFS transferred 25 mt from the Reserve category to the General category, resulting in an adjusted October through November time period subquota of 117.4 and 87.2 mt for the Reserve

category (88 FR 67654, September 28, 2023).

Under § 635.28(a)(1), NMFS files a closure action with the Office of the Federal Register for publication when a BFT quota (or subquota) is reached or is projected to be reached. Retaining, possessing, or landing BFT under that quota category is prohibited on or after the effective date and time of a closure notice for that category until the opening of the relevant subsequent quota period or until such date as specified.

Closure of the October Through November 2023 General Category Fishery

To date, reported landings for the General category October through November time period total approximately 60.1 mt. Based on these landings, NMFS has determined that the adjusted October through November time period subquota of 117.4 mt is projected to be reached and exceeded shortly. Therefore, retaining, possessing, or landing large medium or giant (*i.e.,* measuring 73 inches (185 cm) curved fork length or greater) BFT by persons aboard vessels permitted in the Atlantic Tunas General category and HMS Charter/Headboat permitted vessels (while fishing commercially) must cease at 11:30 p.m. local time on October 9, 2023. This action applies to Atlantic Tunas General category (commercial) permitted vessels and HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT and is taken consistent with the regulations at § 635.28(a)(1). The General category will automatically reopen December 1, 2023, for the December 2023 time period with a retention limit of one large medium or giant BFT per vessel per day/trip.

Adjustment of Daily Retention Limit for Selected Dates

On May 25, 2023 (88 FR 33839), NMFS published a final rule implementing RFDs every Tuesday, Friday, and Saturday from July 1 through November 30, 2023. Since the fishery will be closed for the remainder of the October through November time period, NMFS waives the previously-scheduled RFDs for the remainder of that time period.

With the RFDs waived during the closure, consistent with § 635.23(a)(4), fishermen aboard General category permitted vessels and HMS Charter/Headboat permitted vessels may tag and release BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure/.*

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustments, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *https://www.hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling 888–872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

After the fishery reopens on December 1, depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may access *https://www.hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act and regulations at 50 CFR part 635 and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and opportunity to provide comment on this action, as notice and comment would be impracticable and contrary to the public interest for the following reasons. Specifically, the regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Providing for prior notice and an opportunity to comment is impracticable and contrary to the public interest as this fishery is currently underway and, based on landings information, the available time period subquota is projected to be reached shortly. Delaying this action could result in BFT landings exceeding the October through November time period subquota. Taking this action does not raise conservation or management concerns. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S. BFT quota and the inseason adjustment criteria.

For all of the above reasons, the AA also finds that pursuant to 5 U.S.C. 553(d), there is good cause to waive the 30-day delay in effective date.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: October 6, 2023.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–22563 Filed 10–6–23; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 230810–0190; RTID 0648–XD416]

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Gulf of Maine Cod Possession and Trip Limit Adjustment for the Common Pool Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; in-season adjustment.

SUMMARY: This action decreases the possession and trip limits for Gulf of Maine (GOM) cod for Northeast multispecies common pool vessels for the remainder of the 2023 fishing year, through April 30, 2024. The National Marine Fisheries Service projects that, at its current trajectory, the common pool will exceed its 2023 sub-Annual Catch Limit for GOM cod. This decrease in the possession and trip limit for Gulf of Maine cod is intended to prevent the common pool fishery from exceeding its

allocation for this stock prior to the end of the fishing year.

DATES: This action is effective October 12, 2023, through April 30, 2024.

FOR FURTHER INFORMATION CONTACT: Spencer Talmage, Fishery Policy Analyst, (978) 281–9232.

SUPPLEMENTARY INFORMATION: The regulations at § 648.86 (o) provide that NMFS may adjust the possession and trip limits for common pool vessels in order to help prevent the overharvest or underharvest of the common pool quotas. The fishing year 2023 common pool sub-annual catch limit (ACL) for Gulf of Maine GOM cod is 10.6 metric tons (mt). Catch through Trimester 1, which ended on August 31, 2023, was 8.5 mt, or 80.2 percent of the sub-ACL. As a result, as of September 1, 2023, 2.1 mt remained of the common pool sub-ACL of GOM cod. Common pool catch of GOM cod triggered a closure of the Trimester 1 Total Allowable Catch Area for the stock on July 27, 2023 (88 FR 50065), which was effective through August 31, 2023, the end of Trimester 1.

An analysis was conducted to project common pool catch from the start of Trimester 2 on September 1, 2023, through the end of the fishing year on April 30, 2024. Fishing history during this time period from fishing years 2020, 2021, and 2022 was used to estimate common pool catch under a range of different trip limit options, including the 150-pound (lb) (68-kilogram (kg)) per Day-at-Sea (DAS)/300-lb (136.1-kg) per trip limit currently in place. The resulting estimates were compared to the amount of quota remaining in the common pool sub-ACL of GOM cod on September 1, 2023.

Based on this analysis, NMFS projects that, at the current trip limit of 150 lb (68 kg) per DAS/300 lb (136.1 kg) per trip, the common pool will exceed its fishing year 2023 sub-ACL. If this occurs, regulations require that the overage must be deducted from the common pool's fishing year 2024 sub-ACL for GOM cod, which would have a negative economic impact on common pool vessels. Therefore, we are implementing a decrease to the possession and trip limits for GOM cod to help prevent the common pool fishery from exceeding its fishing year 2023 sub-ACL for GOM cod.

Effective October 12, 2023, the GOM cod possession and trip limits are decreased to 50 lb (22.7 kg) per DAS, up to 100 lb (45.4 kg) per trip, as summarized in Table 1 below.

TABLE 1—NEW POSSESSION AND TRIP LIMITS FOR GOM COD

Permit type	Current possession/trip limits	New possession/trip limits
Days-At-Sea (A DAS)	150 lb (68 kg) per DAS, up to 300 lb (136.1 kg) per trip	50 lb (22.7 kg) per DAS, up to 100 lb (45.4 kg) per trip.
Handgear A	150 lb (68 kg) per trip	50 lb (22.7 kg) per trip.
Handgear B	25 lb (11.3 kg) per trip	Unchanged.
Small Vessel Category	150 lb (11.3 kg) per trip, within combined 300 lb (136.1 kg) trip limit for cod, haddock, and yellowtail flounder.	50 lb (22.7 kg) per trip, within combined 300 lb (136.1 kg) trip limit for cod, haddock, and yellowtail flounder.

Since the analysis on which this action was based was conducted, additional catch has been landed. Catch data reported through September 12, 2023, showed that the common pool has now caught 8.7 mt of GOM cod, 82.5 percent of the sub-ACL, leaving 1.9 mt of catch available from that date until the sub-ACL is achieved.

Weekly quota monitoring reports for the common pool fishery are on our website at: *https://www.greateratlantic.fisheries.noaa.gov/ro/fso/reports/h/nemultispecies.html.* We will continue to monitor common pool catch through vessel trip reports, dealer-reported landings, Vessel Monitoring System (VMS) catch reports, and other available information and, if necessary, will make additional adjustments to common pool management measures.

Common pool groundfish vessels that have declared their trip through the VMS or the interactive voice response system, and crossed the VMS demarcation line prior to October 12, 2023, are not subject to the new possession and trip limits for that trip.

Classification

This action is authorized by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA, finds good cause pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3) to waive prior notice and the opportunity for public comment and the 30-day delayed effectiveness period because it would be impracticable and contrary to the public interest.

Regulations at § 648.86 (o) provide that NMFS may adjust the Northeast multispecies possession and trip limits for common pool vessels in order to prevent the overharvest or underharvest of the pertinent common pool quotas. We have projected that the 150-lb (68-kg) per DAS, up to 300-lb (136.1-kg) per trip limits for GOM cod will result in the common pool exceeding its fishing year 2023 sub-ACL for this stock. This action reduces these trip limits to help prevent the common pool exceeding its fishing year 2023 sub-ACL.

The time necessary to provide for prior notice and comment, and a 30-day delay in effectiveness, would prevent these reductions from being implemented in a timely manner. This action could not have taken place sooner because the catch data and analysis used as the basis for this action have only recently become available on September 21, 2023. Delays in implementation increase the probability of an overage of the common pool sub-ACL for this stock, which would undermine the conservation objectives of the Northeast Multispecies Fishery Management Plan and trigger the implementation of accountability measures that would require deduction of the overage from common pool's quota for the next fishing year. These deductions would have negative economic impacts to the common pool fishery. The regulations authorizing this action have been in effect for many years, and the fishing industry expects NMFS to take timely in-season action to prevent overages and their payback requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 6, 2023.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–22589 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 196
Thursday, October 12, 2023

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 993

[Doc. No. AMS–SC–23–0021]

Dried Prunes Produced in California; Suspension of the Marketing Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would suspend the Federal marketing order regulating dried prunes produced in California (Order) effective at the beginning of the 2023–2024 crop year. After operating for 18 years without handling regulations, the Prune Administrative Committee (Committee) recommended the Agricultural Marketing Service (AMS) indefinitely suspend the Order. After reviewing the Committee's recommendation, AMS determined that regulatory suspension with a sunset provision of seven years is appropriate. This suspension period would extend through the end of the 2029–2030 crop year and would provide industry sufficient time to assess whether the Order's reinstatement is beneficial. If no recommendation is made by the Committee to reinstate the Order by the end of the 2029–2030 crop year, AMS would proceed to terminate the Order.

DATES: Comments must be received by November 13, 2023 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments may be sent to the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237. Comments may also be sent to the Docket Clerk electronically by Email: *MarketingOrderComment@usda.gov* or via the internet at: *https://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this proposed rule will be included in the record and will be made available to the public and can be viewed at: *https://www.regulations.gov.* Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Jeremy Sasselli, Marketing Specialist, or Gary Olson, Chief, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, or Email: *Jeremy.Sasselli@usda.gov* or *GaryD.Olson@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This proposed action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement No. 110 and Marketing Order No. 993, both as amended (7 CFR part 993), regulating the handling of dried prunes produced in California. Part 993 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Prune Administrative Committee (Committee) locally administers the Order and is comprised of producers and handlers of dried prunes operating within the area of production, and one public member.

The Agricultural Marketing Service (AMS) is issuing this proposed rule in conformance with Executive Orders 12866, 13563, and 14094. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 reaffirms, supplements, and updates Executive Order 12866 and further directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this proposed rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect, prior to crop year 2023–2024.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the United States Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would suspend the Order's regulatory provisions. The Committee recommended this action at its March 22, 2023, meeting. Section

993.90(a) of the Order provides that the Secretary shall terminate or suspend the operation of any or all of the provisions of the Order, whenever the Secretary finds that such provisions do not tend to effectuate the declared policy of the Act.

The Committee meets regularly to consider recommendations for modification, suspension, or termination of the Order, and such meetings are open to the public where interested persons may express their views at these meetings. AMS reviews Committee recommendations, including information provided by the Committee and from other available sources, and determines whether such recommendations would tend to effectuate the declared policy of the Act.

On May 27, 2005, following a recommendation from the Committee, AMS indefinitely suspended handling and reporting requirements under the Order, extended the temporary suspension of outgoing inspection and volume control regulations, and extended the temporary suspension of the Prune Import Regulation (70 FR 30610). Since 2005, the Committee has continued to perform the administrative duties prescribed under the Order, including the collection of assessments, conducting Committee nominations, and assessing whether to recommend a marketing policy, which may include handling regulations.

On March 22, 2023, the Committee held a public meeting to consider the future of regulation under the Order. The Committee determined that the 2005 suspension of handling and volume regulations did not adversely impact the marketing of California prunes and that there is no value in funding the administrative duties prescribed under the Order when the handling regulations and reserve control provisions are not in effect. The Committee discussed terminating the Order but rejected the idea because its members believe the sector of industry is not yet ready to terminate, given the length of time and expense that would be required to establish a new marketing order should regulation again be deemed necessary in the future. In addition, several Committee members expressed the opinion that future market conditions may warrant regulation, particularly volume control, and urged the Committee not to terminate the Order at this time. After much deliberation, the Committee voted unanimously to indefinitely suspend the Order with the expectation that the Order would either remain indefinitely suspended or AMS would at a future time act to terminate the Order if no recommendation for reinstatement is submitted by industry. In the event of no such recommendation for reinstatement, the Committee would take the necessary steps to ensure an orderly and complete termination of the Order.

The Committee recommended to AMS the Order's suspension for an indefinite period to allow for the reinstatement of regulation to remain an option and to provide industry time to assess the market environment and other external factors affecting California prunes. Under the proposed suspension, handlers would no longer be required to pay assessments. The Committee believes this cost savings would benefit both small and large handlers, and that producers would also be relieved of some costs because such payments are often passed onto them by handlers.

After reviewing the Committee's recommendation and supporting materials, AMS included a sunset provision that if no recommendation is received by July 31, 2030, AMS would then issue a rule proposing termination of the Order. The Committee agreed that a suspension period of seven years is adequate time for the California prune industry to assess future market conditions and reestablishment of the Order, if warranted. This proposed rule would lift the portions of the Order currently under suspension and then suspend the entire Order for seven years, beginning with the 2023–2024 crop year and ending with the 2029–2030 crop year, which ends on July 31, 2030. If industry does not recommend reinstating the Order by the end of the proposed suspension period, AMS will issue a proposal to terminate the Order.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 600 producers of dried prunes in the production area and 27 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $3,500,000, and small agricultural service firms are defined as those whose annual receipts are less than $34,000,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS), the average producer price for California dried prunes for the 2021 crop was $2,000 per ton. NASS further reported 2021 crop year production for California dried prunes was 74,000 tons. The estimated total 2021–22 crop year value of California dried prunes is $148,000,000 (74,000 tons times $2,000 per ton equals $148,000,000). Dividing the estimated total crop value by the estimated number of producers (600) yields an estimated average receipt per producer of $246,667, which is considerably lower than the $3,500,000 SBA small agricultural producer threshold.

In addition, according to USDA Market News data, the reported average terminal market price for 2022 for California dried prunes was $39.04 per carton. Dividing the average carton price by the 28-pound carton size yields an estimated price per pound of $1.39. ($39.04 average price divided by 28 pounds). Multiplying $1.39 per pound by 2,000 pounds yields $2,780 per ton, which, when multiplied by total estimated 2021 production of 74,000 tons, yields estimated total handler receipts of $205,720,000. Dividing this figure by the 27 regulated handlers yields estimated average annual handler receipts of $7,619,259, well below the $34 million SBA threshold for small agricultural service firms. Therefore, using the above data, the majority of producers and handlers of California dried prunes may be classified as small entities.

This proposed rule would suspend all provisions of the Order starting with the 2023–2023 crop year, through the 2029–2030 crop year. On March 22, 2023, the Committee voted unanimously to indefinitely suspend the Order after determining that the 2005 suspension of handling regulations, volume control and reporting requirements did not negatively impact the marketing of California prunes and that the costs to continue the Order outweighs its benefit to industry. The Committee believes that such suspension would provide a cost savings to large and small handlers and producers.

After reviewing the Committee's recommendation and other supporting material, AMS included a sunset provision that if no recommendation for reinstatement is received during the proposed suspension period, AMS

would then proceed to terminate the Order.

This action would suspend the Federal marketing order regulating dried prunes produced in California though July 31, 2030. Authority for this action is provided in section 993.90(a) of the Order.

Committee meetings are widely publicized throughout the production area. The California dried prune industry and all interested persons are invited to attend the meetings and participate in Committee deliberations on all issues. Similarly, the March 22, 2023, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable Crops. OMB's three-year approval of the forms in the Vegetable Crops package expire March 31, 2024. AMS' submission of the renewal package prior to its expiration will retain prune forms but will drawdown the information collection burden to zero during the time when respondents will not be completing and submitting the forms during the seven-year suspension. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large California dried prune handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at*: https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this rule.

List of Subjects in 7 CFR Part 993

Marketing agreements, Plum, Prunes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service proposes to amend 7 CFR part 993 as follows:

PART 993—DRIED PRUNES PRODUCED IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 993 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In Part 993, lift the suspension of May 27, 2005, on §§ 993.21d, 993.41, 993.48, 993.49, 993.50, 993.51, 993.52, 993.53, 993.54, 993.55, 993.56, 993.57, 993.58, 993.59, 993.62, 993.65, 993.72, 993.73, 993.74, 993.75, 993.97, 993.104, 993.105, 993.106, 993.107, 993.108, 993.149, 993.150, 993.156, 993.157, 993.158, 993.159, 993.162, 993.165, 993.172, 993.173, 993.174, 993.400, 993.409, 993.501, 993.503, 993.504, 993.505, 993.506, 993.515, 993.516, 993.517, 993.518, 993.601, and 993.602.

PART 993—[STAYED]

■ 3. Stay 7 CFR part 993 until July 31, 2030.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–22333 Filed 10–11–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–1189]

Propionyl Chloride

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration finds that propionyl chloride is used in the illicit manufacture of the controlled substance fentanyl, as well as fentanyl analogues, and fentanyl-related substances and is important to the manufacture of these substances because it is often used in synthetic pathways to illicitly manufacture fentanyl, fentanyl analogues, and fentanyl-related substances. Prior to proposing to list propionyl chloride as a list I chemical, DEA is soliciting information on the current uses of propionyl chloride (other than for the synthesis of fentanyl) in order to properly determine the effect such a proposed action would have on legitimate industry.

DATES: Comments must be submitted electronically or postmarked on or before November 13, 2023. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–1189'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments.Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is

given, be made available by DEA for public inspection online at *https://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *https://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this advanced proposed rule is available at *https://www.regulations.gov* for easy reference.

Legal Authority

The Controlled Substances Act (CSA) gives the Attorney General the authority to specify, by regulation, chemicals as list I chemicals.[1] A ''list I chemical'' is a chemical that is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of the controlled substances.[2] The current list of all listed chemicals is published at 21 CFR 1310.02. Pursuant to 28 CFR 0.100(b), the Attorney General has delegated his authority to designate list I chemicals to the Administrator of DEA (Administrator). DEA regulations set forth the process by which DEA may add a chemical as a listed chemical. As set forth in 21 CFR 1310.02(c), the agency may do so by publishing a final rule in the **Federal Register** following a published notice of proposed rulemaking with at least 30 days for public comments.

Background

The clandestine manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances remains extremely concerning as the distribution of illicit fentanyl, fentanyl analogues, and fentanyl-related substances continues to drive drug-related overdose deaths in the United States. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950s. Fentanyl was introduced into medical practice and is approved for medical practitioners in the United States to prescribe lawfully for anesthesia and analgesia. Yet, due to its pharmacological effects, fentanyl can be used as a substitute for heroin, oxycodone, and other opioids in opioid dependent individuals. Therefore, despite its accepted medical use in treatment in the United States, DEA controls fentanyl as a schedule II controlled substance due to its high potential for abuse and dependence.[3] Moreover, there are a substantial number of fentanyl analogues and fentanyl-related substances that are being distributed on the illicit drug market despite DEA's actions adding them as schedule I controlled substances. Illicit manufacturers attempt to utilize unregulated precursor chemicals to evade law enforcement detection and precursor chemical controls in order to manufacture fentanyl, fentanyl analogues, and fentanyl-related substances. This strategy allows for the synthesis of a variety of fentanyl analogues and fentanyl-related substances by making slight modifications to the core fentanyl structure while maintaining the same synthetic methodology used to synthesize fentanyl, fentanyl analogues, and fentanyl-related substances.

The unlawful trafficking of fentanyl, fentanyl analogues, and fentanyl-related substances in the United States continues to pose an imminent hazard to the public safety. Since 2012, fentanyl has shown a dramatic increase in the illicit drug supply as a single substance, in mixtures with other illicit drugs (*i.e.,* heroin, cocaine, and methamphetamine), and in forms that mimic pharmaceutical preparations including prescription opiates and benzodiazepines.[4]

DEA has noted a significant increase in overdoses and overdose fatalities from fentanyl, fentanyl analogues, and fentanyl-related substances in the United States in recent years. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids (which includes fentanyl), are predominantly responsible for drug overdose deaths in recent years. According to CDC WONDER,[5] drug-induced overdose deaths involving synthetic opioids (excluding methadone) in the United States increased from 36,359 in 2019 to 56,516 in 2020 to 70,601 in 2021. Based on provisional data, the predicted number of drug overdose deaths involving synthetic opioids (excluding methadone) in the United States for the 12 months ending October 2022 is 73,570 individuals, or approximately 68 percent of all drug-induced overdose deaths for that time period.[6] The increase in overdose fatalities involving synthetic opioids coincides with a dramatic increase in law enforcement encounters of fentanyl, fentanyl analogues, and fentanyl-related substances. According to the National Forensic Laboratory Information System (NFLIS-Drug),[7] reports from forensic laboratories of drug items containing fentanyl, fentanyl analogues, and fentanyl-related substances increased dramatically since 2014, as shown in Table 1.

[1] 21 U.S.C. 802(34).

[2] Id.

[3] 21 U.S.C. 812(c) Schedule II(b)(6) and 21 CFR 1308.12(c).

[4] United Nations Office on Drugs and Crime, Global SMART Update Volume 17, March 2017. *https://www.unodc.org/documents/scientific/Global_SMART_Update_17_web.pdf.*

[5] Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018–2021, and from provisional data for years 2022–2023, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at *https://wonder.cdc.gov/mcd-icd10-provisional.html* on March 16, 2023.

[6] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023. Accessed at *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm* on March 15, 2023.

[7] The National Forensic Laboratory Information System (NFLIS-Drug) is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, State and local forensic laboratories in the United States. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332 (December 12, 2011). NFLIS-Drug data was queried on July 31, 2023.

TABLE 1—ANNUAL REPORTS OF FENTANYL AND SELECT FENTANYL ANALOGUES AND FENTANYL-RELATED SUBSTANCES IDENTIFIED IN DRUG ENCOUNTERS

Year	2014	2015	2016	2017	2018	2019	2020	2021	2022
Annual Fentanyl Reports	5,554	15,461	37,154	61,640	89,966	108,131	125,999	164,890	165,067
Annual Reports of select fentanyl analogues and fentanyl-related substances	78	2,317	7,624	21,980	16,177	20,917	7,800	26,368	29,404

Role of Propionyl Chloride in the Synthesis of Fentanyl

Fentanyl, fentanyl analogues, and fentanyl-related substances are not naturally occurring substances. As such, the manufacture of these substances requires them to be produced through synthetic organic chemistry. Synthetic organic chemistry is the process in which a new organic molecule is created through a series of chemical reactions, which involve precursor chemicals. Through chemical reactions, the chemical structures of precursor chemicals are modified in a desired fashion. These chemical reaction sequences, also known as synthetic pathways, are designed to create a desired substance. Several synthetic pathways to fentanyl, fentanyl analogues, and fentanyl-related substances have been identified in clandestine laboratory settings; these include the original ''Janssen method,'' the ''Siegfried method,'' and the ''Gupta method.'' In response to the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances using these methods, DEA controlled *N*-phenethyl-4-piperidone (NPP),[8] *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl), *N*-phenylpiperidin-4-amine (4-anilinopiperidine; including its amides and carbamates),[9] and 4-piperidone (piperidin-4-one)[10] as list I chemicals and 4-anilino-*N*-phenethylpiperidine (ANPP)[11] and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl)[12] as schedule II immediate precursors under the CSA.

In 2017, the United Nations Commission on Narcotic Drugs placed NPP and ANPP in Table I of the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (1988 Convention) in response to the international reintroduction of fentanyl on the illicit drug market. As such, member states of the United Nations are required to regulate these precursor chemicals at the national level. Importantly, the People's Republic of China regulated NPP and ANPP on February 1, 2018.[13] Subsequently in 2022, the United Nations Commission on Narcotic Drugs placed norfentanyl, 1-boc-4-anilinopiperidine, and 4-anilinopiperidine in Table I of the 1988 Convention in response to the international reintroduction of fentanyl on the illicit drug market and the introduction of new precursors used in the illicit manufacture of fentanyl.

Propionyl Chloride

The original published synthetic pathway to fentanyl, known as the Janssen method, involves the list I chemical benzylfentanyl and schedule II immediate precursor norfentanyl. In this synthetic pathway, benzylfentanyl, a list I chemical under the CSA,[14] is synthesized by reacting propionyl chloride with 4-anilino-1-benzylpiperidine, which is then converted to norfentanyl, the schedule II immediate precursor in this synthetic pathway.[15] Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Propionyl chloride also serves as a precursor chemical in the Siegfried method. In this synthetic pathway, propionyl chloride is reacted with ANPP,[16] the schedule II immediate precursor in the Siegfried method, to complete the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

In addition to the Janssen and Siegfried methods, clandestine manufacturers are using other methods to synthesize fentanyl, one of which is known as the Gupta method. In this synthetic pathway, 4-piperidone, a list I chemical under the CSA, is used to synthesize 4-anilinopiperidine, another list I chemical under the CSA,[17] which serves as an alternative precursor chemical to NPP, a list I chemical, in the synthesis of ANPP, a schedule II immediate precursor albeit through a different synthetic process. The resulting ANPP is reacted with propionyl chloride to manufacture the schedule II controlled substance, fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Propionyl chloride is attractive to illicit manufacturers because of the lack of regulations on this chemical, it is readily available from chemical suppliers, and it can be easily used in many known synthetic pathways used in the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances.

Solicitation for Information

With this advanced notice of proposed rulemaking, DEA is soliciting information on any possible legitimate uses of propionyl chloride unrelated to fentanyl production (including industrial uses) in order to assess the potential economic impact of controlling propionyl chloride as a list I chemical. DEA seeks to document any unpublicized use(s) and other proprietary use(s) of propionyl chloride that are not in the public domain. Therefore, DEA is soliciting comment on the uses of propionyl chloride in the legitimate marketplace.

DEA is soliciting input from all potentially affected parties regarding: (1) The types of legitimate industries using propionyl chloride; (2) the legitimate uses, legitimate needs and quantity produced, used, and distributed of propionyl chloride; (3) the size of the domestic market for propionyl chloride; (4) the number of manufacturers of propionyl chloride; (5) the number of distributors of propionyl chloride; (6) the level of import and export of propionyl chloride; (7) the potential burden that controlling propionyl chloride as a list I chemical may have on any legitimate industry and trade; (8)

[8] 72 FR 20039 (April 23, 2007).

[9] 85 FR 20822 (May 15, 2020).

[10] 88 FR 21902 (May 12, 2023).

[11] 75 FR 37295 (August 30, 2010).

[12] 85 FR 21320 (May 18, 2020).

[13] *https://www.dea.gov/press-releases/2018/01/05/china-announces-scheduling-controls-two-fentanyl-precursor-chemicals.* Accessed March 9, 2022.

[14] 85 FR 20822 (May 15, 2020).

[15] 85 FR 21320 (May 18, 2020).

[16] 75 FR 37295 (August 30, 2010).

[17] 85 FR 20822 (May 15, 2020).

the potential number of individuals/firms that may be adversely affected by such regulatory controls (particularly with respect to the impact on small businesses); and (9) any other information on the manner of manufacturing, distribution, consumption, storage, disposal, and uses of propionyl chloride by industry and others. DEA invites all interested parties to provide any information on any legitimate uses of propionyl chloride in industry, commerce, academia, research and development, or other applications. DEA seeks both quantitative and qualitative data.

Such information may be submitted electronically to the address listed above and is requested by November 13, 2023. This information will be used to properly determine the effect that proposed regulations to make propionyl chloride a list 1 chemical under the CSA would have on industry.

Handling of Confidential or Proprietary Information

Confidential or proprietary information may be submitted as part of a comment regarding this advanced notice of proposed rulemaking. Please see the ''POSTING OF PUBLIC COMMENTS'' section above for a discussion of the identification and redaction of confidential business information and personally identifying information.

Regulatory Analyses

This ANPRM was developed in accordance with the principles of Executive Order (E.O.) 12866, ''Regulatory Planning and Review'' and E.O. 13563, ''Improving Regulation and Regulatory Review.'' Since this action is an ANPRM, the requirement of E.O. 12866 to assess the costs and benefits of this action does not apply.

Furthermore, the requirements of the Regulatory Flexibility Act do not apply to this action because, at this stage, it is an ANPRM and not a ''rule'' as defined in 5 U.S.C. 601. Following review of the comments received in response to this ANPRM, if DEA proceeds with a notice of proposed rulemaking regarding this matter, DEA will conduct all relevant analyses as required by statute or E.O.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 5, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–22570 Filed 10–11–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0795]

RIN 1–AA00

Safety Zone; Potomac River, Between Charles County, MD and King George County, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters of the Potomac River. This action is necessary to provide for the safety of life on these navigable waters at the old Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge, during demolition operations from November 8, 2023 through January 30, 2024. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port, Sector Maryland-National Capital Region or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before October 27, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0795 using the Federal Decision-Making Portal at *https://www.regulations.gov*. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LCDR Kate Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2519, email *MDNCRWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

Skanska-Corman-McLean, Joint Venture notified the Coast Guard that it will be conducting demolition of the old Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge, which will occur from 12:01 a.m. on November 8, 2023, to 11:59 p.m. on January 30, 2024. The bridge is located on the Potomac River, at mile 43.3, between Charles County, MD and King George County, VA. The segment of the old bridge over waters that include the bridge piers sections between Piers 14 and the east riverbank of the Potomac River requires the use of explosives, and debris removal and hydrographic surveying equipment. Marine equipment, including barges, positioned in the Potomac River will be used to support the bridge demolition and debris removal operation. This operation also requires the use of a temporary commercial mooring buoy in the Potomac River south of the old bridge where the explosives barge will be kept. Hazards from the demolition and debris removal work include accidental discharge of explosives, dangerous projectiles, hanging ropes or cables, and falling objects or debris. The Captain of the Port, Maryland-National Capital Region (COTP) has determined that potential hazards associated with the demolition and removal of the old Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge would be a safety concern for anyone within or near project area.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within or near the Federal navigation channel at the old Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone from 12:01 a.m. on November 8, 2023, to 11:59 p.m. on

January 30, 2024. The safety zone would cover the following areas:

Area 1. All navigable waters of the Potomac River, encompassed by a line connecting the following points beginning at 38°21′49.10″ N, 076°59′32.46″ W, thence south to 38°21′40.04″ N, 076°59′30.62″ W, thence east to 38°21′43.52″ N, 076°59′15.22″ W, thence south along the shoreline to 38°21′52.49″ N, 076°58′59.70″ W, and west back to the beginning point, located between Charles County, MD and King George County, VA.

Area 2. All navigable waters of the Potomac River, within 1,500 feet of the explosives barge located in approximate position 38°21′21.47″ N, 076°59′45.40″ W.

The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled demolition and debris removal. Except for marine equipment and vessels operated by Skanska-Corman-McLean, Joint Venture, or its subcontractors, no vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The term designated representative also includes an employee or contractor of Skanska-Corman-McLean, Joint Venture for the sole purposes of designating and establishing safe transit corridors, to permit passage into or through the safety zone, or to notify vessels and individuals that they have entered the safety zone and are required to leave.

The COTP will notify the public that the safety zone will be enforced by all appropriate means to the affected segments of the public, as practicable, in accordance with 33 CFR 165.7(a). Such means of notification will also include, but are not limited to, Broadcast Notice to Mariners. Vessels or persons violating this rule are subject to the penalties set forth in 46 U.S.C. 70036 and 46 U.S.C. 70052. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location and time of year of the safety zone. The temporary safety zone comprises two separate geographic areas which total a maximum of approximately 900 yards in width and 350 yards in length. This safety zone would impact a small, designated area of the Potomac River for a maximum 84 total days, but we anticipate that there would be no vessels that are unable to conduct business because of the safety zone. Excursion vessels and commercial fishing vessels are not impacted by this rulemaking. Excursion vessels do not operate in this area, and commercial fishing vessels are not impacted because of their draft. Some towing vessels may be impacted, but bridge project personnel have been conducting outreach throughout the project to coordinate with those vessels. This safety zone would be established outside the normal recreational boating season for this area, which occurs during the summer. Moreover, the Coast Guard would issue Local Notices to Mariners and a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone on days it is being enforced.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rulemaking would economically affect it. Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the

aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting 84 total days that would prohibit entry within a portion of the Potomac River. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2023–0795 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a ''Subscribe'' option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T05–0145 to read as follows:

§ 165.T05–0145 Safety Zone; Potomac River, Between Charles County, MD and King George County, VA.

(a) *Location.* The following areas are a safety zone: These coordinates are based on datum NAD 83.

(1) *Area 1.* All navigable waters of the Potomac River, encompassed by a line connecting the following points beginning at 38°21′49.10″ N, 076°59′32.46″ W, thence south to 38°21′40.04″ N, 076°59′30.62″ W, thence east to 38°21′43.52″ N, 076°59′15.22″ W, thence south along the shoreline to 38°21′52.49″ N, 076°58′59.70″ W, and west back to the beginning point, located between Charles County, MD and King George County, VA.

(2) *Area 2.* All navigable waters of the Potomac River within 1,500 feet of the explosives barge located in approximate position 38°21′21.47″ N, 076°59′45.40″ W.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region.

Designated representative means any Coast Guard commissioned, warrant, or petty officer, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Maryland-National Capital Region (COTP) in the enforcement of the safety zone. The term also includes an employee or contractor of Skanska-Corman-McLean, Joint Venture for the sole purposes of designating and establishing safe transit corridors, to permit passage into or through the safety zone, or to notify vessels and individuals that they have entered the safety zone and are required to leave.

Marine equipment means any vessel, barge or other equipment operated by Skanska-Corman-McLean, Joint Venture, or its subcontractors.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, except for marine equipment, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP, Skanska-Corman-McLean, Joint Venture, or the COTP's designated representative. If a vessel or person is notified by the COTP, Skanska-Corman-McLean, Joint Venture, or the COTP's designated representative that they have entered the safety zone without permission, they are required to immediately leave in a safe manner following the directions given.

(2) Mariners wishing to transit any of these safety zone areas must first contact the Skanska-Corman-McLean, Joint

Venture designated representative, the on-site project manager by telephone number 785–953–1465 or on Marine Band Radio VHF–FM channels 13 and 16 from the pusher tug Miss Stacy to request permission. If permission is granted, mariners must proceed at their own risk and strictly observe any and all instructions provided by the COTP, Skanska-Corman-McLean, Joint Venture, or designated representative to the mariner regarding the conditions of entry to and exit from any area of the safety zone. The COTP or the COTP's representative can be contacted by telephone number 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz).

(3) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue marine information broadcasts on VHF–FM marine band radio announcing specific enforcement dates and times.

(d) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section will be subject to enforcement from 12:01 a.m. on November 08, 2023, to 11:59 p.m. on January 30, 2023.

Dated: October 05, 2023.

David E. O'Connell,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2023–22545 Filed 10–11–23; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 2 and 51

[EPA–HQ–OAR–2004–0489; FRL–8604–04–OAR]

Revisions to the Air Emissions Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for the proposed revisions to the Air Emissions Reporting Requirements (AERR), published in the **Federal Register** on August 9, 2023. The current comment period for the proposed rule is set to end on October 18, 2023. EPA has received numerous requests to extend the comment period given the complexity and length of the proposed rulemaking. The EPA is extending the comment period for the proposed action to November 17, 2023. The EPA is also extending the comment period for the associated Information Collection Request (ICR), number 2170.09, for the proposed AERR to November 17, 2023.

DATES: The comment period for the proposed rule and ICR published on August 9, 2023, at 88 FR 54118 is extended. Comments must be received on or before November 17, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2004–0489, by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov*. Fax: (202) 566–9744.
- *Mail:* Air Emissions Reporting Requirements Rule, Docket No. EPA–HQ–OAR–2004–0489, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Please include two copies.
- *Hand Delivery:* Docket No. EPA–HQ–OAR–2004–0489, EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Marc Houyoux, Office of Air Quality Planning and Standards, Air Quality Assessment Division, Emission Inventory and Analysis Group (C339–02), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–3649; email: *NEI_Help@epa.gov* (and include ''AERR'' on the subject line).

SUPPLEMENTARY INFORMATION: On Wednesday, August 9, 2023, the EPA published proposed revisions to the Air Emissions Reporting Requirements along with an associated ICR in the **Federal Register**. The comment period for the proposed AERR was for 70 days, ending on October 18, 2023. On September 14, 2023, the EPA reopened the comment period for the ICR (88 FR 63046). The EPA received numerous comments requesting that the Agency extend the comment period for the proposed AERR. To ensure the public has sufficient time to review the proposed AERR and the associated ICR, the EPA is extending the comment periods for both by 30 days, ending on November 17, 2023.

Dated: October 5, 2023.

Richard A. Wayland,

Director, Air Quality Assessment Division, Office of Air Quality and Planning Standards.

[FR Doc. 2023–22530 Filed 10–11–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0494; FRL–11442–01–R9]

Air Plan Approval; California; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the South Coast Air Quality Management District (SCAQMD or ''the District'') portion of the California State Implementation Plan (SIP) as SIP strengthening. This revision concerns emissions of oxides of nitrogen (NO_X) and particulate matter (PM) from indirect sources associated with warehouses. The EPA is proposing to approve SCAQMD Rule 2305, ''Warehouse Indirect Source Rule—Warehouse Actions and Investments to Reduce Emissions (WAIRE) Program,'' to regulate these emission sources under the Clean Air Act (CAA or the Act). The EPA is taking comments on this proposal and plans to follow with a final action.

DATES: Comments must be received on or before November 13, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2023–0494 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not

consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: La Kenya Evans-Hopper, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3245 or by email at *evanshopper.lakenya@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal with the dates that it was adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULE

Local agency	Rule #	Rule title	Amended	Submitted
SCAQMD	2305	Warehouse Indirect Source Rule—Warehouse Actions and Investments to Reduce Emissions (WAIRE) Program.	05/07/2021	08/13/2021

On February 13, 2022, the submittal for SCAQMD Rule 2305 was deemed complete by operation of law with respect to the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

B. Are there other versions of this rule?

SCAQMD Rule 2305 is a new rule. There are no previously approved versions of the rule in the applicable SIP.

C. What is the purpose of the rule?

Emissions of NO_X contribute to the production of ground-level ozone, smog and PM, which harm human health and the environment. Emissions of PM, including PM equal to or less than 2.5 microns in diameter ($PM_{2.5}$) and PM equal to or less than 10 microns in diameter (PM_{10}), contribute to effects that are harmful to human health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires States to submit regulations that control NO_X and PM emissions for purposes of attainment and maintenance of the National Ambient Air Quality Standards (NAAQS) and to meet other CAA requirements.

The purpose of SCAQMD Rule 2305 is to reduce local and area-wide emissions of NO_X and PM, by facilitating emission reductions associated with warehouses and the mobile sources attracted to warehouses in order to assist in meeting State and Federal air quality standards for ozone and $PM_{2.5}$. Mobile sources of emissions associated with warehouses include the trucks that deliver goods to and from the facilities, yard trucks, transport refrigeration units (TRUs) located on trucks and trailers, and passenger vehicle trips associated with employees and visitors.[1] Most of these vehicles are diesel powered, except for passenger vehicles which are typically gasoline powered. Heavy-duty trucks contribute roughly 90% of the overall mobile source inventory of NO_X emissions from warehouse operations, followed in order of importance from an emissions standpoint by TRUs, passenger vehicles, and then yard trucks.[2] Additional emissions sources can include onsite stationary equipment (*e.g.,* diesel backup generators or manufacturing equipment).[3] The rule applies within the jurisdiction of the SCAQMD, which includes all of Orange County, the non-desert portions of Los Angeles and San Bernardino counties, and all of Riverside County (except for the Palo Verde Valley in far eastern Riverside County).

Also, through adoption of the 2016 South Coast Air Quality Management Plan (AQMP), the SCAQMD committed to assess and identify potential actions to further reduce emissions associated with emission sources operating in and out of warehouse distribution centers,[4] and the SCAQMD adopted Rule 2305 to fulfill that commitment. The purpose of the 2016 South Coast AQMP is to establish a path toward the goal of attainment for ozone and $PM_{2.5}$ NAAQS in the nonattainment areas subject to SCAQMD jurisdiction.

The EPA has taken several actions on the 2016 South Coast AQMP. With certain exceptions not relevant here, the EPA approved portions of the 2016 South Coast AQMP addressing the Serious Area requirements for the 2006 24-hour $PM_{2.5}$ NAAQS in the South Coast Air Basin (''South Coast''); the portions of the 2016 South Coast AQMP updating the control strategies and attainment demonstrations for the 1-hour and 1997 8-hour ozone NAAQS, and addressing the 2008 8-hour ozone NAAQS in the South Coast; the portions of the 2016 South Coast AQMP addressing the Moderate Area requirements for the 2012 annual $PM_{2.5}$ NAAQS in the South Coast; and the portions of the 2016 South Coast AQMP addressing the Severe Area requirements for the 2008 8-hour ozone NAAQS in Coachella Valley.[5] In so doing, the EPA approved the SCAQMD's Stationary and Mobile

[1] SCAQMD, Final Staff Report, ''Proposed Rule 2305—Warehouse Indirect Source Rule—Warehouse Actions and Investments to Reduce Emissions (WAIRE) Program and Proposed Rule 316—Fees for Rule 2305'', May 2021, ''SCAQMD Final Staff Report'', 12.

[2] SCAQMD Final Staff Report, 13.

[3] Id.

[4] SCAQMD, Final 2016 Air Quality Management Plan, March 2017, pages 4–25, 4–28, and 4–29. The 2016 South Coast AQMP designates the warehouse measure as MOB–03 (''Emission Reductions at Warehouse Distribution Centers'').

[5] 84 FR 3305 (February 12, 2019), corrected at 84 FR 19680 (May 3, 2019) (2006 $PM_{2.5}$ NAAQS); 84 FR 52005 (October 1, 2019) (1-hour, 1997 and 2008 Ozone NAAQS in South Coast); 85 FR 71269 (November 9, 2020) (2012 $PM_{2.5}$ NAAQS); and 85 FR 57714 (September 16, 2020) (2008 Ozone NAAQS in Coachella Valley).

Source Control Measures, including the facility-based mobile source measures such as the Emission Reductions at Warehouse Distributions Center measure. The 2016 South Coast AQMP includes enforceable commitments by the SCAQMD to achieve certain aggregate emissions reductions by certain years through adoption and implementation of the SCAQMD's Stationary and Mobile Source Control Measures.

D. What requirements does the rule establish?

Rule 2305 applies to owners and operators of warehouses located in the SCAQMD with greater than 100,000 square feet of indoor floor space in a single building and who operate at least 50,000 square feet of the warehouse for warehousing activities. Warehouse operators are required either to earn points, as discussed below, from emission reducing activities, or to pay a mitigation fee. Warehouse facility owners or warehouse land owners may opt in to earn Warehouse Actions and Investments to Reduce Emissions Points (''WAIRE Points'') and transfer these points to a warehouse operator at the same site. Both warehouse facility owners and operators must comply with certain recordkeeping and reporting requirements under the rule. Warehouse facility owners were required to submit initial Warehouse Operations Notifications to the SCAQMD by September 1, 2021, and then again within certain prescribed periods thereafter if certain conditions occur. Warehouse operators are also required to submit their Initial Site Information Reports (ISIR) and Annual WAIRE Reports to the SCAQMD. All of the notifications and reports are to be submitted through the WAIRE Program Online Portal (WAIRE POP). In addition, records which document the accuracy and validity of all information submitted to the SCAQMD as required by the rule must be kept by the warehouse owner, or operator as applicable, for a minimum of seven years from the reporting deadline. Records must be made available upon request to the SCAQMD during normal business hours.

The principal substantive requirement in the rule is the requirement that each warehouse operator meet an annual compliance obligation by earning WAIRE Points. The annual compliance obligation, referred to as the WAIRE Points Compliance Obligation (WPCO), for each warehouse operator is calculated based on Weighted Annual Truck Trips (WATTs) multiplied by a stringency factor (0.0025 points per WATT) and an annual variable (which accounts for the phased implementation of the rule).[6] WATT reflects all trips in a given year by trucks with gross vehicle weight ratings (GVWR) greater than 8,500 pounds but multiplies trips by trucks with GVWRs greater than 33,000 pounds (''Class 8'' trucks) by 2.5.[7] The WATTs parameter serves as a proxy for overall warehouse activity and emissions.[8] A warehouse owner may earn WAIRE Points and may transfer them to any warehouse operator at the site where the WAIRE Points were earned within a three-year period.

The requirement to earn WAIRE points to meet a WPCO does not apply to warehouse operators who use less than 50,000 square feet for warehousing activities of a warehouse that is greater than or equal to 100,000 square feet.[9] This exemption does not apply if the same parent company owns or controls multiple operators in the same building who collectively use more than 50,000 square feet of space for warehousing activity.[10] A warehouse operator with a WPCO that is less than 10 in any compliance period also is exempt from earning WAIRE Points for that compliance period. In both cases, certain recordkeeping and reporting requirements (as stated above) under the rule continue to apply.

In situations where investments or actions that were completed by a warehouse owner or operator perform significantly lower than anticipated due to unforeseen circumstances beyond the control of the warehouse owners or operators resulting in lower than anticipated earned WAIRE Points, the warehouse owner or operator may apply to the Executive Officer[11] for a partial or complete exemption.[12] This application must specify what portion of the WPCO that the malfunctioning equipment would have satisfied, and all relevant details on why the anticipated action was unable to earn the expected WAIRE Points. The Executive Officer will use the following criteria to grant a partial or complete exemption: (a) there is a manufacturing defect or an installation defect when using manufacturer-approved methods, and (b) the warehouse operator can demonstrate that despite good faith efforts for repairs on the vehicle or equipment, through either the warranty or other manufacturer and/or installer-approved methods, the repairs were not completed in a timely manner.

Warehouse owners (who opt in) and operators are required to earn WAIRE Points either: through the completion of specified actions from the list of actions in the WAIRE Menu,[13] completion of actions in an approved custom plan, through payment of a mitigation fee, or through a combination of these three options.[14] The WAIRE Points provision within Rule 2305 includes a WAIRE Menu with a list of specific actions that a warehouse owner or operator may take to earn points to meet the annual WPCO.[15] The menu includes nine different types of actions or investments that qualify for points: (i) acquire Zero Emission (ZE)/Near-Zero Emission (NZE) Trucks, (ii) number of ZE/NZE Truck Visits,[16] (iii) acquire ZE Yard Truck, (iv) use ZE Yard Truck, (v) install onsite ZE charging or fueling infrastructure, (vi) use onsite ZE charging or fueling infrastructure, (vii) install and energize onsite solar panels, (viii) use onsite solar panels, and (ix)

[6] SCAQMD Rule 2305(d)(1)(A) and Tables 1 and 2.

[7] SCAQMD Rule 2305(d)(1)(B).

[8] SCAQMD Final Staff Report, 27, 35. As explained in footnote 44 of the SCAQMD Final Staff Report, the SCAQMD adopted WATTs as the parameter for determining the WPCO for warehouses rather than emissions or vehicle miles travelled (VMT). SCAQMD decided against a parameter like emissions or VMT to reduce the administrative burden on warehouse operators and the SCAQMD compliance staff. Also, the SCAQMD notes that motor carriers had expressed concern that they do not want to reveal where or how far they travel to warehouse operators or SCAQMD in order to keep their clients private.

[9] In Rule 2305(c)(33), the term ''warehousing activities'' is defined as meaning operations at a warehouse related to the storage and distribution of goods, including but not limited to the storage, labelling, sorting, consolidation and deconsolidation of products into different size packages. Supporting office administration, maintenance, manufacturing areas, or retail sales areas open to the general public, within the same warehouse building, that are physically separate from the warehouse area, are not considered warehousing activities for the purpose of the rule.

[10] The exemptions are set forth in SCAQMD Rule 2305(g).

[11] Executive Officer refers to the Executive Officer or designee of the SCAQMD. The Executive Officer is the Air Pollution Control Officer for the SCAQMD.

[12] For example, if a warehouse operator purchases a zero-emission truck and anticipates using this same truck to earn WAIRE Points, but a malfunction in the powertrain due to an equipment manufacturer defect (*e.g.,* malfunctioning electric motor, fuel cell stack, etc.) results in an inability to use the equipment, then the operator may apply for relief for the WAIRE Points that would have be earned. The exemption would be granted if the vehicle or equipment is shown to be due to a manufacturer defect or an installation defect. SCAQMD Final Staff Report, 37.

[13] SCAQMD Rule 2305, Table 3.

[14] SCAQMD Rule 2305(d)(1) and (2).

[15] SCAQMD Rule 2305, Table 3.

[16] NZE and ZE truck visits can come from the warehouse operator's own fleet or by any other third-party fleet (whether contracted by the warehouse operator or not). See SCAQMD Final Staff Report, at 99. The term ''truck visits'' refers to the round-trip a truck takes to and from a warehouse. For example, 520 ''truck visits'' is the same as 1,040 one-way ''truck trips'' as explained in the SCAQMD Final Staff Report, 30.

install MERV 16 or greater filters or filter systems in residences, schools, daycares, hospitals, or community centers.

Rule 2305 specifies the number of points for the different types of actions or investments, ranging from 1 point (per 165,000 kilowatt-hours) from the use of onsite solar panels to 1,680 points for installation of a 700-kilogram-per-day hydrogen (H_2) fueling station. SCAQMD assigned WAIRE Points to the different types of actions or investments based on three key parameters: cost, regional emissions reductions, and local emissions reduction.[17] For example, under Rule 2305, acquiring a new class 8 ZE/NZE truck in the warehouse operator fleet would be worth 126 points. Similarly, 365 visits by class 8 ZE/NZE trucks to a warehouse would be worth 51 points during a given annual compliance period.

Based on the most current information contained in the first Annual Report for the WAIRE Program, the average WPCO per warehouse operator was rounded to 80 points for the 2022 compliance period.[18] The same number of WATTs in 2023 and 2024 (and beyond) for the same warehouse operators would result in an average WPCO of 160 points and 240 points, respectively, taking into account the annual variable under Phase I (which applies to warehouses equal to or greater than 250,000 square feet) for those years.[19]

Under the rule, the Custom WAIRE Plan is a second option that allows warehouse owners or operators to earn WAIRE Points through a customized plan specific for a warehouse facility.[20] Custom WAIRE Plan applications must demonstrate how the proposed action will earn WAIRE Points based on the incremental cost of the action, the NO_X emission reductions from the action, and the diesel PM (DPM) emission reductions from the action, relative to baseline conditions. Custom WAIRE Plans may not include actions that are included in the WAIRE Menu on Table 3 of Rule 2305. The methodology to determine the total WAIRE Points for an action in a Custom WAIRE Plan application must be consistent with methods in the WAIRE Program Implementation Guidelines.[21] Any WAIRE Points earned from a Custom WAIRE Plan for emission reductions must be quantifiable, verifiable, and real as determined by the Executive Officer and consistent with the WAIRE Implementation Guidelines.

Warehouse owners or operators have a third option to meet the annual compliance obligation that involves payment of a mitigation fee in the amount of $1,000 for each WAIRE Point.[22] The mitigation fee is an option for warehouse operators to fulfill all or a portion of their WPCO. In adopting Rule 2305, the SCAQMD Governing Board directed the Executive Officer to develop the WAIRE Mitigation Program with funds generated from mitigation fee payments.[23] Any solicitations for requests for funding, or funding allocations that would be spent from the WAIRE Mitigation Program, must be approved by the SCAQMD Governing Board in a public meeting.[24] In adopting the Rule 2305, the Board also specified that proposed solicitations and project awards must be presented to the Governing Board no less frequently than on an annual basis. The Board directed the Executive Officer to track mitigation fees paid by warehouse operators according to the Source Receptor Area (SRA) [25] and county in which they are located to achieve or facilitate emission reductions in the same SRAs and counties in which the mitigation fees were paid. As adopted by the Board, if sufficient projects are not identified in each individual SRA relative to the available funding, then funds may be directed either to an adjacent SRA in the same county or held for a subsequent funding. The SCAQMD states that the mitigation fees collected from Rule 2305 will go towards the purchase of NZE and ZE trucks, installation of ZE charging and/or hydrogen fueling infrastructure.[26] Funds may also be combined with other incentive programs, such as Carl Moyer and Proposition 1B, as allowable on a case-by-case basis.

As noted above, warehouse operators have three basic options, or any combination of these options, through which to earn or obtain points sufficient to meet their WPCO. Warehouse owners may also earn WAIRE Points using the same methods or options available to warehouse operators and may transfer these WAIRE Points to any warehouse operator at the site where the WAIRE Points were earned within a three-year period.

In the SCAQMD's first Annual Report for the WAIRE Program, the SCAQMD compiled information from 380 ISIR's that had been submitted by warehouse operators through September 30, 2022. The first Annual Report suggests that warehouse operators expect to meet their WPCOs, at least in the early years of the program, primarily through ZE hostler usage, (*i.e.,* yard tractors that move trailers and containers around warehouse facilities; approximately 40% of the anticipated WAIRE points based on the ISIRs received), NZE Class 8 Truck Visits (approximately 27%), and ZE hostler acquisition (approximately 8%).[27] The submitted ISIRs also suggest that, in addition to taking actions from the WAIRE Menu, warehouse operators anticipate earning about 5,500 points through mitigation fees, representing about 3% of total points earned, and about $5.5 million.[28]

The SCAQMD developed emissions reduction estimates for various scenarios representing different compliance approaches to Rule 2305.[29] The estimates of reductions in emissions of NO_X and DPM vary widely among the scenarios and from year to year but represent positive emission reductions beyond those that are expected by the SCAQMD to occur due to CARB regulations (such as CARB's Advanced Clean Trucks, Low NO_X Omnibus, and Heavy Duty Inspection and Maintenance (I/M) regulations).[30]

Lastly, the rule includes recordkeeping and reporting requirements. The three types of reports that are due under Rule 2305 include: (1) the Warehouse Operations Notification (WON), which is the responsibility of the warehouse owner, (2) the ISIR, and (3) the Annual WAIRE Report, both of which are the responsibility of warehouse operators. The rule also specifies a sunset date after the EPA finds that all air basins within the SCAQMD have attained the

[17] SCAQMD Final Staff Report, 111.

[18] SCAQMD, Annual Report for the Warehouse Actions and Investments to Reduce Emissions (WAIRE) Program, January 2023, 16. The report represents 47% of warehouses in the SCAQMD. The average WPCO estimate of 80 points reflects SCAQMD's anticipated aggregate WPCO of approximately 30,000 divided by 380, the number of Phase I warehouses for which Initial Site Information Reports (ISIR) were submitted in time for the report. The 30,000 aggregate point value reflects a 0.33 annual variable for the first compliance period for Phase I warehouses.

[19] Rule 2305, table 2 (''Annual Variable'').

[20] SCAQMD Rule 2305(d)(4).

[21] SCAQMD Final Staff Report, 86. A copy of the current version of the SCAQMD's WAIRE Implementation Guidelines, version 1.1, is included in the docket for this rulemaking.

[22] SCAQMD Rule 2305(d)(5).

[23] SCAQMD, Resolution 21–9, signed June 4, 2021, 6.

[24] SCAQMD Final Staff Report, 40.

[25] Source Receptor Areas (SRAs) are shown in a SCAQMD-prepared map titled ''General Forecast Areas & Air Monitoring Areas''.

[26] SCAQMD Final Staff Report, 40.

[27] SCAQMD, Annual Report for the Warehouse Actions and Investments to Reduce Emissions (WAIRE) Program, January 2023, 15.

[28] Id.

[29] SCAQMD Final Staff Report, Tables 15 and 16.

[30] SCAQMD Final Staff Report, 62.

2015 ozone NAAQS and that CARB finds that all air basins within the SCAQMD have attained the California ozone ambient air quality standard (which is numerically the same as the 2015 ozone NAAQS).[31]

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rule?

The EPA has evaluated SCAQMD Rule 2305 against the applicable procedural and substantive requirements of the CAA for SIPs and SIP revisions and has concluded that, with certain exceptions discussed below, Rule 2305 meets the applicable requirements and would strengthen the SIP. Generally, SIPs must include enforceable emission limitations and other control measures, means, or techniques, as well as schedules and timetables for compliance, as may be necessary to meet the requirements of the Act (see CAA section 110(a)(2)(A)); must provide necessary assurances that the State will have adequate personnel, funding, and authority under State law to carry out such SIP (and is not prohibited by any provision of Federal or State law from carrying out such SIP) (see CAA section 110(a)(2)(E)); must be adopted by a State after reasonable notice and public hearing (see CAA section 110(a)(1); section 110(a)(2); section 110(l)); and must not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the Act (see CAA section 110(l)).[32]

The SCAQMD jurisdiction covers all the South Coast Air Basin, and portions of the Salton Sea and Mojave Desert Air Basins, and includes air quality planning areas that are designated as nonattainment for the 1-hour ozone NAAQS and the 1997, 2008 and 2015 8-hour ozone NAAQS (South Coast and Coachella Valley areas); the 1997 24-hour and annual $PM_{2.5}$ NAAQS, the 2006 24-hour $PM_{2.5}$ NAAQS and the 2012 annual $PM_{2.5}$ NAAQS (South Coast area), and the 1987 24-hour PM_{10} NAAQS (Coachella Valley area).[33] The South Coast Air Basin is currently classified as an Extreme nonattainment area for the 1-hour ozone NAAQS and the 1997, 2008, and 2015 8-hour ozone NAAQS, as a Moderate nonattainment area for the 1997 annual and 24-hour $PM_{2.5}$ NAAQS, and as a Serious nonattainment area for the 2006 24-hour and 2012 annual $PM_{2.5}$ NAAQS. The Coachella Valley portion of the Salton Sea Air Basin is classified as a Severe nonattainment area for the 1-hour ozone NAAQS, as an Extreme nonattainment area for the 1997 and 2008 8-hour ozone NAAQS,[34] as a Severe nonattainment area for the 2015 8-hour ozone NAAQS; and as a Serious nonattainment area for the 1987 24-hour PM_{10} NAAQS.

CAA section 172(c)(1) requires States with ozone nonattainment areas to implement all reasonably available control measures (RACM), including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology (RACT), as expeditiously as practicable. CAA sections 182(b)(2) and 182(f) specify that implementation of RACT under CAA section 172(c)(1) is required for all major stationary sources of NO_X in the area. In addition, the CAA requires States with Serious PM_{10} and $PM_{2.5}$ NAAQS nonattainment areas to implement Best Available Control Measures (BACM), including Best Available Control Technology (BACT) (see CAA section 189(b)(1)(B)). As noted above, SCAQMD includes both Extreme and Severe ozone nonattainment areas and Moderate and Serious PM nonattainment areas.

With respect to rule stringency, the EPA is prohibited by the CAA from requiring States and local air agencies to submit indirect source review (ISR) programs as a condition to approving a SIP.[35] Because the EPA cannot require a State or local air agency to adopt and implement an ISR program, the EPA reasons that it likewise cannot require that such a program meet any particular level of stringency otherwise required to meet SIP requirements, such as attainment plan requirements for the ozone or PM NAAQS. Therefore, the EPA is not evaluating SCAQMD Rule 2305 for compliance with the RACM/RACT or BACM/BACT requirements.

B. Does the rule meet the evaluation criteria?

1. Did the State provide for reasonable public notice and hearing prior to adoption?

Under CAA section 110(l), SIP revisions must be adopted by the State, and the State must provide for reasonable public notice and hearing prior to adoption. Pursuant to 40 CFR 51.102, States must provide at least 30-days' notice of any public hearing to be held on a proposed SIP revision. States must provide the opportunity to submit written comments and allow the public the opportunity to request a public hearing within that period. Rule 2305 was adopted by SCAQMD on May 7, 2021, through Resolution 21–9, following a public hearing held on the same day. Prior to adoption, the SCAQMD published notice of the May 7, 2021 public hearing on March 31, 2021, and provided more than 30 days for submission of written comments. The CARB subsequently adopted the rule as a revision to the SIP on August 13, 2021, through Executive Order S–21–012. The CARB then submitted SCAQMD Rule 2305 to the EPA on August 13, 2021, as an attachment to a letter with the same date. Various other materials comprising the SIP submission package were submitted as well, including copies of public comments received during the comment period, District responses to comments, and environmental and socioeconomic impact assessments.

Based on the materials provided in the August 13, 2021 SIP submission summarized above, we propose to find that the District and the CARB have met the procedural requirements for adoption and submission of SIPs and SIP revisions under CAA section 110(l) and 40 CFR 51.102.

2. Does the State have adequate legal authority to implement the rule?

The SCAQMD has been granted both general and specific authority under the California Health & Safety Code (CH&SC) to adopt and implement Rule 2305.[36] Specific authority is found in CH&SC section 40440 (''Rules and

[31] SCAQMD Rule 2305(e) and (h).

[32] CAA section 193, which prohibits any pre-1990 SIP control requirement relating to nonattainment pollutants in nonattainment areas from being modified unless the SIP is revised to insure equivalent or greater emission reductions of such air pollutants, does not apply to the SCAQMD Rule 2305 because, as a new rule, it does not represent a pre-1990 SIP control requirement.

[33] 40 CFR 81.305. In addition, a portion of Los Angeles County is designated nonattainment for the lead NAAQS, but SCAQMD Rule 2305 does not affect lead emissions, and thus, the lead NAAQS is not germane to our proposed action and is not discussed further.

[34] The EPA recently finalized a reclassification requested by CARB for Coachella Valley from Severe to Extreme for the 2008 ozone NAAQS. 88 FR 14291 (March 8, 2023).

[35] CAA section 110(a)(5)(A)(i); *National Association of Home Builders* v. *San Joaquin Valley Unified Air Pollution Control District,* 627 F.3d 730, 737–38 (9th Cir. 2010) (''*NAHB* v. *SJVUAPCD*'') (''Congress added section 110(a)(5) to the Act in 1977 after the EPA had tried to force the states to regulate indirect sources of pollution. When the states had not regulated indirect sources to the EPA's satisfaction, the EPA began to promulgate its own rules for indirect sources. The EPA's move 'drew heavy criticism because [it] represented a significant federal intrusion into the traditionally local domain of land use control.' In response to the EPA's actions, a 1977 amendment to the Act 'severely limit[ed] the EPA's authority' over indirect sources, but 'left largely to the states' the matter of 'whether and how to regulate' indirect sources.'' (Internal citations omitted)).

[36] General authority is found in CH&SC sections 40000 and 40001.

regulations''), which authorizes the SCAQMD to provide for indirect source controls in those areas of the South Coast District in which there are high-level, localized concentrations of pollutants.

Moreover, the EPA knows of no obstacle under State or Federal law in the SCAQMD's ability to implement Rule 2305. With respect to State law, the EPA notes that, during the rule development phase, certain commenters challenged the mitigation fee option in Rule 2305 on the grounds that it imposes an unlawful tax under State law. However, CARB's August 13, 2021 SIP submission package includes a legal analysis from the State Attorney General's Office [37] that concludes that the mitigation fee is not an unlawful tax under the California Constitution because, as a compliance option, the fee is not compulsory.[38] In explaining how the mitigation fee option is not compulsory, the State Attorney General's Office letter notes that, under Rule 2305, ''warehouse operators have numerous options to reduce their emissions or otherwise earn compliance points. If they elect not to take actions to reduce their emissions or environmental impacts, warehouse operators may comply by paying the in-lieu fee. A 'hallmark' of a tax is that 'it is compulsory.' The in-lieu fee is not compulsory, so it is not a tax.'' [39] (Internal citations omitted.) Also, even if viewed as compulsory, the Attorney General's Office explains how the mitigation fee option falls under two exceptions to the meaning of ''tax'' under the relevant provisions of State law.[40] The EPA proposes to find that the State Attorney General's Office letter provides the necessary assurances that State law with respect to the mitigation fee option is not an obstacle to the SCAQMD's ability to implement Rule 2305.

With respect to Federal law, the EPA is aware of an ongoing legal challenge by the California Trucking Association (CTA), among others, to the SCAQMD's legal authority to implement Rule 2305 in litigation to which the EPA is not a party.[41] In the CTA case, plaintiff CTA and plaintiff-intervenor Airlines for America assert that implementation and enforcement of Rule 2305 by the SCAQMD is preempted under the CAA, the Airline Deregulation Act (ADA) and the Federal Aviation Administration Authorization Act (FAAAA or F4A). Based on the information currently before the EPA at this time, the EPA proposes to find that Rule 2305 is not preempted under the CAA, ADA or the F4A. If the District Court were to issue a decision against the SCAQMD in the pending litigation before the EPA takes final action on Rule 2305 pursuant to this proposal, we will take that decision into account and evaluate appropriate action at that time.[42]

With respect to the CAA, the EPA's evaluation of Rule 2305 indicates that the SCAQMD is authorized to adopt this program for inclusion into the California SIP. CAA section 110(a)(5) authorizes States to include any ISR program in their SIPs. Under CAA section 110(a)(5), the EPA may not require a State to adopt an ISR program as part of its SIP, but the EPA may approve an ISR program that a State chooses to adopt and submit for inclusion into its approved SIP. In this context, ''indirect source'' means a facility, building, structure, installation, real property, road, or highway that attracts, or may attract, mobile sources of pollution.[43] ''Indirect source review program'' means the facility-by-facility review of indirect sources of air pollution, including such measures as are necessary to assure, or assist in assuring, that a new or modified indirect source will not attract mobile sources of air pollution, the emissions from which would cause or contribute to air pollution concentrations—

- Exceeding any national primary ambient air quality standard for a mobile source-related air pollutant after the primary standard attainment date; or
- Preventing maintenance of any such standard after such date.[44]

Rule 2305 involves the facility-by-facility review of existing and new warehouses, which are facilities that attract mobile sources of air pollution. Based on this review, the rule provides a list of specific measures that, when implemented by the warehouse operator, will reduce or offset the related mobile source emissions that contribute to the exceedances of the NAAQS for $PM_{2.5}$ and ozone in areas under SCAQMD jurisdiction. The rule also provides options to allow the operator of the warehouse to develop a custom WAIRE plan or pay a mitigation fee or a combination of these options. More specifically, under Rule 2305, warehouse operators are required, on an annual basis, to earn or obtain WAIRE points sufficient to meet their WPCO, a value that reflects the WATTs associated with each warehouse. As noted previously, the WATTs parameter represents a calculated value that reflects the number of truck trips to and from a warehouse in a given year and serves as a proxy for overall warehouse activity and emissions.

To earn or obtain WAIRE points, warehouse owners and operators have the option of: (i) taking various types of actions or making variety types of investments specified in the WAIRE menu; (ii) following an approved Custom WAIRE Plan; (iii) paying a mitigation fee; (iv) or any combination of such options (see section I.D of this document). The SCAQMD anticipates that the same types of actions and investments that are specified in Rule 2305 will also occur under the WAIRE Mitigation Program funded by the mitigation fee option under the rule (see section I.D of this document). As such, Rule 2305 is designed to reduce, offset, or mitigate the emissions generated by mobile sources attracted to warehouses in the SCAQMD. This includes the associated contribution to area-wide exceedances of the NAAQS and to the local pollutant burden on communities in the vicinities of warehouses.

Rule 2305 is similar to the ISR review program previously adopted by the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) to reduce or offset emissions of NO_X and PM in the San Joaquin Valley from the construction-phase and operational-phase of development projects through design features, on-site measures, and through off-site measures paid through implementation of an in-lieu mitigation fee.[45] The SJVUAPCD ISR program was

[37] Robert Swanson, Deputy Attorney General, California Department of Justice, letter to Ellen Peter, Chief Counsel, CARB, dated May 6, 2021, included as an enclosure to Ellen M. Peter, Chief Counsel, CARB, letter to Wayne Nastri, Executive Officer, SCAQMD, dated May 6, 2021.

[38] Id. at 12–14.

[39] Id. at 12.

[40] Id. at 12–14.

[41] *California Trucking Association* v. *South Coast Air Quality Management District,* C.D. Cal., Docket #21–cv–06341 (*CTA*).

[42] For instance, the EPA may re-propose action or supplement the proposed action depending upon the implications of the decision on the District's authority to implement and enforce the rule, among other considerations. If an adverse decision were to be issued after the EPA approves Rule 2305, then the EPA would consider withdrawal of the approval, again, depending upon the implications of the decision on the District's authority to implement and enforce the rule, among other considerations.

[43] CAA section 110(a)(5)(C). The term ''indirect source'' as defined in the CAA includes parking lots, and parking garages, and other facilities subject to any measure for management of parking supply, including regulation of existing off-street parking but such term does not include new or existing on-street parking. ''Indirect source'' does not include direct emissions sources or facilities at, within, or associated with, any indirect source.

[44] CAA section 110(a)(5)(D). Indirect source review programs are not considered ''transportation control measures.'' CAA section 110(a)(5)(E).

[45] SJVUAPCD Rule 9510 (''Indirect Source Review (ISR)''), approved by the EPA at 76 FR

Continued

upheld by the Ninth Circuit in a challenge that claimed that the program was characterized as an ISR program but was in reality a rule regulating emissions from nonroad equipment in violation of CAA section 209(e).[46]

Commenters, objecting to Rule 2305 during its adoption, contended that an ISR program, for the purposes of CAA section 110(a)(5), is limited to new or modified indirect sources and that, therefore, Rule 2305 is not authorized under the CAA, at least as it applies to existing warehouses. This contention is based on the clause in the definition of the term ''indirect source review program'' describing such programs as ''including such measures as are necessary to assure, or assist in assuring, that a new or modified indirect source will not attract mobile sources of air pollution.'' [47]

In its own rulemaking process, the SCAQMD responded to this issue by noting that the SCAQMD's authority derives from State law, not Federal law. State law does not limit the authority of the SCAQMD to regulating only new or modified (as opposed to existing) indirect sources.[48] The SCAQMD also noted that CAA section 110(a)(5) does not prescribe limits on State authority but rather prescribes certain limits on the EPA. Finally, the SCAQMD stated that it has authority under CAA section 116 for this type of provision.

In reviewing Rule 2035, the EPA has specifically evaluated whether it is consistent with the requirements of CAA section 110(a)(5). When taking action on any SIP submission, the EPA must evaluate whether the SIP provisions as issue meet applicable statutory and regulatory requirements. The EPA acknowledges that there are ambiguities in the language of section 110(a)(5). For example, section 110(a)(5)(D) superficially appears to define the term ''indirect source review program'' in terms of ''new or modified'' indirect sources. That provision in relevant part defines an indirect source program as one ''including'' such measures at new or modified sources. The EPA does not, however, interpret this definition to restrict States from having such programs that extend to existing sources if they elect to do so. Instead, the use of ''including'' preceding the reference to ''new or modified indirect source'' indicates that regulation of new or modified indirect sources is illustrative of the scope of this provision, not limiting.

Other provisions support this interpretation. Section 110(a)(5)(C) defines the term ''indirect source'' itself to include many things such as a building ''which attracts, or may attract, mobile sources of pollution.'' This definition could encompass both existing and future structures. By contrast, with respect to parking, section 110(a)(5)(C) expressly states that an indirect source program can include ''existing off-street parking'' but not ''new or existing on-street parking.'' If such an ''indirect source program'' could apply to existing off-street parking, then it is unclear why this conceptually would not extend to other existing sources such as existing buildings, notwithstanding the reference to new or modified sources in the definition of ''indirect source program.'' At most, there is a small degree of ambiguity with respect to whether Congress actually intended the definition of ''indirect source program'' to function as a restriction on the EPA's authority to approve a State indirect source program that extends to existing buildings into the State's SIP. The EPA does not consider such a restrictive reading of the provision to be reasonable or logical, absent a clearer prohibition.

As further support for this interpretation, the EPA notes that CAA section 116 explicitly provides that States retain authority to regulate more stringently in SIP provisions than otherwise required by Federal law, except where preempted from doing so. Even if Congress anticipated that States might typically elect to adopt such programs that would include new or modified sources, Congress did not explicitly appear to preclude States from adopting indirect source programs that extend to existing sources as well, except with respect to ''new or existing on street parking.'' In other words, by defining the term ''indirect source program'' in CAA section 110(a)(5)(D), Congress was not diminishing existing State authority under CAA section 116 to adopt such programs that apply to existing sources, such as existing warehouses, if they elect to do so. Thus, the EPA concludes that the State is not precluded from regulating both existing and new warehouses in Rule 2305, and thus this poses no issue with respect to the EPA proposing approval of the rule into the SIP.

During the rule development process, the SCAQMD received comments objecting to Rule 2305 on the grounds that the rule, while structured as an ISR program, represents a de facto purchase mandate for ZE or NZE trucks and is thus preempted under CAA section 209(a). These adverse comments cited to the Supreme Court decision in *Engine Mfrs. Ass'n* v. *S. Coast Air Quality Mgmt. Dist,* 541 U.S. 246 (2004) (*EMA*). In *EMA,* the Supreme Court held that a ''standard'' under CAA section 209(a), which the Court described as ''a requirement that a vehicle or engine not emit more than a certain amount of pollutant, be equipped with a certain type of pollution-control device, or have some other design feature related to the control of emissions,'' is preempted under Section 209(a) whether applied to manufacturers through a sales mandate or to buyers through a purchase mandate.[49]

As noted above, the question of whether an ISR program is preempted under Section 209 of the CAA was squarely addressed by the Ninth Circuit in *NAHB* v. *SJVUAPCD.* The EPA agrees with the Ninth Circuit's interpretation of the statute on this point and proposes to find that Rule 2305 is similar in relevant respects to the ISR program the Court determined in *NAHB* was not preempted. Most critically, Rule 2305 regulates at the level of the indirect source, and not at the level of mobile sources the indirect source may attract. In Rule 2305 ''[t]the 'baseline' amount of emissions, and the required reduction in emissions from that baseline, are both calculated in terms of the [indirect source site] as a whole.'' [50] This ''site-based'' approach to regulating emissions ''is precisely what allows the Rule to avoid preemption under section 209(e)(2).'' [51] That Rule 2305 is properly characterized as an ISR program under Section 110(a)(5) distinguishes it from the vehicle purchase mandate at issue in the Supreme Court *EMA* case.[52]

26609 (May 9, 2011), and approved as amended at 86 FR 33542 (June 25, 2021).

[46] *NAHB* v. *SJVUAPCD,* 627 F.3d 730, 734 (9th Cir. 2010); at 739: ''The Act, by allowing states to regulate indirect sources of pollution, necessarily contemplates imputing mobile sources of pollution to an indirect source as a whole. If an indirect source review program could not attribute the emissions from mobile sources, while they are stationed at an indirect source, to the indirect source as a whole, states could not adopt any indirect source review program. What allows Rule 9510 to qualify as an indirect source review program under section 110(a)(5) is precisely what allows the Rule to avoid preemption under section 209(e)(2): its site-based regulation of emissions. In this way, the two sections do not conflict, but rather fit together neatly like two interlocking puzzle pieces.''

[47] CAA section 110(a)(5)(D).

[48] Final SCAQMD Staff Report, Master Responses, 157–158.

[49] *Engine Manufacturers Ass'n* v. *South Coast Air Quality Management District,* 541 U.S. 246, 253–255 (2004).

[50] *NAHB* v. *SJVUAPCD,* 627 F.3d 730, 737.

[51] Id., 739.

[52] ''Rule 9510 escapes preemption because its regulation of construction equipment is indirect. Rule 9510 does not measure emissions by fleets or groups of vehicles; it measures emissions on a ''facility-by-facility'' basis. 42 U.S.C. 7410(a)(5)(D). Its unit of measurement is the indirect source, not the fleet. It regulates development sites directly, but as the term ''indirect source'' implies, it regulates

The EPA has previously acknowledged the possibility that a rule styled as an ISR program may in effect be a regulation of direct sources, including motor vehicles or nonroad sources. In other words, the EPA is not obligated merely to accept at face value a State or local authority's characterization, but may consider how the program will work in practice. In its 2011 final approval action on the SJVUAPCD ISR, the EPA noted factors that might indicate a rule ostensibly measuring emissions from a site was a *de facto* regulation of nonroad engines.[53] As explained below, Rule 2305 lacks the indicia of a *de facto* regulation of either motor vehicles or nonroad vehicles or engines.

As explained in section I.D above, Rule 2305 applies to warehouse operators and provides multiple options for meeting the annual WPCO. As noted by the SCAQMD in response to comments on proposed Rule 2305, ''the WPCO is not based on truck *emissions;* it is based on truck *trips.* The proposed rule uses truck trips as a proxy for total warehouse emissions when setting the compliance obligation because the number of truck visits is representative of the total activity at, and emissions associated with, a warehouse.'' [54] The various options available (WAIRE Menu, Custom WAIRE Plan, or Mitigation Fee) to warehouse operators that do not involve acquisition of, or contracting for, ZE or NZE trucks to earn WAIRE Points support a conclusion that in Rule 2305, the SCAQMD has not adopted or attempted to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines for the purposes of CAA section 209(a).[55]

Commenters objecting to the SCAQMD's adoption of Rule 2305 contended that the requirements are preempted under the ADA and F4A. Under the ADA, with certain exceptions not applicable here, a State or political subdivision of a State may not enact or enforce a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier or carrier affiliated with a direct air carrier through common controlling ownership when such carrier is transporting property by aircraft or by motor vehicle (whether or not such property has had or will have a prior or subsequent air movement).[56] The F4A extends the same preemptive language to any motor carrier (''common carrier'') or any motor private carrier, broker, or freight forwarder with respect to the transportation of property.[57] Rule 2305 applies to owners and operators of warehouses greater than 100,000 square feet of indoor floor space in a single building, and both air carriers and common carriers are subject to the requirements of Rule 2305 because both types of carriers own or operate such warehouses in the SCAQMD.

The EPA does not consider the requirements under Rule 2305 as relating directly to the ''price, route, or service'' of any air carrier or common carrier but do recognize that an indirect effect on price is a foreseeable consequence of the additional costs borne by warehouse owners or operators to comply with the annual WAIRE points compliance obligation. However, the EPA proposes to find that Rule 2305 is not preempted under either the ADA or F4A because any price effect is indirect and remote. Moreover, the District is acting under its delegated police powers to protect public health in a way that is explicitly authorized under CAA section 110(a)(5) and CAA section 116. Any incremental increase in price for delivery services due to compliance with Rule 2305 internalizes costs otherwise borne by the public, particularly members of the public living and working in the vicinities of warehouses, through the types of health effects associated with elevated concentrations of PM.

3. Is the rule enforceable as required under CAA section 110(a)(2)?

The EPA has evaluated the enforceability of Rule 2305 with respect to applicability and exemptions; standard of conduct; compliance dates; sunset provisions; discretionary provisions; and test methods, recordkeeping and reporting,[58] and the EPA believes, for the reasons given below, that the regulation is generally enforceable for the purposes of CAA section 110(a)(2) but with certain deficiencies.

First, with respect to applicability, the EPA generally finds that Rule 2305 is sufficiently clear as to which entities are subject to the requirements in the regulation and which entities are exempt.[59] The EPA finds that Rule 2305 is sufficiently specific so that the persons affected by the regulation are fairly on notice as to what the requirements and related compliance dates are.[60] To a large extent, the EPA has already described the substantive requirements and compliance dates set forth in Rule 2305 in section I.D of this document. The EPA notes, however, that two definitions in Rule 2305 cite to sections of the California Code of Regulations (CCR), and thus, the two definitions in Rule 2305 would be ambiguous for the purposes of enforcement of the SIP unless the CCR sections on which Rule 2305 relies are submitted and approved into the SIP.[61] The CCR sections on which Rule 2305 relies are included in two new CARB mobile source regulations that the EPA anticipates that CARB will submit to the EPA for approval as part of the California SIP. If these two CCR sections are submitted and the EPA subsequently approves them into the SIP, then Rule 2305 will avoid this particular potential ambiguity and the related implications for enforceability.

Second, with respect to compliance dates, the EPA notes that all warehouses subject to the rule will be required to meet their WAIRE points annual compliance obligation requirements beginning with calendar year 2024. This is consistent with achieving emission reductions in advance of the July 20,

mobile emissions only indirectly. For that reason, the fleet-based regulations [that were at issue in *EMA*] are not analogous to Rule 9510.'' *NAHB* v. *SJVUAPCD,* 627 F.3d 740.

[53] ''[I]n the TSD, EPA evaluates the potential for Rule 9510, as an ISR rule otherwise authorized under CAA section 110(a)(5), to nevertheless run afoul of CAA section 209(e), and in so doing, EPA identified two ways that an ISR rule that on its face is authorized under CAA section 110(a)(5) could nonetheless be preempted. First, the ISR rule could be preempted if the rule in practice as applied acts to compel the manufacturer or user of a nonroad engine or vehicle to change the emission control design of the engine or vehicle, or second, an ISR rule could be preempted if it creates incentives so onerous as to be in effect a purchase mandate.'' 76 FR 26609, 26611 (May 9, 2011).

[54] SCAQMD Final Staff Report, 160.

[55] SCAQMD's Final Socioeconomic Impact Assessment for Proposed Rule 2305—Warehouse Indirect Source Rule—Warehouse Actions and Investments to Reduce Emissions (WAIRE) Program and Proposed Rule 316—Fees for Rule 2305 (May 2021), particularly pages ES–5—ES–7, and table 18, indicates that the ZE/NEZ non-acquisition (or contracting) scenarios are generally 4 to 5 times more costly (in terms of average annual dollars per square foot) than the ZE/NZE acquisition (or contracting) scenarios so as to incentive acquisition and use of ZE/NZE trucks over the non-acquisition options. However, the scenarios were developed to identify the widest range of possible costs assuming that warehouse owners and operators would only comply with a single scenario approach from 2022 through 2031. The EPA expects warehouse operators will select multiple points-earning actions or investments along with mitigation fees to meet the annual compliance obligation, and that the selection will change over the years in light of the ever-changing circumstances of individual businesses and the composition of vehicle fleets.

[56] 49 U.S.C. 41713(b).

[57] 49 U.S.C. 14501(c)(1).

[58] These concepts are discussed in detail in an EPA memorandum dated from September 23,1987, from J. Craig Potter, EPA Assistant Administrator for Air and Radiation, et al., to Addressees, Subject: ''Review of State Implementation Plans and Revisions for Enforceability and Legal Sufficiency.''

[59] 13 CCR 2023.

[60] 13 CCR 2023.1.

[61] The definitions in Rule 2305 of ''Near Zero-Emission'' truck and ''Zero-Emission'' truck cite to 13 CCR 1956.8 and 1963, respectively.

2032 attainment deadline for the South Coast Air Basin and Coachella Valley Extreme nonattainment areas for the 2008 ozone NAAQS. By extension, Rule 2305 compliance dates are compatible with the applicable attainment deadlines for the 2015 ozone NAAQS: August 3, 2033, for the Coachella Valley ''Severe'' nonattainment area; and August 3, 2038, for the South Coast Air Basin ''Extreme'' nonattainment area. The compliance dates in Rule 2305 are also consistent with providing emission reductions in advance of the applicable attainment deadlines in the South Coast of October 16, 2025 for the 2006 24-hour $PM_{2.5}$ NAAQS and December 31, 2025 for the 2012 annual $PM_{2.5}$ NAAQS.[62]

Third, Rule 2305 includes a sunset provision.[63] Specifically, Rule 2305 provides that the WAIRE points annual compliance obligation requirements expire in the year following the determinations by the EPA that the South Coast Air Basin and Coachella Valley have attained the 2015 ozone NAAQS and the determinations by CARB that the South Coast Air Basin and Coachella Valley have attained the State ambient air quality standard for ozone (which is numerically the same as the 2015 ozone NAAQS). Generally, the EPA finds sunset provisions in SIP rules to be a deficiency that must be addressed for full approval because of the potential to interfere with reasonable further progress (RFP) or attainment of the NAAQS, and potential inconsistency with CAA section 110(l) requirements through purported elimination of existing control requirements without a sufficient demonstration at that future date. In this instance, we are not crediting Rule 2305 at this time with a specific level of emissions reductions for RFP or attainment demonstration purposes. This does not mean that the rule would not achieve emissions reductions in practice over the near-term and well into the future and, therefore, does not mean that sunsetting the rule would not result in foregone emissions reductions that would be relevant for both the ozone and $PM_{2.5}$ NAAQS at that future time. We recommend that SCAQMD amend Rule 2305 to eliminate the sunset clause. The SCAQMD is free to rescind the rule at any time, but a future rescission of Rule 2305 must be effectuated though adoption and submission of the rescission as a SIP revision to the EPA for review and action under CAA section 110(k), and consistent with CAA section 110(l), at that time.

The EPA notes that Rule 2305 includes provisions that allow for discretion on the part of the SCAQMD's Executive Officer. Such ''director's discretion'' provisions can undermine enforceability of a SIP regulation, and thus prevent full approval by EPA. In the case of Rule 2305, it allows for director's discretion in connection with the determination of whether WAIRE Points from a Custom WAIRE Plan are quantifiable, verifiable, and real and the determination of whether the warehouse owner or operator is making adequate progress to complete an approved Custom WAIRE Plan.[64] Inclusion of such provisions that in effect give a State official, unilateral, and unbounded authority to make decisions concerning whether a regulated entity is, or is not, in compliance that bind the EPA or other parties are inconsistent with basic SIP requirements.

Lastly, Rule 2305 includes recordkeeping and reporting requirements that are sufficient to ensure compliance with the applicable requirements.[65] The EPA notes that, in adopting Rule 2305, the SCAQMD Board directed the Executive Officer to develop an online portal for the purpose of submitting required reports and documents as required by Rule 2305. The online portal (WAIRE POP) will provide the public information about how warehouse operators and owners are complying with Rule 2305 and how WAIRE Mitigation Program funds are spent.[66] The SCAQMD has since developed a WAIRE program tab under Rules & Compliance portion of the District's website. It includes a portal to the WAIRE POP for warehouse operators to submit reports and includes general information on the program such as the implementation guidelines, applications, guidance, and analytical tools, among other things.

4. Does the rule interfere with reasonable further progress (RFP) and attainment or any other applicable requirement of the Act?

The SCAQMD adopted Rule 2305 in part to meet a commitment in the 2016 South Coast AQMP to assess and identify potential actions to further reduce emissions associated with emission sources operating in and out of warehouse distribution centers. While the EPA is not proposing to credit Rule 2305 with achieving a specific amount of emissions reductions, the EPA's evaluation of Rule 2305 indicates that the rule will achieve additional emission reductions. These additional reductions will incrementally contribute to the overall reductions needed to attain the NAAQS in the South Coast Air Basin and Coachella Valley air quality planning areas.

However, as discussed previously, we find that the sunset clause in Rule 2305 could interfere with attainment or reasonable further progress by foregoing emissions reductions that may be needed for attainment or maintenance of the NAAQS. Thus, the EPA recommends that the SCAQMD remove the sunset clause and follow the normal course of action in rescinding rules from the SIP, *i.e.,* through a SIP revision and EPA approval under CAA section 110(k) and section 110(l).

5. Will the State have adequate personnel and funding for the rule?

The SCAQMD adopted a specific rule, Rule 316 (''Fees for Rule 2305''), for the purpose of recovering the SCAQMD's costs associated with implementing Rule 2305. In light of the adoption of Rule 316, the EPA finds that the SCAQMD will have adequate personnel and funding to implement Rule 2305.

6. EPA's Rule Evaluation Conclusion

Based on the above discussion, the EPA believes Rule 2305 is consistent with the relevant CAA requirements, policies, and guidance, except as otherwise noted. As an ISR program under CAA section 110(a)(5), Rule 2305 is not a required submission. The EPA proposes to find that the District has the authority to implement and enforce Rule 2305 and is not prohibited from doing so by any State or Federal law. While Rule 2305, as stated previously, will reduce emissions associated with warehouses, the EPA proposes to find that the rule is not fully enforceable, and that the amount of associated emissions reductions is not sufficiently quantifiable for credit at the present time. The EPA proposes to find that Rule 2305 is SIP-strengthening and proposes to approve it on this basis. A recent decision by the Ninth Circuit upheld the EPA's approval of a SIP submission for the San Joaquin Valley on SIP strengthening grounds.[67] In that case, like our proposed action on Rule 2305, the EPA deemed the SIP provision at issue not fully enforceable and accordingly granted no SIP credit for

[62] See 85 FR 57733 (September 16, 2020) and 40 CFR 51.1004(a)(3) (2006 24-hour $PM_{2.5}$ NAAQS); and 85 FR 71264 (November 9, 2020) and 40 CFR 51.1004(a)(2) (2012 annual $PM_{2.5}$ NAAQS).

[63] SCAQMD Rule 2305(h).

[64] SCAQMD Rule 2305(d)(4)(A)(iii) and (d)(4)(D).

[65] 13 CCR 2023.8 and 2023.9.

[66] SCAQMD Resolution 21–9, 7.

[67] *Association of Irritated Residents* v. *EPA,* 10 F.4th 937 (9th Cir. 2021).

emissions reductions from the provision.

C. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to approve the submitted rule. The EPA concludes that, while SCAQMD Rule 2305 does not meet all the evaluation criteria for enforceability, we are proposing approval because the submitted rule is not a required SIP element and would strengthen the SIP. In light of the deficiencies identified above, however, the EPA concludes that the submitted rule should not be credited in any attainment and rate of progress/reasonable further progress demonstrations.

We will accept comments from the public on the proposed action, the rationale and basis for the proposed action, and other relevant matters until November 13, 2023. If the EPA takes final action to approve the submitted rule, the final action will incorporate this rule into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference SCAQMD Rule 2305, adopted on May 7, 2021, that establishes an ISR program for certain warehouse owners and operators, as described in section I of this preamble. The EPA has made, and will continue to make, these materials available through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993), 13563 (76 FR 3821, January 21, 2011) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The SCAQMD did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. However, the Community Steering Committees for four environmental justice communities admitted into the State's AB 617 program in the affected area requested development of a warehouse ISR rule due to concerns regarding air pollution impacts from trucks and DPM.[68] The EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being proposed here, this proposed action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

Lastly, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: October 5, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2023–22518 Filed 10–11–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA–HQ–OPP–2023–0420; FRL–10637–01–OCSPP]

RIN 2070–AL13

Pesticides; Review of Requirements Applicable to Treated Seed and Treated Paint Products; Request for Information and Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Environmental Protection Agency (EPA) is soliciting public

[68] SCAQMD Final Staff Report, 9 and 10.

comments and suggestions about seeds treated with a pesticide registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as well as treated paint. The Agency is considering whether a rule under FIFRA to regulate certain use of treated seed and treated paint products or other administrative action is appropriate considering questions raised by stakeholders. To inform this consideration, EPA is requesting comment and information from all stakeholders on the use and usage of treated seed, including storage, planting, and disposal of the treated seed, and on whether or to what extent treated seed products are being distributed, sold, and used contrary to treating pesticide and treated seed product labeling instructions. Similarly, EPA is requesting comment from stakeholders on the addition of labeling requirements on the labels of treated paint products and potential language that should be included in those labels.

DATES: Comments must be received on or before December 11, 2023.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPP–2023–0420, is available online at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Bartow, Chemical Review Manager, Pesticide Reevaluation Division, Office of Chemical Safety and Pollution Prevention (7508M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; phone: 202–566–2280; email address: *OPPTreatedArticles@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you manufacture, distribute, sell, treat, or use pesticide-treated seed or treated paint products. EPA has promulgated several exemptions for pesticide products of a character not requiring regulation under FIFRA, including for treated articles and substances; EPA is now considering modifying the treated article exemption. This exemption is codified in 40 CFR 152.25(a). The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, rather it provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Pesticide and other agricultural chemical manufacturers (NAICS codes 325320 and 325311).
- Manufacturers who may also be distributors of these products, which includes farm supplies merchant wholesalers (NAICS code 424910).
- Retailers of pesticide products (some of which may also be manufacturers), which includes nursery, garden center, and farm supply stores (NAICS code 444220).
- Government establishments engaged in regulation, licensing, and inspection (NAICS code 926150).
- Users of treated seed products and persons involved in crop production (NAICS code 111).
- Persons involved in support activities for crop production (NAICS code 1151).

If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

This advance notice of proposed rulemaking (ANPRM) is issued under the authority of FIFRA, 7 U.S.C. 136 *et seq.,* particularly FIFRA sections 3 and 25. FIFRA section 3(a) authorizes EPA to regulate the distribution, sale, or use of any unregistered pesticide ''[t]o the extent necessary to prevent unreasonable adverse effects on the environment'' (defined at FIFRA section 2(bb), in pertinent part, as ''any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide''). 7 U.S.C. 136a(a) and 136(bb). Exemptions to the requirements of FIFRA are issued under the authority of FIFRA section 25(b). Eligible products may be exempted from among other things, registration requirements under FIFRA section 3. In addition, FIFRA section 25(a) authorizes EPA to ''prescribe regulations to carry out the provisions of [FIFRA]'' and FIFRA section 25(b) authorizes exemptions from, among other things, registration requirements under FIFRA section 3. 7 U.S.C. 136w(a) and (b).

C. What action is the Agency taking?

EPA is requesting comments on specific issues related to seed treated with conventional pesticides (''treated seed'') and paint treated with conventional or antimicrobial pesticides (''treated paint''). As to treated seed products, EPA has typically included on the label of the treating pesticide labeling instructions regarding both the use of the treating pesticide and the distribution, sale, and use of the treated seed product, and EPA's exposure assessments and registration decisions take those instructions into consideration. However, states and other stakeholders have raised questions about the clarity and enforceability of instructions specifically relating to use of the treated seed products (*i.e.,* instructions relating to the storage, planting, and management of the treated seed). EPA is seeking to improve labeling on both treating pesticide labeling and labeling on treated seed products (*e.g.,* seed bag tags) during registration and registration review processes, and is requesting comment in response to this FRN on such labeling instructions. EPA is also requesting comment on use and usage of treated seed products, including storage, planting, and disposal of treated seed, and on whether or to what extent treated seed products are being distributed, sold, and/or used contrary to treating pesticide labeling instructions for each separate crop seed product. To EPA's knowledge, treated seed are generally being used consistent with the instructions on the label of the treated seed product. However, the Agency is seeking any specific information from all stakeholders to further inform this issue (*e.g.,* whether there are specific cases of use contrary to label instructions) before considering EPA's next steps with respect to how EPA regulates treated seed products. EPA is looking for this information from a broad range of stakeholders, including those who treat seed in commercial facilities or on the farm and those who use treated seed products.

For treated paint products, pesticide labeling requirements do not currently exist. EPA is exploring the option of requiring labeling instructions on treated paint products to address potential risks of concern for professional painters exposed to the pesticide in the treated paint without the use of personal protection equipment (PPE), such as respirators, when applying the paint using a spray method. Thus far, labeling for treated paint has been proposed for only one active ingredient (*i.e.,* diuron), but is being considered for other active ingredients that are registered for use as paint preservatives. EPA is requesting comments among other things on requiring such labeling instructions on treated paint containers.

EPA will consider comments and information to determine whether to amend its approach for allowing treated

seed and treated paint products to be wholly exempt from FIFRA requirements (*e.g.,* through issuance of a rule pursuant to FIFRA section 3(a) to regulate distribution, sale, and use of treated seed product and/or other administrative action). FIFRA section 3(a) authorizes EPA to limit the distribution, sale, or use of an unregistered pesticide ''[t]o the extent necessary to prevent unreasonable adverse effects on the environment.'' Such a FIFRA section 3(a) rule and conforming amendments to the treated article exemption would be intended to allow for enforcement of certain use instructions on labeling of treated seed and treated paint as an alternative to registration of such products. Other actions could include amending the treated article exemption to limit the scope of the exemption so that some FIFRA requirements would still apply (*e.g.,* requiring seed treatment facilities to identify as establishments), and other administrative actions could include addressing specific use concerns with treated seed through further action on the specific treating pesticide registration (*e.g.,* clarifying labeling instructions, reducing or eliminating use of the treating pesticide for some seed treatments, or including terms and conditions on the registration for expiration of the use or imposition of use restrictions should use contrary to labeling instructions be reported). This ANPRM initiates the rulemaking process by specifically soliciting public comments and suggestions about the potential FIFRA 3(a) rule and/or other related amendments, as it relates to treated seed and paint products.

D. What are the incremental costs and benefits of this action?

This ANPRM does not impose or propose any requirements, and instead seeks comments and suggestions that will help the Agency identify whether and to what extent there is a potential need for a FIFRA section 3(a) rule and/or other regulatory or administrative action. If EPA decides to propose changes to the regulations, it will conduct the appropriate assessments of the costs and benefits of those changes and provide opportunities for further public comment.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.*

Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.*

When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Background

A. Brief Summary of EPA's Registration Process for Pesticides

Applications for registration of a pesticide may be submitted to EPA and must meet the requirements in FIFRA sections 3(c) and 33. 7 U.S.C. 136a and 136w–8. Those requirements include, among other things, submission of complete labeling of the pesticide, including claims made for the pesticide and instructions on use; complete data in support of that registration request; and requisite fees in support of that application. 7 U.S.C. 136a(c); 7 U.S.C.136a(b); and 7 U.S.C. 136w–8; *see also,* 40 CFR part 152 for application procedures and part 158 for data requirements. FIFRA section 3(c)(4) requires EPA to issue a **Federal Register** notice and opportunity for comment in relation to ''each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern.'' 7 U.S.C. 136a(c)(4). *See also* 40 CFR 152.105.

To grant a pesticide registration, FIFRA requires EPA to consider whether the pesticide meets the FIFRA standard that use of the pesticide has no ''unreasonable adverse effects'' to human health and the environment. 7 U.S.C. 136a(c)(5). FIFRA section 2(bb) defines ''unreasonable adverse effects on the environment'' to mean, among other things, ''any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide'' or ''a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal, Food, Drug, and Cosmetic Act'' (FFDCA). 7 U.S.C. 136(bb). EPA is required to review each pesticide registration every 15 years to determine whether the pesticide continues to satisfy the FIFRA standard for registration. 7 U.S.C. 136a(g) and 40 CFR Part 155, subpart C.

It is a violation under FIFRA to sell or distribute an unregistered pesticide or to use a registered pesticide in a manner inconsistent with its labeling. 7 U.S.C. 136j(a)(1)(A) and 136j(a)(2)(G). FIFRA section 12 does not make it a violation to use an unregistered pesticide. However, under FIFRA section 3(a), EPA may, by regulation, impose limits on the distribution, sale, and use of any pesticide that is not registered ''to the extent necessary to prevent unreasonable adverse effects on the environment,'' and compliance with such regulation is enforceable under FIFRA section 12(a)(2)(S). 7 U.S.C. 136a(a) and 136j(a)(2)(S).

B. Background on the Treated Article or Substance Exemption

FIFRA section 25(b)(2) provides that the Administrator may, by regulation, exempt from the requirements of FIFRA, including the registration requirements, any pesticide which the Administrator determines to be of ''a character which is unnecessary'' to be subject to FIFRA ''in order to carry out the purposes'' of FIFRA. 7 U.S.C. 136w(b)(2). Several exemptions under FIFRA section 25(b)(2) were adopted in 1988 and included a ''treated articles and substances'' exemption at 40 CFR 152.25(a).

The regulation at 40 CFR 152.25 provides that ''the pesticides or classes of pesticides listed in this section have been determined to be of character not requiring regulation under FIFRA and are therefore exempt from all provisions of FIFRA when intended for use, only in the manner specified.'' The regulation in 40 CFR 152.25 identifies the types of pesticides and conditions applicable for an exemption to apply. 40 CFR 152.25(a) identifies treated articles or substances and defines them as ''an article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.''

It has been EPA's longstanding position that FIFRA section 25(b)(2) authorized the 1988 final rule exempting pesticide-treated articles or substances because EPA's assessment of the treating pesticide comprehensively addresses the use of and exposure to the treating pesticide and to the article or substance that is permissibly treated and distributed, sold, and used consistent with labeling instructions. The FIFRA finding to grant the

registration or continue the registration of the pesticide is based on that assessment, which again addresses the risks from use of the treating pesticide and use of the treated article or substance. No new assessment or risk finding is necessary for the exemption to apply and no new FIFRA section 25(b)(2) finding is required for each and every article or substance treated. Rather, once a pesticide is registered under FIFRA for use in treating an article or substance, the only conditions applicable to a determination as to whether the treated article exemption applies to the article or substance treated by that pesticide are those stated in the regulatory text at 40 CFR 152.25(a).

It has also been EPA's longstanding position that treated seed products meeting the regulatory conditions at 40 CFR 152.25(a) are exempt from FIFRA requirements. Those conditions include that a pesticide ''registered for such use'' is used, which EPA has interpreted to require compliance with labeling instructions relating to distribution, sale, and use of the pesticide registered under FIFRA to treat seed and the distribution, sale, and use of the treated seed product itself. If distribution, sale, and/or use of the treating pesticide or treated seed product is not consistent with such labeling for the treating pesticide or treated seed product, then the ''registered for such use'' criterion is not met and the exemption does not apply. For example, if the treating pesticide requires that the treated seed bag tag include specific labeling information and instructions, but such bag tag does not include the required labeling or instructions, the ''registered for such use'' condition is not met. In such a case, the exemption does not apply and the treated seed product must be registered under FIFRA and must comply with other FIFRA requirements, such as the requirement in FIFRA section 7 to register the establishment in which the pesticide is produced and the requirements in FIFRA section 17(c) and 19 CFR 2.110 through 2.117 to file an EPA Notice of Arrival of Pesticides and Devices (EPA Form 3540–1) or its electronic equivalent for importation of treated seed product (Ref. 1). Similarly, if the treated seed product is not used consistent with the instructions on treating pesticide labeling as communicated on the seed bag tag, the condition that a pesticide ''registered for such use'' is not met and use of the treated seed product would be use of an unregistered pesticide. The required labeling information and instructions are helpful to farmers who use the treated seed and may be considered in EPA risk assessments. As a result, compliance with the requirements for such labeling and the instructions relating to distribution, sale, and use may be necessary to protect against unreasonable risks to the environment.

A more thorough discussion of EPA's approach for evaluating pesticides for use in treating seeds, which includes an evaluation of the use of the treated seed product itself, and the treated article exemption is discussed in EPA's Treated Seed Petition Response which is discussed in the next section.

C. Background on the Petition Relating to Treated Seed and EPA's Response

In April 2017, the Center for Food Safety (CFS or the Petitioner) filed a petition with EPA seeking a rulemaking or a formal agency interpretation relating to pesticide treated seed (hereinafter Treated Seed Petition) (Ref. 2). Specifically, CFS petitioned EPA to take the following actions: (1) Amend 40 CFR 152.25(a) to clarify that it does not apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself; (2) Alternatively, publish a final, formal, Agency interpretation in the **Federal Register** stating that EPA interprets the exemption in 40 CFR 152.25(a) not to apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself; and (3) Aggressively enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical.

EPA responded to the petition on September 27, 2022 (hereinafter Treated Seed Petition Response) (Ref. 1). In that response, EPA explained the history of the regulatory treated article exemption, the comprehensive nature of assessments of pesticides that are intended for use in treating seeds which includes assessment of the impact with use of the treated seed, and the regulatory conditions for the article exemption to apply. EPA noted that if the conditions for the exemption are met, the exemption applies; no new assessment or risk finding is necessary and no new FIFRA section 25(b)(2) finding specific to the article or substance treated is required. EPA also noted that it has been reviewing and will continue to review labeling instructions for pesticides registered for seed treatment use(s) in registration and registration review to verify the completeness of these instructions for both use of the treating pesticide and the distribution, sale, and use of the treated seed products. Finally, EPA acknowledged that use of the treated seed product in a manner contrary to labeling instructions is not generally enforceable under FIFRA. As a result, while the Agency did not grant the petition requests, it noted that it intends to issue this ANPRM to seek additional information on pesticide seed treatment, including use and usage information and whether treated seed products are being used contrary to labeling instructions, and to explore the option of issuing a rule pursuant to FIFRA section 3(a) to regulate the use of treated seed products. As explained in the petition response, plant-incorporated protectants (PIPs) are not subject to the treated article exemption for reasons articulated at 40 CFR 174.1 (because the characteristics of PIPs ''distinguish them from traditional chemical pesticides,'' PIPs are subject to ''different regulatory requirements, criteria, and procedures than traditional chemical pesticides''). As a result, PIPs are not within the scope of this ANPRM. For further information, please see docket ID number EPA–HQ–OPP–2018–0805 at *https://www.regulations.gov/docket/EPA-HQ-OPP-2018-0805.*

D. State FIFRA Issues Research and Evaluation Group (SFIREG) Treated Seed Issue Paper

In August 2022, SFIREG provided EPA with the ''Treated Seed Issue Paper'' for consideration and response (Ref. 3). Shortly following the submittal of this issue paper by SFIREG, EPA released the Treated Seed Petition Response discussed in Unit II.C., which addressed many of the issues raised in the SFIREG issue paper in full or in part. In June 2023, the Agency responded to the SFIREG issue paper, based on its understanding of the issues that were raised (Ref. 4). Part of that response included EPA's intention to include in this ANPRM the issues that were raised and to particularly focus on those not fully addressed in the Treated Seed Petition Response. Some of the issues raised in the SFIREG issue paper that are included in this ANPRM include use of treated seed products and available data systems to track the active ingredients used for seed treatments, change in use patterns of other pesticides due to availability of treated seeds, and label language on seed treatment products and treated seed products (*e.g.,* seed bag tags). Other issues raised in the SFIREG issue paper that were addressed in the Treated Seed Petition Response, some of which have

requests for comment discussed in Unit III., include assessments of treated seed and effects to different taxa, including pollinators, non-target terrestrial and aquatic organisms, and human health.

E. Background on Treated Paint

Paint and coating products are often treated with pesticides for a variety of reasons, such as to increase the longevity of the products by controlling microbial contamination of the paint applied to a surface. Pesticide labeling requirements for treated paint or coatings do not currently exist. However, recent EPA risk assessments on paint preservative pesticides suggest that there may be risks of concern for professional painters exposed to treated paint without use of PPE such as respirators when applying paint using a spray method. The concept of adding labeling requirements for treated paint on the paint container has, thus far, only been proposed for one active ingredient (*i.e.,* Diuron Proposed Interim Registration Review Decision Case Number 0046) but is being considered for many other active ingredients that are registered for use as paint preservatives and using the spray method of application. The Agency believes that the proposed labeling requirements for paint containers would help occupational users of paint, particularly those using sprayers to apply the paint, mitigate any potential risks of concern. EPA notes that similar risk mitigation measures are in the process of being implemented in Canada by the Pest Management Regulatory Agency.

III. Request for Comment and Information

A. General

EPA invites public feedback on the questions posed in this document regarding use and usage of treated seed products and whether there are cases of use contrary to treating pesticide or treated seed product (*e.g.,* seed bag tag) labeling instructions. EPA also invites comments on whether the Agency should take action through a potential FIFRA 3(a) rule and conforming amendments and/or other regulatory or administrative action to address concerns with the potential for noncompliance with labeling instructions. EPA is also requesting public feedback regarding similar questions with respect to treated paint. Please provide EPA with your thoughts as well as a rationale supporting your suggestions. If you can, provide examples or describe situations. Commenters are encouraged to present any data or information that should be considered by EPA during its consideration of these issues with treated seed and treated paint products and for the potential development of a section 3(a) rule and/or other regulatory or administrative action. EPA is not seeking comment to this docket on EPA assessments to support any particular registration or registration review decision. Such comments must be timely submitted to the dockets for those actions.

As explained in the Treated Seed Petition Response, EPA's assessments for treating pesticides are based on all reasonably available and reliable information, including exposure assessments based on the treating pesticide labeling instructions defining the maximum amount of active ingredient that may be used on the seed. These assessments and labeling instructions are subject to public comment during the registration and registration review processes. In addition, outside of the registration and registration review processes, EPA recently solicited further public comment on proposed updates to all treated seed labeling on treating pesticide products and on treated seed products, to reduce exposures to non-target organisms, which might include federally listed threatened or endangered species. EPA has updated the labeling language for such products for future active ingredients undergoing registration review in response to comments and in anticipation of seeking further comment in response to this ANPRM. In addition, its public processes under registration and registration review for specific pesticide products intended for use in treating seed, EPA will continue to consider further updates to treated seed product label language to take into account additional public comments and new information, if any submitted.

This ANPRM is a separate effort to consider whether to amend its approach for regulation of treated seed products (*e.g.,* through issuance of a rule pursuant to FIFRA section 3(a) to regulate distribution, sale, and use of treated seed products and/or other regulatory or administrative action).

This ANPRM is also intend to explore the option of adding instructions on the labels of pesticides used to treat paint, similar to the approach take for labeling of treated seed, and/or whether to amend its approach for allowing treated paint to be exempt from FIFRA requirements (*e.g.,* through issuance of a rule pursuant to FIFRA section 3(a) to regulate distribution, sale, and use of treated seed products and/or other regulatory or administrative action).

B. Specific Topics Related to Treated Seed and Paint

EPA is specifically requesting comment and information on the following topics:

- Effectiveness of instructions on treated seed product labeling (*e.g.,* on the seed bag tags) to mitigate potential risks;
- Use, usage, and tracking of treated seed products;
- Management of spilled or excess treated seed;
- Treated paint; and
- Administrative action, amendment of the treated article exemption, and/or FIFRA section 3(a) Rule.

1. *Effectiveness of instructions on treated seed product labeling (e.g., on the seed bag tags) to mitigate potential risks.*

EPA currently is reviewing labeling instructions for pesticides registered for seed treatment use(s) in registration and registration review. EPA intends to ensure that treating pesticide labeling instructions include: (1) the requirement that seed bag tag labeling accompany the treated seed when distributed and sold; (2) that such labeling include specified clear and effective instructions on use of the treated seed, including the name of the active ingredient and pesticide product used (including the EPA product registration number), and instructions on the storage, planting, and/or management of spilled or excess treated seed, as appropriate; and, (3) that the distribution or sale of the treated seed products without such labeling is the distribution or sale of an unregistered pesticide.

The Treated Seed Petition raised a number of issues with the potential for harm from the planting of treated seed or with the planting process used to plant treated seed. The Treated Seed Petition Response discusses each of the issues, including how EPA assessments of the treating pesticide address these issues. The response also discusses the regulatory conditions for application of the treated article exemption and how those conditions apply to treated seed products, including, among other things, the need for use of the treating pesticide and treated seed products to be consistent with the treating pesticide and related seed product labeling instructions. Examples of such labeling are in the document ''Labeling Instructions for Pesticide-Treated Seed and Pesticide-Treated Paint Products'' (referred to as the ''Labeling Instructions'' document from hereon) (Ref. 5), which can be found in the

docket EPA–HQ–OPP–2023–0420. For example, the specified labeling language on storage includes instructions on storing away from food and feedstuffs and not allowing children, pets, or livestock to have access to treated seed. Other instructions on use include, for example, the prohibition on use of the treated seed for food or feed; instructions detailing planting methods or management of spilled or excess seed to ensure reduced risk, for example, to pollinators and aquatic environments; and instructions on managing the potential for dusts generated from the abrasion of treated seed coatings during planting (*i.e.,* dust-off).

EPA is requesting comment on the following:

- Labeling instructions presented in the Labeling Instructions document (Ref. 5) and whether there are any necessary improvements to such language.
- Are the examples of current instructions for storage, planting, and management of treated seed clear, generally achievable, *etc.*?
- Are there other recommendations to increase the clarity of instructions on treated seed product (*i.e.,* seed bag tag labeling) for the end user?
- Are there additional or alternative instructions that would be effective in reducing dust-off?

2. *Use, usage, and tracking of treated seed products.*

EPA's exposure estimates reflect both use and usage information. Use information is focused on the maximum amount of particular pesticide that may be applied based on the treating pesticide labeling instructions (*e.g.,* total active ingredient that may be applied to the seed). Exposure estimates are also based on the modeling parameters for the assessment (*e.g.,* the seeding rate for a particular crop per acre). For FIFRA ecological assessments of seed treatment uses, EPA assumes that the maximum amount of the pesticide is available as if the maximum permitted amount of the pesticide had been directly applied to the soil as shown in the T-Rex User Guide (Ref. 6). The term ''usage'' has been used broadly to refer to documented applications of a pesticide, including information such as actual application rates and timing, and spatial distribution of applications (usually based on survey data) (Ref. 7 and Ref. 8). Usage information is typically used to allow assessments to be more precise as compared to using worst case assumptions (*e.g.,* on the percentage of a particular crop that is treated with every pesticide registered for use on that crop). EPA does not have current and reliable information quantifying the total pounds of active ingredient used to treat seed or the location and the number of acres planted with treated seed. Kynetec USA, the primary source of agricultural usage data for seed treatment in the years 2005–2014, stopped providing seed treatment estimates and supporting use of the existing 2005–2014 estimates in 2015 due to concerns about the reliability of those data (Ref. 7). However, applications of pesticides to treat seed may be generally characterized as common for a wide variety of crop seeds and seed pieces for planting based on agricultural extension services' recommendations and other information. EPA assessments detail the basis for use and usage information and such details are subject to public comment during the registration and registration review processes and the Agency continues to work to identify, investigate, and procure additional sources of usage data for seed treatments. As suitable data are procured and determined to meet EPA data quality standards, they will be integrated into usage analyses to help inform risk assessments (Ref. 9).

The Treated Seed Petition noted the lack of pesticide usage data collected by EPA but acknowledged that one EPA assessment assumed nearly 100% of one crop is treated with the referenced pesticide and in another case identified the percentage of the pesticide use that is on treated seed. In response, EPA acknowledged the lack of usage data but more recently, data from two sources (*i.e.,* Ben Kirk and Kline and Company) were identified, procured, and determined to meet EPA data quality standards. Data from those sources have been evaluated and will be integrated into usage analyses to inform risk assessments as appropriate.

The SFIREG issue paper sought additional information on the general use of treated seed and data systems to track use of active ingredients to treat seed. The SFIREG issue paper also sought more information on the impact of the use of treated seed on the other types of applications such as soil or foliar applications (*i.e.,* replacement and reduction in use of other types of applications). Finally, the SFIREG issue paper noted that there is no clear mechanism to address interstate commerce of treated seed and thus no means for a comprehensive state review of environmental impacts of seeds that could be legally planted in that state. The paper notes that state regulation of treated seed would conflict with the regulatory exemption for treated articles, and thus one state is considering prohibiting use of certain types of treated seed.

EPA is seeking comment on the certain issues summarized below as raised in the SFIREG issue paper and the Treated Seeds Petition.

- Information on the use and usage of treated seed.
- Given the scope of EPA assessments, whether the potential for tracking of treated seed distribution, sale, and/or use would provide any meaningful improvements in the assessment of the risks of pesticides used to treat seeds.
- Are there available data detailing the replacement or reduction of other types of pesticides with increasing use of treated seed, since this issue is of interest to states and other stakeholders? EPA would normally address replacement and use reduction on an individual chemical basis, taking into account alternative control strategies to seed treatment (*e.g.,* application of a pesticide at-plant (soil level) or immediately upon germination (foliar)) when there are risks associated with the treated seed (Ref. 10).
- Are there additional data sets available that may serve to complement the recently acquired data sources (*e.g.,* data that trade organizations might have that can provide a better picture of how much of an active ingredient is used in seed treatment)?
- EPA requests information on the volume of imported treated seed products and whether amending the treated article exemption so that importers of treated seed products must comply with FIFRA section 17(c) and 19 CFR 12.110 through 2.117, including filing an EPA Notice of Arrival of Pesticides and Devices (EPA Form 3540–1) or its electronic equivalent would assist in tracking the import and distribution of treated seed products (*e.g.,* to track compliance with the exemption conditions).
- Should the treated article exemption be amended so that treated seed manufacturers would be subject to FIFRA section 7 registration and reporting requirements (Ref. 11)? Would this information help track use of seed treatment pesticides or provide any helpful treated seed usage information?

3. *Management of spilled or excess treated seed.*

EPA included additional labeling instructions for management of spilled and excess treated seed in the registration review Proposed Interim Decisions (PIDs) and Interim Decisions (IDs) of several chemicals (see for example Ref. 12 and Ref. 13) as appropriate. This labeling included instructions on the collection and burial

of spilled treated seed, incorporation of treated seed into soil, limiting the broadcast planting of treated seed, and proper disposal of excess treated seed. In 2022, EPA requested additional comment on the labeling instructions as part of the ESA Workplan Update (Ref. 14) to reduce the potential for exposures to non-target organisms from spilled treated seed or disposal of excess treated seed, which might include federally listed threatened/endangered species.

Comments on the ESA Workplan Update (Ref. 14) raised concerns with disposal of treated seed, particularly for use in ethanol production. The proposed labeling instructions that are presented in Labeling Instructions document (Ref. 5) are intended to address concerns relating to disposal of treated seed, exposure to wildlife, contamination of ground and surface water, sufficiency of current disposal instructions on both the registered treating pesticide product and treated seed product labeling, and disposal by way of ethanol production (for oil seed crops such as corn and soybeans). The concern regarding disposal of treated seeds stems from the possibility of a buildup of pesticide material as a byproduct of ethanol production.

The Agency previously approved labels for oil seed crops that allowed for the use of excess treated seeds in ethanol production. EPA became aware of the potential for the use of excess, unmarketable treated seeds of oilseed crops in ethanol production and was concerned about the potential for pesticide residues found in the ethanol production by-products getting into food or feed. The byproducts of the process (*e.g.,* wet distiller's grain or spent mash) can be used as livestock feed or applied as fertilizer but may also contain pesticide residues. To mitigate the risk, EPA allowed the use of treated seeds of oilseed crops for ethanol production but with the following conditions: (1) Byproducts are not used for livestock feed; and (2) No measurable residues of pesticide remain in ethanol byproducts that are used in agronomic practice. However, these measures may not be sufficient to protect against pesticide buildup after ethanol production. To address this concern, the Agency's proposed labeling instructions include language to prohibit the use of excess treated seeds for ethanol production (see Ref. 5).

EPA requests comment on the following:

- Are additional instructions for collection of spilled seed needed?
- What is currently done with excess treated seed if not used in a planting season? For example, what do farming operations do with excess seed; can that seed be returned to the distributor or seed company?
- Similarly, what do distributors and seed companies do with excess treated seed that is not sold or delivered to or is returned from farming operations?

4. *Treated paint.*

Paints and coatings are often treated with pesticides for a variety of reasons, such as to increase the longevity of the products by controlling microbial contamination of the paint applied to a surface. Pesticide labeling requirements for treated paint do not currently exist. However, recent EPA risk assessments on paint preservative pesticides suggest that some treated paints may pose risks of concern to professional painters when applying paint using a spray method, without use of PPE such as respirators. The concept of adding labeling requirements for treated paint on the paint container has, thus far, only been proposed for one active ingredient (*i.e.,* Diuron Proposed Interim Registration Review Decision Case Number 0046) but is being considered for many other active ingredients that are registered for use as paint preservatives (Ref. 15). The Agency proposed labeling requirements for paint containers that would help occupational users of paint, particularly those using sprayers to apply the paint, to potentially mitigate the identified risks of concern.

EPA assesses risks to Do-It-Yourself painters as well as professional painters (*i.e.,* those who provide the service of applying paint to the interior and exterior of homes, businesses, other building projects, machinery, and industrial equipment for compensation) from use of treated paint, and such assessments are based on long-standing EPA modeling parameters. An example includes the default value that 5 gallons of paint (applied by a brush or roller) or 50 gallons of paint (applied by airless sprayer) are typically used daily by a professional painter. For Do-It-Yourself painters, the default value is 2 gallons (brush or roller) or 15 gallons (airless sprayer) of paint are typically used daily. EPA has used these values for many years. These values are used to estimate exposure from treated paint. Based on that exposure and the severity of inhalation and dermal hazard of the chemical, EPA determines the level of risk posed by those paints. EPA requests specific comment on the topics discussed further in this unit.

a. *Implementation and enforcement concerns.*

EPA is considering requiring certain treated paint products to include labeling instructions relating to precautionary label language and proper use. See Ref. 5. Distribution and sale of the treated paint products with such instructions would be an exempted treated substance and thus registration of the treated paint would not be required. For the exemption to apply, and similar to treated seed, the registration and labeling for the treating pesticide will make clear that specified instructions and precautionary language must appear on the treated paint labeling. If more than one pesticide is used to treat the paint, the registration and labeling for the treating pesticides will also likewise make clear that the exemption will only apply if the most restrictive label language is used on the paint label. If the appropriate instructions and precautionary language are not on the paint product labeling, the treated paint would not qualify as an exempt treated article, making it an unexempt, unregistered pesticide that may not be sold or distributed under FIFRA section 3 and subject to enforcement under FIFRA section 12(a)(1)(A).

EPA is also considering adding specific use instructions for professional painters based on recent risk assessments for paint preservatives that have identified risks for professional painters. EPA may propose a FIFRA section 3(a) rule to apply to certain treated paint, making certain use instructions enforceable under FIFRA section 12(a)(2)(S). Similar to the discussion on treated seed, other administrative actions may also be considered (*e.g.,* limiting or cancelling use of specific active ingredients to treat paint based on risk assessment).

EPA requests specific comment on the following topics:

- If EPA were to establish label requirements for treated paint products, what should be included to increase the clarity of the labeling and its safe use for the end user and the environment?
- Is there evidence that the lack of label or labeling requirements on treated paint has resulted in harm to human health or the environment? This may include harm experienced by professional painters from use of treated paint, improper disposal of treated paint, *etc.* This evidence could come in the form of work-related treated paint accident reports.
- Would requiring on the treated paint label the EPA registration number for each treating pesticide and the appropriate use instructions relating to painter protection be effective in reducing the identified risk concerns? If not, what additional information or requirements should EPA consider?

• Should the treated article exemption be amended so that paint manufacturing establishments producing pesticide-treated paint would be subject to FIFRA section 7 registration and reporting requirements (Ref. 11)? If so, should the establishment registration number be included on the label of the treated paint? How many paint manufacturers might be subject to such a requirement?

• If EPA were to establish enforceable use requirements for professional painters using treated paint, what additional information or requirements should EPA consider in this rulemaking to ensure effective enforcement? This may include information on additional resources, processes, *etc.* needed by states for enforcement.

b. *Importation.*

As noted previously, the condition in the exemption that the treating pesticide be ''registered for such use'' specifies that the exemption only applies to treated paint that is formulated with a FIFRA-registered pesticide product. EPA requests information on the volume of imported treated paint and whether amending the treated article exemption so that importers of treated paint must comply with FIFRA section 17(c) and 19 CFR 12.110 through 2.117, including filing an EPA Notice of Arrival of Pesticides and Devices (EPA Form 3540–1) or its electronic equivalent would assist in tracking the import and distribution of treated paint (*e.g.,* to track compliance with the exemption conditions).

5. *Administrative action, amendment of the treated article exemption, and/or FIFRA section 3(a) rule.*

EPA's assessments for seed and paint treatment uses are comprehensive, and EPA processes allow for comment on those assessments. As noted in the Treated Seed Petition Response, amending the regulatory exemption for treated articles to require registration of pesticide-treated seed where there is general compliance with labeling instructions for the FIFRA registered pesticides and treated seed products would provide little to no human health or environmental benefits. This is based on the comprehensive nature of EPA assessments for treating pesticides and treated seed and given EPA has no information suggesting that users of treated seed products are distributing, selling, or using the seed products contrary to labeling instructions. This is the same case for other treated articles and substances, including treated paint. However, concerns were raised by the Treated Seed Petition and the SFIREG issue paper regarding a lack of enforceability relating to use of treated seeds contrary to label instructions and possible effects of such use on human health and the environment. The same concerns also apply to treated paint products. Thus, EPA is requesting comment from stakeholders on whether or to what extent there might be use of treated seed and paint products contrary to labeling instructions for the treated seed and paint.

EPA will take into consideration comments and information submitted in response to this ANPRM to determine whether to amend its approach for regulation of treated seed and treated paint (*e.g.,* through issuance of a rule pursuant to FIFRA section 3(a) to regulate distribution, sale, and use of treated seed and paint products and/or other regulatory or administrative action). FIFRA section 3(a) authorizes EPA to limit the distribution, sale, or use of an unregistered pesticide ''[t]o the extent necessary to prevent unreasonable adverse effects on the environment.'' EPA believes a FIFRA section 3(a) rulemaking could be a more efficient and less resource-intensive means to address some of the concerns that have been raised by Petitioner and states relating to use of the treated seed, where there is some indication that compliance with such labeling is in question. Other regulatory approaches could include limiting the scope of the exemption so that some FIFRA requirements would still apply (*e.g.,* requiring seed treatment facilities to identify as establishments). Other administrative approaches could include addressing specific use concerns through further action during registration review for specific active ingredients (*e.g.,* clarifying labeling instructions, further reducing or eliminating use of the treating pesticide for some seed or paint treatments, or including further terms and conditions on the registration for expiration of the use or imposition of use restrictions should use contrary to labeling instructions be reported).

EPA requests comment on the following:

• Is a FIFRA section 3(a) rule and/or other regulatory or administrative action necessary or appropriate to prevent unreasonable adverse effects on human health and the environment, considering the concerns raised regarding enforceability of any particular type of labeling instructions on use of treated seed and paint products? Is a FIFRA section 3(a) rule and/or other regulatory or administrative action the best way of ensuring use consistent with instructions on the treating pesticide labeling relating to use of the treated seed or paint?

• Are there examples of use of treated seed contrary to labeling instructions, and whether adopting a FIFRA section 3(a) rule or the other options noted are the best means of ensuring appropriate use of treated seed?

• Would there be any impacts that might result to states if such a FIFRA section 3(a) rule is finalized? Are there existing tools that would be impacted, or are new ones needed for state investigation and enforcement? For example, state statutes or rules may need to be amended, new standard operating procedures developed, additional personnel hired, or some form of record keeping added.

• Are there specific examples of misuse by seed treatment applicators or from on-farm seed treatments and what type of evidence has been collected to support this claim?

• What are the enforcement measures that are used in regions and individual states for misuse of pesticides and are there barriers to applying such measures to treated articles, such as treated seed and treated paint?

• What are some examples of state statutory authority concerning treated seed and/or paint, and successful enforcement measures that have been exercised regarding treated seed and/or paint?

• What are some considerations, including enforcement considerations, that need to be included in EPA's approach for assessment and management of pesticide-treated seed and paint?

C. Potential Environmental Justice Concerns

Under EPA policy, environmental justice is ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' See *https://www.epa.gov/environmentaljustice.* In addition, Executive Order 12898 (59 FR 7629, February 16, 1994), entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' directs agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority (people of color and/or indigenous

peoples) and low-income populations. EPA has not identified any such disproportionate effects from the issuance of this ANPRM as specified in Executive Order 12898. This ANPRM solicits comments from the public regarding pesticides under the treated article exemption including treated seed and treated paint. The Agency welcomes public input on the consideration of environmental justice concerns in the context of the issues raised in this ANPRM. If and when the Agency proposes regulatory options regarding exemptions under FIFRA or the related procedures, EPA will seek additional input from the public, as appropriate.

1. *Environmental justice concerns for treated seed.*

It is estimated that there are 2.5–3 million agricultural workers in the United States. The Department of Labor conducted a National Agricultural Workers Survey in 2019–2020. In this survey, more than 2,100 farmworkers were interviewed in person. Approximately 78% of those workers identified themselves as Hispanic and 62% said that Spanish was the language in which they were most comfortable conversing. Among U.S.-born farmworkers, 32% were Hispanic. Ten percent of farmworkers were self-identified as indigenous. EPA requests specific comment on the following topic:

- Are there any sources of data that could address whether exposure to treated seeds may be an environmental justice concern (*e.g.,* given the potential for language barriers)?

2. *Environmental justice concerns for treated paint.*

EPA has limited sources of data to address whether there could be disproportionate impact to certain demographics that might be more likely to be exposed to treated paint. The Bureau of Labor Statistics (BLS) data from 2021 include demographics on ''painting workers'' and ''painters and paperhangers.'' For both categories, the BLS data suggest that the majority of workers are Hispanic or Latino. According to 2021 U.S. Census data, Hispanics/Latinos make up 18.9% of the population. However, according to BLS, 32.3% of ''painting workers'' and 59.3% of ''painter and paperhangers'' are Hispanic or Latino. EPA requests specific comment on the following topics:

- Are there any sources of data that could address whether exposure to treated paint may be an environmental justice concern?
- Does either, or both, of the BLS categories (*i.e.,* painting workers; painters and paperhangers) represent the type of painter that may be exposed to treated paint?

D. Potential Impacts on Children's Health

In addition to the statutory obligations in FIFRA and FFDCA to consider children's health in registration decisions, EPA's 2021 Policy on Children's Health (Ref. 16) states that protecting children's health from environmental risks is fundamental to EPA's mission because varying behavioral and physiological characteristics can affect children's exposure and health risks, children's health should be viewed through the lens of a sequence of ''lifestages'' (from conception, infancy, early childhood, and adolescence through until 21 years of age).

Children may be more susceptible to environmental exposures and/or the associated health effects, and therefore more at risk than adults. These risks arise because children generally eat more food, drink more water, and breathe more air relative to their body size than adults do, and consequently may be exposed to relatively higher amounts of contaminants. Normal childhood activity, such as putting hands and objects in mouths, playing on the ground, or crawling, can result in exposures to contaminants that adults do not face. In addition, environmental contaminants may affect children disproportionately because they are still developing; for example, their immune system defenses are not fully developed, and their growing organs are more easily harmed.

The Agency welcomes public comment and information regarding the consideration of potential children's health concerns in the context of the issues raised in this ANPRM. If and when the Agency proposes regulatory options regarding exemptions under FIFRA, other actions or the related procedures, EPA will seek additional input from the public to facilitate the Agency's consideration of potential children's health concerns related to those actions.

IV. Next Steps

EPA intends to review all the comments and information received in response to this ANPRM, as well as previously collected and assembled information, to help determine whether to propose a FIFRA section 3(a) rule or take other regulatory or administrative action to adjust its approach for treated seed or treated paint. In addition to comments received in response to this ANPRM, EPA may seek additional information from states, industry or other stakeholders. Should EPA decide to move forward with changes to the program, the next step would be to identify, develop and evaluate specific options, including whether amendment to the current regulation in 40 CFR 152.25(a) is appropriate, and if so, to develop a proposed rule for public review and comment. During the development of the proposed rule, the Agency may also engage stakeholders or provide other opportunities for public engagement and comment before issuing a final action.

V. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these references and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the reference is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. United States Environmental Protection Agency (USEPA). 2022. EPA Response to the April 2017 Petition from Center for Food Safety and Others Relating to EPA Regulation of Pesticide-Treated Seed. September 27, 2022. *https://www.regulations.gov/document/EPA–HQ-OPP-2018-0805-0104.*
2. Center for Food Safety (CFS) *et al.* 2017. Citizen Petition to the United States Environmental Protection Agency. April 26, 2017. *https://www.regulations.gov/document/EPA-HQ-OPP-2018-0805-0002*. **Federal Register**. 83 FR 66260, December 26, 2018 (FRL–9987–54).
3. SFIREG (State FIFRA Issues Research and Evaluation Group). 2022. SFIREG Treated Seed Regulation Issue Paper. August 31, 2022.
4. USEPA. 2023. EPA Response to 08/31/2022—(State FIFRA Issues Research and Evaluation Group SFIREG) Treated Seed Issue Paper. June 28, 2023.
5. USEPA. 2023. Labeling Instructions for Pesticide-Treated Seed and Pesticide-Treated Paint Products. September 2023. *https://www.regulations.gov* (under Docket ID No. EPA–HQ–OPP–2023–0420).
6. USEPA. 2012. T–REX Version 1.5 User's Guide for Calculating Pesticide Residues on Avian and Mammalian Food Items. March 22, 2012. *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/t-rex-version-15-users-guide-calculating-pesticide#Section2_1.*
7. USEPA. 2019. Assessment of Usage, Benefits, and Impacts of Potential Mitigation in Stone Fruit Production for Four Nitroguanidine Neonicotinoid Insecticides (Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam). December 6, 2019. *https://*

www.regulations.gov/document/EPA-HQ-OPP-2011-0865-1178.
8. USEPA. 2020. Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides. March 12, 2020. *https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional#:~:text=The%20Revised%20Method%20for%20National,to%20develop%20BEs%20for%20pesticides.*
9. USEPA 2022. Response to Public Comments Received on Draft Biological Evaluations for Imidacloprid, Thiamethoxam, and Clothianidin. June 2022. *https://www3.epa.gov/pesticides/nas/final/cloth-imi-thixam-rtc.docx.*
10. USEPA. 2018. Benefits and Impacts of Potential Mitigation for Neonicotinoid Seed Treatments on Small Grains, Vegetables, and Sugarbeet Crops. August 30, 2018. *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1622.*
11. USEPA. 2022. Pesticide Establishment Registration and Reporting. November 30, 2022. *https://www.epa.gov/compliance/establishment-registration-and-reporting.*
12. USEPA. 2022. Tebuconazole Proposed Interim Registration Review Decision Case Number 7004. June 30, 2022. *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0378-0095.*
13. USEPA. 2021. Triticonazole Interim Registration Decision Case Number 7036. March 17, 2021. *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0602-0039.*
14. USEPA. 2022. ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions. November 2022. *https://www.epa.gov/endangered-species/epas-workplan-and-progress-toward-better-protections-endangered-species.*
15. USEPA. 2022. Diuron Proposed Interim Registration Review Decision Case Number 0046. April 2, 2022. *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0077-0065.*
16. USEPA. 2021. 2021 Policy on Children's Health. October 5, 2021. *https://www.epa.gov/system/files/documents/2021-10/2021-policy-on-childrens-health.pdf.*

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to a requirement for Executive Order 12866 review.

B. Other Regulatory Assessment Requirements

Because this action does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various other review requirements in statutes and Executive Orders that apply when an agency imposes requirements do not apply to this ANPRM. Should EPA subsequently determine to pursue a rulemaking, EPA will address the requirements in the statutes and Executive Orders as applicable to that rulemaking.

Nevertheless, the Agency welcomes comments and/or information that would help the Agency to assess any of the following:

- Potential economic impacts of a rulemaking on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*);
- Potential impacts on Federal, state, or local governments pursuant to the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538);
- Potential federalism implications pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, November 2, 1999);
- Potential Tribal implications pursuant to Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000);
- As discussed in Unit III.C., potential human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994);
- As discussed in Unit III.D., potential disproportionate environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997);
- Potential availability of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272).
- Potential energy effects pursuant to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001); and
- Potential impacts in terms of costs and burdens associated with regulation options that the Agency may consider in developing a proposed rulemaking or other requirements, including potential activities and burdens associated with potential paperwork burdens pursuant to the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

The Agency will consider such comments and information in developing options as it considers appropriate steps to address any applicable requirements.

List of Subjects in 40 CFR Part 152

Administrative practice and procedure; Agricultural commodities; Environmental protection; Exemptions from pesticide regulation; Pesticides and pests; Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2023–0106; FF09E21000 FXES11130900000234]

Endangered and Threatened Wildlife and Plants; 90-Day Findings for Two Petitions To Reclassify the West Indian Manatee

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notification of petition findings and initiation of status review.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce two 90-day findings on petitions to reclassify the West Indian manatee (*Trichechus manatus*), or populations thereof, under the Endangered Species Act of 1973, as amended (Act). Two valid subspecies of the West Indian manatee, the Florida manatee (*Trichechus manatus latirostris*) and Antillean manatee (*Trichechus manatus manatus*), are currently protected under the Act as part of the threatened West Indian manatee species-level listing. One petition requests the Puerto Rico population of the Antillean manatee be listed as an endangered distinct population segment (DPS) and critical habitat be designated for this entity under the Act. The second petition

requests to reclassify the West Indian manatee, including its subspecies the Antillean manatee and Florida manatee, as endangered species under the Act. Based on our review, we find that the petitions present substantial scientific or commercial information indicating that the petitioned actions may be warranted. Therefore, with the publication of this document, we announce that we plan to initiate a status review to determine whether the petitioned actions are warranted. To ensure that the status review is comprehensive, we are requesting new scientific and commercial data and other information regarding the West Indian manatee throughout its range, including information specific to the Puerto Rico population of Antillean manatee, and factors that may affect their status. Based on the status review, we will issue a 12-month petition finding, which will address whether or not the petitioned actions are warranted, in accordance with the Act.

DATES: The findings announced in this document were made on October 12, 2023.

ADDRESSES:

Supporting documents: A summary of the basis for the petition findings contained in this document is available on *https://www.regulations.gov* in Docket No. FWS–R4–ES–2023–0106. In addition, this supporting information is available by contacting the person specified in **FOR FURTHER INFORMATION CONTACT**.

Status reviews: If you have new scientific or commercial data or other information concerning the status of, or threats to, the West Indian manatee, the Puerto Rico population of Antillean manatee, or their habitats, particularly new information available since our April 5, 2017, reclassification (April 5, 2017; 82 FR 16668), please provide those data or information by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R4–ES–2023–0106, which is the docket number for this action. Then, click on the ''Search'' button. After finding the correct document, you may submit information by clicking on ''Comment.'' If your information will fit in the provided comment box, please use this feature of *https://www.regulations.gov,* as it is most compatible with our information review procedures. If you attach your information as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.

(2) *By hard* copy: Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R4–ES–2023–0106, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send information only by the methods described above. Any information we receive during the course of our status review will be considered, and we will post all information we receive on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us.

FOR FURTHER INFORMATION CONTACT: Nicole Rankin, Division of Conservation and Classification Manager, telephone: 404–679–7089, email: *Nicole_Rankin@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Information Submitted for a Status Review

You may submit your comments and materials concerning the status of, or threats to, the West Indian manatee, its subspecies or populations, including the Puerto Rico population of Antillean manatee, or their habitats, by one of the methods listed above in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**. Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing these findings, will be available for public inspection on *https://www.regulations.gov.*

Background

Section 4 of the Act (16 U.S.C. 1533 *et seq.*) and its implementing regulations in title 50 of the Code of Federal Regulations (50 CFR part 424) set forth the procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants (Lists) in 50 CFR part 17. Section 4(b)(3)(A) of the Act requires that we make a finding on whether a petition to add a species to the Lists (*i.e.,* ''list'' a species), remove a species from the Lists (*i.e.,* ''delist'' a species), or change a listed species' status from endangered to threatened or from threatened to endangered (*i.e.,* ''reclassify'' a species) presents substantial scientific or commercial information indicating that the petitioned action may be warranted. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition and publish the finding promptly in the **Federal Register**.

Our regulations establish that substantial scientific or commercial information with regard to a 90-day petition finding refers to credible scientific or commercial information in support of the petition's claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted (50 CFR 424.14(h)(1)(i)).

A species may be determined to be an endangered species or a threatened species because of one or more of the five factors described in section 4(a)(1) of the Act (16 U.S.C. 1533(a)(1)). The five factors are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range (Factor A);

(b) Overutilization for commercial, recreational, scientific, or educational purposes (Factor B);

(c) Disease or predation (Factor C);

(d) The inadequacy of existing regulatory mechanisms (Factor D); and

(e) Other natural or manmade factors affecting its continued existence (Factor E).

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to, or are reasonably likely to, affect individuals of a species negatively. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition, or the action or condition itself. However, the mere identification of any threat(s) may not be sufficient to compel a finding that the information in the petition is substantial information indicating that the petitioned action may be warranted. The information presented in a petition must include evidence sufficient to suggest that these threats may be affecting the species to the point that the species may meet the definition of an endangered species or threatened species under the Act.

If we find that a petition presents such information, our subsequent status review will evaluate all identified threats by considering the individual-, population-, and species-level effects and the expected response by the species. We will evaluate individual threats and their expected effects on the species, then analyze the cumulative effect of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that are expected to have positive effects on the species—such as any existing regulatory mechanisms or conservation efforts that may ameliorate threats. It is only after conducting this cumulative analysis of threats and the actions that may ameliorate them, and the expected effect on the species now and in the foreseeable future, that we can determine whether the species meets the definition of an endangered species or threatened species under the Act. If we find that a petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, the Act requires that we promptly commence a review of the status of the species, and we will subsequently complete a status review in accordance with our prioritization methodology for 12-month findings (81 FR 49248; July 27, 2016).

We note that designating critical habitat is not a petitionable action under the Act. Petitions to designate critical habitat (for species without existing critical habitat, including a potential DPS of the Puerto Rico population of Antillean manatee) are reviewed under the Administrative Procedure Act (5 U.S.C. 1531 *et seq.*) and are not addressed in this finding (see 50 CFR 424.14(j)). To the maximum extent prudent and determinable, any proposed critical habitat will be addressed concurrently with a proposed rule to list a species, if applicable.

Species and Range

The West Indian manatee (*Trichechus manatus*) is currently listed on the List of Endangered and Threatened Wildlife at 50 CFR 17.11(h) as a threatened species under the Act (April 5, 2017; 82 FR 16668). The West Indian manatee includes two valid subspecies, the Florida manatee (*Trichechus manatus latirostris*) and Antillean manatee (*Trichechus manatus manatus*). The range of the Florida manatee includes the U.S. Atlantic and Gulf of Mexico coasts, as well as northern portions of the Caribbean, from the Bahamas to Turks and Caicos. The Antillean manatee is found in the southern portions of the Caribbean, including Cuba, Hispaniola, Puerto Rico, Virgin Islands, Cayman Islands, and Jamaica; in Central America from Mexico's southeast Caribbean coast to the Caribbean coast of Panama; Trinidad and Tobago; and south to Brazil's Atlantic coastline.

History of the Petitions Received

On October 21, 2021, we received a petition from Julio C. Colón requesting that the Puerto Rico population of the Antillean manatee be listed as an endangered distinct population segment (DPS) and that critical habitat be designated for this entity under the Act. On November 21, 2022, we received a petition from the Center for Biological Diversity, Brooks McCormick Jr. Animal Law & Policy Program at Harvard Law School, Miami Waterkeeper, Save the Manatee Club, and Frank S. González García requesting that the West Indian manatee, including its subspecies Florida manatee and Antillean manatee, be reclassified as endangered. Both petitions clearly identified themselves as such and included the requisite identification information for the petitioner, required at 50 CFR 424.14(c). This finding addresses both of those petitions.

Summary of Petition Findings

Evaluation of a Petition To Designate and Reclassify (Uplist) the Puerto Rico Population of Antillean Manatee

Because the West Indian manatee includes two recognized subspecies, the Florida manatee (*Trichechus manatus latirostris*) and the Antillean manatee (*Trichechus manatus manatus*), the Puerto Rico population of the Antillean manatee is currently protected under the Act as part of the threatened West Indian manatee species-level listing. Julio C. Colón's petition requests that we determine the Puerto Rico population of the Antillean manatee is a DPS, uplist it as an endangered species, and designate critical habitat for the DPS under the Act. We find that the petition presents substantial information that the Puerto Rico population of Antillean manatee may qualify as a DPS. Additionally, we find that the petition presents substantial information that boat collisions (Factor E) and low genetic diversity and isolation (Factor E) may be threats to the Puerto Rico manatee population such that the population may meet the definition of an endangered species under the Act. Therefore, we find that the petition presents substantial information that the petitioned action, identifying and then reclassifying as endangered a Puerto Rico DPS, may be warranted, and we will commence a status review to determine if the action is warranted. During our 12-month status review, if we determine the Puerto Rico manatee population is a DPS, we will fully evaluate all relevant threats and conservation actions in detail pursuant to the Act's requirement to review the best scientific and commercial information available to support a finding that the Puerto Rico DPS is in danger of extinction throughout all or a significant portion of its range.

Evaluation of a Petition To Reclassify (Uplist) the West Indian Manatee and Subspecies Florida Manatee and Antillean Manatee

The petition from the Center for Biological Diversity, Brooks McCormick Jr. Animal Law & Policy Program at Harvard Law School, Miami Waterkeeper, Save the Manatee Club, and Frank S. González García requests that we reclassify the West Indian manatee, including its subspecies Florida manatee and Antillean manatee, as an endangered species under the Act. We find the petition presents substantial information that seagrass loss (Factor A) may be a threat to the species such that it may meet the definition of an endangered species under the Act. Therefore, we find that the petition presents substantial information that the petitioned action, reclassifying the West Indian manatee as endangered, may be warranted and we will commence a status review to determine if the action is warranted.

The petition also presented information suggesting other activities may be threats to the West Indian manatee, including loss of warm-water refugia, loss of freshwater access, coastal development, and boating and recreational disturbance (Factor A); harassment (Factor B); bacterial infections (Factor C); and boat strikes, marine debris, contaminants, invasive species, and climate change (Factor E). Our status review will evaluate all relevant threats and conservation actions in detail based on the best scientific and commercial data available, including whether these threats towards the listed or listable entities may be ameliorated or exacerbated by any existing regulatory mechanisms or conservation efforts to support a finding that the West Indian manatee, Florida manatee, or Antillean manatee is in danger of extinction throughout all or a significant portion of its range.

Evaluation of Information Summary and Finding

We reviewed the petitions, sources cited in the petitions, and other readily available information. We considered the factors under section 4(a)(1) of the Act and assessed the effect that the threats identified within the factors may have on the Puerto Rico population of Antillean manatee and the West Indian manatee now and in the foreseeable future. We also considered existing regulatory mechanisms or conservation efforts that may ameliorate, reduce, or exacerbate the threats. Based on our review of the petitions and readily available information regarding boat collisions, genetic diversity loss, and seagrass loss, we find that these two petitions present credible and substantial information that the petitioned actions may be warranted. We will fully evaluate these and all other potential threats for the listed and listable entities, as well as the validity of the Puerto Rico DPS, in detail based on the best scientific and commercial data available when we conduct a status assessment and make the 12-month findings.

In accordance with the requirements of the statute, our 12-month findings on these two petitions to identify and reclassify a DPS in Puerto Rico, as well as reclassify (uplist) the West Indian manatee and its subspecies, the Florida manatee and Antillean manatee, will be based upon the best scientific and commercial data available and will not be limited to the information presented in the petitions. Similarly, if we make one or more ''warranted'' 12-month findings, we may identify a DPS in that finding based on the best scientific and commercial data available; we will not be limited to the possible DPS described in the petition. If we do identify and propose to uplist a DPS, we will consider that proposal in the context of the ongoing recovery for the rest of the population in the larger currently listed entity.

The basis for our finding on these petitions, and other information regarding our review of the petitions, including the 2017 reclassification and 2007 5-year status review, can be found at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2023–0106 under the Supporting & Related Material section.

Conclusion

On the basis of our evaluation of the information presented in the petitions under sections 4(b)(3)(A) and 4(b)(3)(D)(i) of the Act, we have determined that the two petitions summarized above for the Puerto Rico population of Antillean manatee, as well as the West Indian manatee, present substantial scientific or commercial information indicating that the petitioned actions may be warranted. We are, therefore, initiating a status review of the West Indian manatee rangewide. This status review will include a determination on whether a Puerto Rico DPS for the Antillean manatee has the same or a different status than the Antillean manatee rangewide. This status review will determine whether the petitioned actions are warranted under the Act. At the conclusion of the status review, we will issue a finding, in accordance with section 4(b)(3)(B) of the Act, as to whether the petitioned actions are not warranted, warranted, or warranted but precluded by pending proposals to determine whether other species are an endangered or threatened species.

Authors

The primary authors of this document are staff members of the Division of Conservation and Classification, Ecological Services Program, U.S. Fish and Wildlife Service.

Authority

The authority for these actions is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Janine Velasco,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2023–21674 Filed 10–11–23; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 88, No. 196
Thursday, October 12, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Interagency Generic Clearance for Federal Land Management Agencies Collaborative Visitor Surveys on Recreation and Transportation Related Programs and Systems

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking public comment on reapproval of a currently approved information collection request, *Interagency Generic Clearance for Federal Land Management Agencies Collaborative Visitor Surveys on Recreation and Transportation Related Programs and Systems.*

DATES: Comments must be received in writing by December 11, 2023.

ADDRESSES: Comments concerning this notice should be addressed to Kenli Kim via mail at USDA Forest Service, Yates Building, 201 14th Street SW, Washington, DC 20520 or email at *kenli.kim@usda.gov* or to Nicholas Grisham via mail at Transportation Systems Planner, U.S. Department of Transportation, Federal Highway Administration, Office of Federal Lands Highway, 610 East 5th Street, Vancouver, WA 98661 or email at *nicholas.grisham@dot.gov*.

All timely comments, including names and addresses, will be placed in the record and will be available for public inspection and copying. The public may inspect comments received at USDA Forest Service, Yates Building, 201 14th Street SW, Washington, DC 20520, during normal business hours. Visitors are encouraged to call ahead to 202–205–0925 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Kenli Kim, USDA Forest Service, *kenli.kim@usda.gov* or 202–205–0925, or Nicholas Grisham, U.S. Department of Transportation, *nicholas.grisham@dot.gov* or 202–839–1409.

Individuals who use telecommunication devices for the hearing impaired (TDD) may call the Federal Relay Service at 800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title: Interagency Generic Clearance for Federal Land Management Agencies Collaborative Visitor Surveys on Recreation and Transportation Related Programs and Systems.

OMB Number: 0596–0236.

Expiration Date of Approval: March 31, 2024.

Type of Request: Reapproval of a currently approved information collection request.

Abstract: Federal land management agencies (FLMAs) need to acquire visitor and user feedback about site- and area-specific recreational services and facilities and supporting road, trail, and other transportation programs and systems. FLMAs include but are not limited to the USDA Forest Service; U.S. Department of the Interior National Park Service, Bureau of Land Management, U.S. Fish and Wildlife Service, Bureau of Reclamation, U.S. Geological Survey, and Presidio Trust; and U.S. Army Corps of Engineers.

Visitor feedback allows the FLMAs to enhance customer service by establishing and revising objectives for FLMA recreational services and facilities and recreation-related transportation programs and systems; inform FLMA land use plans; and facilitate interagency coordination across FLMA jurisdictions. This feedback augments the ability of FLMAs to meet the recreational needs of the public and more effectively utilize the resources under FLMA management. In addition, this generic, interagency information collection request saves visitor and agency time and costs by allowing multiple FLMAs in an area to work jointly on data collection. The information collected may also help FLMAs respond to queries from the public, Congressional staffs, the media, and transportation and recreation organizations.

The authorities for the FLMAs to conduct public surveys on recreation and supporting transportation programs and systems include:

- Forest Service Organic Administration Act of 1897.
- Forest Service Multiple Use–Sustained Yield Act.
- National Park Service Act of 1916.
- National Wildlife Refuge System Administration Act of 1966.
- National Wildlife Refuge System Centennial Act.
- Federal Land Policy and Management Act of 1976.
- Government Performance and Results Act of 1993.

Respondents include visitors and potential visitors to FLMA-managed lands and residents of communities in or near those lands, as well as state, local, or Tribal agency staff who are involved with public land management and businesses operating on or near FLMA-managed lands. Many of the FLMA information collections may be similar in terms of the populations surveyed, types of questions asked, research methods, and data applications. The information collection may occur at one location, several locations, across FLMA units, across regions, or nationally and may be multi-jurisdictional at any of these levels. The information collection may occur once, multiple times over a short time period, or periodically over a long period. Individual, organizational, agency, or business feedback could be collected through facilitated focus groups, in-person or telephonic interviews, or electronic or handwritten comment cards or questionnaires. Potential participants may be contacted at pertinent sites, including FLMA access points, or pre- or post-visit.

In general, questions relate to recreational use of one or more specific locations on FLMA-managed lands and may address one or more of the following:

- Mobility and access, such as different transportation modes used to access sites; satisfaction with transportation-related services and facilities; use and satisfaction with traveler information; reasons for non-visitation.
- Resource management, such as support for different management approaches.
- Safety, for example, safety-related incidents that have occurred.
- Environment, including for example visitor priorities with respect to natural and cultural resources and perceptions related to sound.

• Economic development, such as the amount of money visitors spend in an area.
• Trip characteristics, for example, length of trip and trip purpose, activities, and destinations.
• Visitor or user demographics and use data, such as city and state of residence, age group, gender, race, and number of people or vehicles in a party.

All results are aggregated so that specific responses cannot be connected to specific respondents. If any names, addresses, or telephone numbers are collected, FLMAs will not store that information with responses. Contact information will be purged from FLMAs' files once data collections are completed.

Participation in the FLMA surveys, interviews, focus groups, and other data collections under this information collection is strictly voluntary. The information may be collected and analyzed by FLMA personnel, private contractors, other federal agencies, or universities or other educational institutions conducting the information collection on behalf of the FLMAs. All results will be aggregated so specific responses cannot be connected to specific respondents.

Without coordinated information collections on recreation and supporting transportation programs and systems on federal land, the FLMAs will lack the information necessary to identify and implement improvements in recreational services and facilities and supporting transportation programs and systems that address public needs, protect federal land and resources, and enhance the visitor experience. These information collections will become more important as demand for access to FLMA recreation sites and opportunities continues to grow.

Estimated Annual Burden per Respondent: 0.35 hour for surveys, 1.5 hours for focus groups, 1 hour for interviews, and 0.05 hour for comment cards.

Type of Respondents: Individuals and households, businesses and non-profit organizations, and state, local, and Tribal governments.

Estimated Annual Number of Respondents: 50,000.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 8,000 hours.

Comment Is Invited

Comment is invited on (1) whether this information collection request is necessary for the stated purposes and the proper performance of the functions of the FLMAs, including whether the information collected will have practical or scientific utility; (2) the accuracy of the Forest Service's estimate of the burden of the information collection request, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection request on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request for Office of Management and Budget approval.

David Lytle,

Deputy Chief, Research and Development.

[FR Doc. 2023–22459 Filed 10–11–23; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Services Surveys: BE–140, Benchmark Survey of Insurance Transactions by U.S. Insurance Companies With Foreign Persons

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance, in accordance with the Paperwork Reduction Act of 1995 (PRA) on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on July 19, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis, Department of Commerce.

OMB Control Number: 0608–0073.

Form Number(s): BE–140.

Type of Request: Regular submission. Reinstatement with change of a previously approved collection.

Estimated Number of Respondents: 1,300 annually (1,000 reporting mandatory data and 300 that would file exemption claims or voluntary responses).

Estimated Time per Response: 9 hours is the average for the 600 respondents filing data by country and affiliation, 2 hours for the 400 respondents filing data by transaction type only, and 1 hour for those filing an exemption claim or other response. Hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 6,500.

Needs and Uses: The data are needed to monitor U.S. trade in insurance services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the trade in insurance services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

Affected Public: Business or other for-profit organizations.

Frequency: Every fifth year, for reporting years ending in ''3'' and ''8''.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0608–0073.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary of Economic Affairs, Commerce Department.

[FR Doc. 2023–22576 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–39–2023]

Foreign-Trade Zone (FTZ) 121; Authorization of Production Activity; GE Vernova Operations, LLC; (Turbines and Generators); Schenectady, New York

On June 8, 2023, GE Vernova Operations, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 121, in Schenectady, New York.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 39400, June 16, 2023). On October 6, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: October 6, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–22571 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–38–2023]

Foreign-Trade Zone (FTZ) 163; Authorization of Production Activity; Puerto Rico Steel Products Corporation; (Construction and Fencing Products); Coto Laurel, Puerto Rico

On June 8, 2023, Puerto Rico Steel Products Corporation submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 163L, in Coto Laurel, Puerto Rico.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 38811, June 14, 2023). On October 6, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: October 6, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–22572 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–40–2023]

Foreign-Trade Zone (FTZ) 255; Authorization of Production Activity; Lenox Corporation; (Kitchenware, Tableware, Home Décor Sets); Hagerstown, Maryland

On June 8, 2023, the Board of County Commissioners of Washington County, Maryland, grantee of FTZ 255, submitted a notification of proposed production activity to the FTZ Board on behalf of Lenox Corporation, within FTZ 255, in Hagerstown, Maryland.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 39823, June 20, 2023). On October 6, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: October 6, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–22573 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–53–2023]

Foreign-Trade Zone 124; Application for Expansion of Subzone 124A; Valero Refining—New Orleans L.L.C.; Destrehan, Louisiana

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Port of South Louisiana, grantee of FTZ 124, requesting an expansion of Subzone 124A on behalf of Valero Refining—New Orleans L.L.C. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on October 5, 2023.

The applicant is requesting authority to expand Subzone 124A to include a new site located at 11842 River Road in St. Rose (Site 2, 2.63 acres). No authorization for additional production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is November 21, 2023. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 6, 2023.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov.*

Dated: October 5, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–22484 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–869]

Certain New Pneumatic Off-the-Road Tires From India: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that certain producers/exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR) March 1, 2021, through February 28, 2022.

DATES: Applicable October 12, 2023.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian or Caroline Carroll, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6412 or (202) 482–4948, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 6, 2023, Commerce published the *Preliminary Results.*[1] On June 26, 2023, Commerce extended the time period for issuing the final results of this review until October 3, 2023.[2] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3] Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The merchandise subject to the *Order* is certain new pneumatic off-the-road tires, which are tires with an off road tires size designation.[5] The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.20.1025, 4011.20.1035, 4011.20.5030, 4011.20.5050, 4011.70.0010, 4011.62.0000, 4011.80.1010, 4011.80.1020, 4011.90.1050, 4011.70.0050, 4011.80.2010, 4011.80.8010, 4011.80.2020, 4011.80.8020, 8431.49.9038, 8431.49.9090, 8709.90.0020, and 8716.90.1020. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.90.2050, 4011.90.8050, 8424.90.9080, 8431.20.0000, 8431.39.0010, 8431.49.1090, 8431.49.9030, 8432.90.0020, 8432.90.0040, 8432.90.0050, 8432.90.0060, 8432.90.0081, 8433.90.5010, 8503.00.9560, 8708.70.0500, 8708.70.2500, 8708.70.4530, 8716.90.5035, 8716.90.5056 and 8716.90.5059. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice in Appendix I. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain changes to the margin calculations for ATC and ATF.[6]

Rates for Companies Not Selected for Individual Examination

Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance for calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we calculated weighted-average dumping margins of 2.29 percent and 8.57 percent for ATC and ATF, respectively. With two respondents under individual examination, Commerce normally calculates: (A) a weighted-average of the estimated dumping rates calculated for the examined respondents; (B) a simple average of the estimated dumping rates calculated for the examined respondents; and (C) a weighted-average of the estimated dumping rates calculated for the examined respondents using each company's publicly-ranged U.S. sale values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters.[7]

Consistent with our practice, we have determined that 2.56 percent, which is the weighted average of ATC and ATF's margins based on publicly ranged data, will be assigned to the non-examined companies under section 735(c)(5)(A) of the Act.[8] These companies are listed in Appendix II.

Final Results of Review

As a result of this review, we determine the following estimated weighted-average dumping margins for the period March 1, 2021, through February 28, 2022:

Producer or exporter	Weighted-average dumping margin (percent)
ATC Tires Pvt. Ltd	2.29
Asian Tire Factory Ltd	8.57
Companies Not Selected for Individual Review [9]	2.56

Disclosure

Commerce intends to disclose the calculations performed for ATC and ATF in connection with these final results to interested parties within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), because ATC reported the entered value of its U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. ATF did not report the actual entered value for its U.S. sales; thus, we calculated importer-specific per-unit duty assessment rates by aggregating the total amount of

[1] *See Certain New Pneumatic Off-the-Road Tires from India: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 20471 (April 6, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of Antidumping Duty Administrative Review; 2021–2022,'' dated June 26, 2023.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2021–2022 Administrative Review of the Antidumping Duty Order on Certain New Pneumatic Off-the-Road Tires from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Certain Now Pneumatic Off-the-Road Tires from India: Antidumping Duly Order,* 82 FR 12553 (March 6, 2017) (*Order*).

[5] For a complete description of the scope of the *Order, see Preliminary Results* PDM.

[6] For a full description of changes, *see* Issues and Decision Memorandum.

[7] *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

[8] *See* Memorandum, ''Calculation of the Cash Deposit Rate for Non-Selected Companies,'' dated concurrently with this notice.

[9] The exporters or producers not selected for individual review are listed in Appendix II.

antidumping duties calculated for the examined sales and dividing this amount by the total quantity of those sales. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies not selected for individual review, we used an assessment rate based on the weighted average of the cash deposit rates calculated for ATC and ATF. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for the future deposits of estimated duties where applicable.[10]

Commerce's ''automatic assessment'' practice will apply to entries of subject merchandise during the POR produced by ATC or ATF for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies covered in this review will be equal to the weighted-average dumping margin that is established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the cash deposit rate established for the most recently completed segment for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be zero percent, the all-others rate established in the LTFV investigation.[11] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: October 3, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Issues and Decision Memorandum

Appendix II—List of Companies Not Selected for Individual Examination Receiving the Review-Specific Rate

1. Apollo Tyres Ltd.
2. Balkrishna Industries Ltd.[12]
3. Cavendish Industries Ltd.
4. CEAT Ltd.
5. Celite Tyre Corporation [13]
6. Emerald Resilient Tyre Manufacturer
7. Forech India Private Limited
8. HRI Tires India
9. Innovative Tyres & Tubes Limited

[10] *See* section 751(a)(2)(C) of the Act.

[11] *See Order,* 82 FR at 12554 (the dumping margin of 3.67 percent assigned to all other producers/exporters was adjusted for export subsidies found in the companion countervailing duty investigation).

[12] Subject merchandise produced and exported by Balkrishna Industries Ltd. (BKT) was excluded from the *Order. See Certain New Pneumatic Off-the-Road Tires from India: Notice of Correction to Antidumping Duty Order,* 82 FR 25598 (June 2, 2017). Accordingly, BKT is only covered by this administrative review for subject merchandise produced in India where BKT acted as either the manufacturer or exporter (but not both)

[13] The name of this company was incorrectly listed as Celle Tyre Corporation in the *Preliminary Results. See Preliminary Results,* 88 FR at 20473.

10. JK Tyres and Industries Ltd.
11. K.R.M. Tyres
12. M/S. Caroline Furnishers Pvt Ltd.
13. Mahansaria Tyres Private Limited
14. MRF Limited
15. MRL Tyres Limited (Malhotra Rubbers Ltd.)
16. OTR Laminated Tyres (I) Pvt. Ltd.
17. Rubberman Enterprises Pvt. Ltd.
18. Speedways Rubber Company
19. Sun Tyres & Wheel Systems
20. Sundaram Industries Private Limited
21. Superking Manufacturers (Tyre) Pvt., Ltd.
22. TVS Srichakra Limited

[FR Doc. 2023–22452 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–121]

Difluoromethane From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Partial Rescission; 2020–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that the sole mandatory respondent under review, Taizhou Qingsong Refrigerant New Material Co., Ltd./Taixing Meilan New Materials Co., Ltd. (collectively, Qingsong), made sales of subject merchandise at prices below normal value during the period of review (POR) August 27, 2020, through February 28, 2022. Additionally, we are rescinding this review with respect to Zhejiang Sanmei Chemical Ind. Co., Ltd. (Zhejiang Sanmei).

DATES: Applicable October 12, 2023.

FOR FURTHER INFORMATION CONTACT: Paul Gill, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5673.

SUPPLEMENTARY INFORMATION:

Background

On April 6, 2023, Commerce published the *Preliminary Results*.[1] On June 30, 2023, we extended the deadline for these final results to October 3, 2023.[2] For a complete description of the events that occurred subsequent to the *Preliminary Results, see* the Issues and Decision Memorandum.[3] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The merchandise covered by the *Order* is difluoromethane (R–32), or its chemical equivalent, regardless of form, type, or purity level.[5] R–32 is classified under Harmonized Tariff Schedule of the United States (HTSUS) subheading 2903.39.2035. Other merchandise subject to the scope may be classified under 2903.39.2045 and 3824.78.0020. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Analysis of Comments Received

We addressed all the issues raised in the case and rebuttal briefs in the Issues and Decision Memorandum. A list of the issues that parties raised is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* we made certain changes to the margin calculations for Qingsong.[6]

Partial Rescission

In the *Preliminary Results,* we notified parties of our intent to rescind this administrative review for Zhejiang Sanmei because it did not have any reviewable entries during the POR.[7] Because we continue to find that the record does not contain any evidence of reviewable entries for Zhejiang Sanmei, we are rescinding this review with respect to Zhejiang Sanmei in accordance with 19 CFR 351.213(d)(3).

Final Results of Review

As a result of this review, we are assigning the following dumping margin to the respondent for the period August 27, 2020, through February 28, 2022:

Exporter	Dumping margin (percent)
Taizhou Qingsong Refrigerant New Material Co., Ltd.; Taixing Meilan New Materials Co., Ltd	145.23

Disclosure

Commerce intends to disclose the calculations performed in connection with these final results to interested parties within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a

[1] *See Difluoromethane from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission, and Preliminary Intent to Rescind, in Part, of Antidumping Duty Administrative Review; 2020–2022,* 88 FR 20473 (April 6, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Extension of Deadline for Final Results,'' dated June 30, 2023.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Difluoromethane from the People's Republic of China; 2020–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Difluoromethane (R–32) from the People's Republic of China: Antidumping Duty Order,* 86 FR 13886 (March 11, 2021) (*Order*).

[5] For a complete description of the scope of the *Order, see* Preliminary Decision Memorandum.

[6] For a full description of these changes, *see* Issues and Decision Memorandum.

[7] *See Preliminary Results,* 88 FR 20487.

statutory injunction has expired (*i.e.,* within 90 days of publication).

Pursuant to Commerce's assessment practice,[8] for entries that were not reported in the U.S. sales data submitted by Qingsong, we will instruct CBP to liquidate such entries at the China-wide rate. For Zhejiang Sanmei, the respondent for which we are rescinding the administrative review, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the POR, in accordance with 19 CFR 351.212(c)(1)(i).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on, or after, the publication date of the final results of review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Qingsong will be equal to the dumping margin established in the final results of this review; (2) for a previously investigated or reviewed exporter of subject merchandise not listed in the final results of review that has a separate rate, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (3) for all Chinese exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be the cash deposit rate established for the China-wide entity, 221.06 percent; [9] and (4) for all exporters of subject merchandise that are not located in China and that are not eligible for a separate rate, the cash deposit rate will be the rate applicable to the China exporter(s) that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: October 3, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2023–22451 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–133]

Certain Metal Lockers and Parts Thereof From the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Determination of Antidumping Duty Investigation; Notice of Amended Final Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On September 28, 2023, the U.S. Court of International Trade (CIT) issued its final judgment in *List Industries, Inc.* v. *United States,* Court No. 21–00521, Slip Op. 23–143 (CIT September 28, 2023), sustaining the U.S. Department of Commerce's (Commerce) first final results of redetermination pertaining to the antidumping duty (AD) investigation of certain metal lockers and parts thereof from the People's Republic of China (China) covering the period of investigation January 1, 2020, through June 30, 2020. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final determination in that investigation, and that Commerce is amending the final determination with respect to the weighted-average dumping margins assigned to the mandatory respondent, Zhejiang Xingyi Metal Products Co., Ltd./Xingyi Metalworking Technology (Zhejiang) Co., Ltd. (collectively, Zhejiang Xingyi/Xingyi Metalworking) and certain non-selected separate rate respondents.

DATES: Applicable October 8, 2023.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4243.

SUPPLEMENTARY INFORMATION:

Background

On July 7, 2021, Commerce published its *Final Determination* in the AD investigation of certain metal lockers and parts thereof from China.[1] Commerce calculated an estimated weighted-average dumping margin and cash deposit rate (adjusted for subsidy offsets) of 0.00 percent for Hangzhou Xline Machinery & Equipment Co., Ltd. (Hangzhou Xline).[2] Commerce determined a weighted-average dumping margin of 21.25 percent and a cash deposit rate (adjusted for subsidy offsets) of 10.71 percent for Zhejiang Xingyi/Xingyi Metalworking, which it applied to all the separate companies identified below.[3] Commerce applied the highest calculated petition margin of 322.25 percent reported in the *Initiation Notice,* as adverse facts available (AFA), as the AD margin applicable to the China-wide entity.[4] Commerce

[8] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

[9] *See Order,* 86 FR at 13886.

[1] *See Certain Metal Lockers and Parts Thereof from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value,* 86 FR 35737 (July 7, 2021) (*Final Determination*).

[2] *Id.,* 86 FR at 35737–38.

[3] *Id.*

[4] *Id.; see also Certain Metal Lockers and Parts Thereof from the People's Republic of China:*

subsequently published the AD order with respect to certain metal lockers and parts thereof from China.[5]

List Industries, Inc. (the petitioner) appealed Commerce's *Final Determination.* On May 20, 2023, the CIT remanded the *Final Determination* to Commerce either to reconsider or further explain: (1) the disparate treatment of shipping in the calculation of Ayes Celikhasir VE CT's (Ayes) financial ratios, where shipping expenses were excluded from the selling, general, and administrative (SG&A) expense ratio, but shipping revenues were included as an offset to SG&A, in view of Commerce's stated practice of seeking ''consistency in the treatment of both the revenue and expense side of line items on Ayes' financial statements''; (2) the inclusion of incentive income as an offset to SG&A for the *Final Determination* (but not the *Preliminary Determination*[6]) without identifying the corresponding expense category or explaining the reason for the change; (3) the inclusion of rental income as an offset to SG&A in the *Final Determination* (but not the *Preliminary Determination*) without explaining the reason for the change; and (4) the treatment of interest income in the calculation of the financial ratios, with a precise description of its calculations, including a demonstration that any interest income excluded from the SG&A ratio is also excluded from profit.[7]

In its final results of redetermination, issued in August 2023, Commerce provided further explanation for its treatment of shipping revenue, incentive income, interest income, and rental income in the determination of the SG&A expense ratio using Ayes' audited financial statements.[8] In addition, we excluded shipping revenue from the determination of the SG&A ratio, and reduced profit by interest income.[9] Consequently, we recalculated the weighted-average dumping margins for both mandatory respondents in the investigation, which resulted in a change from 21.25 percent to 21.38 percent for Zhejiang Xingyi/Xingyi Metalworking, and no change to the 0.00 percent margin calculated for Hangzhou Xline.[10] Moreover, as Zhejiang Xingyi/Xingyi Metalworking is the only individually-examined respondent with an above-*de minimis* margin in the investigation, and the weighted-average dumping margin calculated for Zhejiang Xingyi/Xingyi Metalworking is, thus, the sole basis for the non-selected separate rate margin, we revised the exporter/producer combination rates for the respondents that are eligible for a separate rate in this investigation to reflect the revision to Zhejiang Xingyi/Xingyi Metalworking's weighted-average dumping margin.[11]

On September 28, 2023, the CIT sustained Commerce's final results of redetermination.[12]

Timken Notice

In its decision in *Timken,*[13] as clarified by *Diamond Sawblades,*[14] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's September 28, 2023, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Determination.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Determination

Because there is now a final court judgment, Commerce is amending its *Final Determination* with respect to the companies below, as follows:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Zhejiang Xingyi Metal Products Co., Ltd./Xingyi Metalworking Technology (Zhejiang) Co., Ltd.	Zhejiang Xingyi Metal Products Co., Ltd./Xingyi Metalworking Technology (Zhejiang) Co., Ltd.	21.38	10.84
Geelong Sales (Macao Commercial Offshore) Limited (a.k.a. Geelong Sales (MCO) Limited, Geelong Sales (Macao Commercial) Limited, and Geelong Sales (MC) Limited).	Zhongshan Geelong Manufacturing Co. Ltd	21.38	10.84
Hangzhou Evernew Machinery & Equipment Company Limited.	Zhejiang Yinghong Metalworks Co., Ltd	21.38	10.84
Hangzhou Zhuoxu Trading Co., Ltd	Shanghai ASI Building Materials Co., Ltd	21.38	10.84
Hangzhou Zhuoxu Trading Co., Ltd	Luoyang Mingxiu Office Furniture Co., Ltd	21.38	10.84
Hangzhou Zhuoxu Trading Co., Ltd	Luoyang Wandefu Import and Export Trading Co. Ltd.	21.38	10.84
Hangzhou Zhuoxu Trading Co., Ltd	Zhejiang Xingyi Metal Products Co., Ltd	21.38	10.84
Jiaxing Haihong Mechanical and Electrical Technology Co. Ltd.	Zhejiang Steelrix Office Furniture Co., Ltd	21.38	10.84
Kunshan Dongchu Precision Machinery Co., Ltd	Kunshan Dongchu Precision Machinery Co., Ltd	21.38	10.84
Luoyang Hynow Import and Export Co., Ltd	Luoyang Jiudu Golden Cabinet Co., Ltd	21.38	10.84
Luoyang Shidiu Import and Export Co., Ltd	Luoyang Yuabo Office Machinery Co., Ltd	21.38	10.84
Luoyang Steelart Office Furniture Co., Ltd	Luoyang Yongwei Office Furniture Co., Ltd	21.38	10.84
Luoyang Steelart Office Furniture Co., Ltd	Luoyang Zhuofan Steel Product Factory	21.38	10.84

Initiation of Less-Than-Fair-Value Investigation, 85 FR 47343, 47346 (August 5, 2020) (*Initiation Notice*).

[5] *See Certain Metal Lockers and Parts Thereof from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 86 FR 46826 (August 20, 2021).

[6] *See Certain Metal Lockers and Parts Thereof from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 86 FR 9051 (February 11, 2021) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[7] *See List Industries, Inc.* v. *United States,* Court No. 21–00521, Slip Op. 23–83 (CIT May 30, 2023) (*Remand Order*).

[8] *See Final Results of Redetermination Pursuant to Court Remand, List Industries, Inc.* v. *United States,* Court No. 21–00521, Slip Op. 23–83 (CIT May 30, 2023), dated August 23, 2023, available at *https://access.trade.gov/resources/remands/23-83.pdf.*

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *See List Industries, Inc.* v. *United States,* Court No. 21–00521, Slip Op. 23–143 (CIT September 28, 2023).

[13] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[14] *See Diamond Sawblades Manufacturers Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Luoyang Steelart Office Furniture Co., Ltd	Luoyang Flyer Office Furniture Co., Ltd	21.38	10.84
Pinghu Chenda Storage Office Co., Ltd	Pinghu Chenda Storage Office Co., Ltd	21.38	10.84
Tianjin Jia Mei Metal Furniture Ltd	Tianjin Jia Mei Metal Furniture Ltd	21.38	10.84

Cash Deposit Requirements

Commerce will issue revised cash deposit instructions to U.S. Customs and Border Protection.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: October 4, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–22453 Filed 10–11–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–876]

Welded Line Pipe From the Republic of Korea: Notice of Court Decision Not in Harmony With the Final Results of the Antidumping Duty Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 14, 2023, the U.S. Court of International Trade (CIT) issued its final judgment in *NEXTEEL Co., Ltd. et al.* v. *United States,* Slip. Op. 23–103, Consol. Court No. 20–03898 (CIT 2023), sustaining the U.S. Department of Commerce's (Commerce) second final results of redetermination pertaining to the administrative review of the antidumping duty order on welded line pipe (WLP) from the Republic of Korea (Korea) covering the period of review (POR) December 1, 2017, through November 30, 2018. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's *Final Results* of the administrative review and that Commerce is amending the *Final Results* with respect to the dumping margins assigned to NEXTEEL Co., Ltd. (NEXTEEL), SeAH Steel Corporation (SeAH), and non-selected respondents Husteel Co., Ltd. (Husteel) and Hyundai Steel Company/Hyundai HYSCO (Hyundai Steel).

DATES: Applicable July 24, 2023.

FOR FURTHER INFORMATION CONTACT: Adam Simons, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6172.

SUPPLEMENTARY INFORMATION:

Background

On November 30, 2020, Commerce published its final results in the 2017–2018 antidumping duty administrative review of WLP from Korea.[1] Commerce calculated weighted-average dumping margins of 15.07 percent for NEXTEEL, 9.33 percent for SeAH, and 11.60 percent for the non-selected respondents.[2]

Husteel, Hyundai Steel, NEXTEEL, and SeAH appealed Commerce's *Final Results.* On April 19, 2022, the CIT remanded the *Final Results* to Commerce regarding its: (1) particular market situation (PMS) determination and resulting adjustment to the reported cost of production (COP) for WLP for SeAH and for purposes of calculating constructed value (CV) for NEXTEEL; (2) application of the PMS adjustment to SeAH for purposes of the sales-below COP test; (3) adjustment to NEXTEEL's CV to account for sales of non-prime products; (4) reclassification of NEXTEEL's reported losses relating to the suspended production of certain product lines; (5) denial of a constructed export price (CEP) offset for SeAH; and (6) calculation of the rate assigned to non-examined companies in light of any adjustments made to the calculations for either of the mandatory respondents stemming from the remand.[3]

In its *First Remand Results,* issued on July 18, 2022, Commerce recalculated NEXTEEL and SeAH's weighted-average dumping margins without making a PMS adjustment.[4] In addition, Commerce recalculated NEXTEEL's weighted-average margin based on the actual costs of prime and non-prime merchandise reported by NEXTEEL. The revised weighted-average dumping margins for NEXTEEL and SeAH were 1.12 percent and zero percent, respectively, and the resulting review-specific rate for the non-selected respondents was 1.12. percent.[5]

The CIT sustained Commerce's *First Remand Results* on all issues except for the reclassification of NEXTEEL's reported losses relating to the suspended production of certain product lines.[6] The CIT again remanded the *Final Results* to Commerce for: (1) clarification on whether NEXTEEL suspended production on the lines in question for all or only part of the POR; and (2) explanation of why NEXTEEL's costs as reported for those lines would not be ''reasonably reflective of the cost associated with the production and sale of merchandise,'' if NEXTEEL suspended production for only part of the POR, consistent with section 773(f)(1)(A) of the Tariff Act of 1930, as amended (the Act).[7] In its *Second Remand Results,* issued on March 3, 2023, Commerce provided clarification on the period of suspension for certain of NEXTEEL's production lines and explanation of why it is appropriate to include the suspension losses as part of NEXTEEL's general and administrative expenses. Because Commerce made no changes to the calculation of the weighted-average dumping margin for NEXTEEL, the weighted-average dumping margin for NEXTEEL did not change from that presented in the *First Remand Results* (*i.e.,* 1.12 percent).[8]

[1] *See Welded Line Pipe From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2017–2018,* 85 FR 76517 (November 30, 2020) (*Final Results*), and accompanying Issues and Decision Memorandum.

[2] *Id.*

[3] *See NEXTEEL Co., Ltd. et al.* v. *United States,* 569 F. Supp. 3d 1354 (CIT 2022).

[4] *See Final Results of Remand Redetermination Pursuant to Court Remand, NEXTEEL Co., Ltd. et al.* v. *United States,* Consol. Court No. 20–03898, Slip Op. 22–37 (CIT April 19, 2022), dated July 15, 2022 (*First Remand Results*), available at *https://access.trade.gov/resources/remands/22-37.pdf.*

[5] *Id.* at 2.

[6] *See NEXTEEL Co., Ltd. et al.* v. *United States,* 601 F. Supp. 3d 1373 (CIT 2022).

[7] *Id.*

[8] *See Final Results of Remand Redetermination Pursuant to Court Remand, NEXTEEL Co., Ltd. et al.* v. *United States,* Consol. Court No. 20–03898, Slip Op. 22–135 (CIT December 6, 2022), dated March 3, 2023 (*Second Remand Results*), available at *https://access.trade.gov/resources/remands/22-135.pdf,* at 2.

The CIT sustained Commerce's *Second Remand Results* on July 14, 2023.[9]

Timken Notice

In its decision in *Timken,*[10] as clarified by *Diamond Sawblades,*[11] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Act, Commerce must publish a notice of court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's July 14, 2023, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Results.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Results

Because there is now a final court judgment, Commerce is amending its *Final Results* with respect to Husteel, Hyundai Steel, NEXTEEL, and SeAH for the period December 1, 2017, through November 30, 2018, as follows:

Producer or exporter	Weighted-average dumping margin (percent)
NEXTEEL Co., Ltd	1.12
SeAH Steel Corporation	0.00
Review-Specific Average Rate Applicable to the Following Companies: [12]	
Husteel Co., Ltd	1.12
Hyundai Steel Company/Hyundai HYSCO	1.12

Cash Deposit Requirements

Because NEXTEEL, SeAH, and the non-selected companies Husteel and Hyundai Steel have a superseding cash deposit rate, *i.e.,* there have been final results published in a subsequent administrative review, we will not issue revised cash deposit instructions to U.S. Customs and Border Protection (CBP). This notice will not affect the current cash deposit rates for those exporters/producers.

Liquidation of Suspended Entries

Because the CIT's ruling has not been appealed, Commerce intends to instruct CBP to assess antidumping duties on unliquidated entries of subject merchandise produced and/or exported by NEXTEEL, SeAH, and the non-selected companies, Husteel and Hyundai Steel, in accordance with 19 CFR 351.212(b). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific *ad valorem* assessment rate is not zero or *de minimis.* Where an import-specific *ad valorem* assessment rate is zero or *de minimis,*[13] we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: October 4, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–22454 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–842]

Certain Uncoated Paper From Brazil: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Suzano S.A. made sales of subject merchandise at prices below normal value during the period of review (POR) March 1, 2021, through February 28, 2022. Commerce also determines that Sylvamo do Brasil Ltda. and Sylvamo Exports Ltda. (collectively, Sylvamo) did not make sales of subject merchandise at prices below normal value during the POR.

DATES: Applicable October 12, 2023.

FOR FURTHER INFORMATION CONTACT: Christopher Maciuba or Nathan James, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0413 or (202) 482–5305, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 6, 2023, Commerce published the *Preliminary Results,* and invited interested parties to comment.[1] On July 19, 2023, we extended the deadline for these final results to October 3, 2023.[2] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3] Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The product covered by this *Order* is certain uncoated paper from Brazil. For

[9] *See NEXTEEL Co., Ltd. et al.* v. *United States,* Slip. Op. 23–103, Consol. Court No. 20–03898 (CIT 2023).

[10] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[11] *See Diamond Sawblades Mfrs. Coal.* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[12] This rate is based on the rates for the respondents that were selected for individual review, excluding rates that are zero, *de minimis,* or based entirely on facts available. *See* section 735(c)(5)(A) of the Act. Husteel and Hyundai Steel are the only two companies not selected for individual review in this administrative review that have unliquidated entries subject to this litigation. Commerce has already liquidated entries for the other non-selected respondents in this administrative review.

[13] *See* 19 CFR 351.106(c)(2).

[1] *See Certain Uncoated Paper from Brazil: Preliminary Results of the Antidumping Duty Administrative Review; 2021–2022,* 88 FR 20478 (April 6, 2023) (*Preliminary Results*).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of the 2021–2022 Antidumping Duty Administrative Review,'' dated July 19, 2023.

[3] *See* Memorandum, ''Certain Uncoated Paper from Brazil: Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

a full description of the scope, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

We addressed the issue raised in the case and rebuttal brief in the Issues and Decision Memorandum. The issue that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice as an appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Following a review of the record and comments received from interested parties, we have made no changes to the *Preliminary Results.*

Final Results of the Review

Commerce determines that the following estimated weighted-average dumping margins exist for the period March 1, 2021, through February 28, 2022:

Exporter/producer	Weighted average dumping margin (percent)
Suzano S.A	7.17
Sylvamo do Brasil Ltda./Sylvamo Exports Ltda	0.00

Disclosure

Because we made no changes to the calculations performed in connection with the *Preliminary Results,* there are no new calculations to disclose, in accordance with 19 CFR 351.224(b), for these final results.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.

Because Suzano's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we calculated importer-specific *ad valorem* assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales. Where an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. For Sylvamo, because its weighted-average dumping margin is zero, we will instruct CBP to liquidate entries reported in this review without regard to antidumping duties.

Consistent with Commerce's assessment practice, for entries of subject merchandise during the POR produced by Suzano or Sylvamo for which they did not know their merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[5]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rates for Suzano and Sylvamo will be the rates established in the final results of this administrative review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 27.11 percent, the all-others rate established in the LTFV investigation.[6] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5) and 19 CFR 351.213(h)(1).

Dated: October 3, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decisions Memorandum

[FR Doc. 2023–22574 Filed 10–11–23; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See Certain Uncoated Paper from Australia, Brazil, Indonesia, the People's Republic of China, and Portugal: Amended Final Affirmative Antidumping Determinations for Brazil and Indonesia and Antidumping Duty Orders,* 81 FR 11174 (March 3, 2016) (*Order*).

[5] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[6] *See Order.*

COMMODITY FUTURES TRADING COMMISSION

Energy and Environmental Markets Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC or Commission) is requesting nominations for Associate Members of the Energy and Environmental Markets Advisory Committee (EEMAC or Committee). The EEMAC is an advisory committee established by the Dodd-Frank Wall Street Reform and Consumer Protection Act.

DATES: The deadline for the submission of nominations is October 19, 2023.

ADDRESSES: Nominations should be emailed to *EEMAC_Submissions@cftc.gov* or sent by hand delivery or courier to Chris Lucas, Chief of Staff to Commissioner Summer K. Mersinger, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. Please use the title ''Energy and Environmental Markets Advisory Committee'' for any nominations you submit.

FOR FURTHER INFORMATION CONTACT: Lauren Fulks, EEMAC Secretary, (816) 960–7719 or email: *lfulks@cftc.gov.*

SUPPLEMENTARY INFORMATION: The EEMAC was established to conduct public meetings; submit reports and recommendations to the Commission; and otherwise serve as a vehicle for discussion and communication on matters of concern to exchanges, trading firms, end users, energy producers, and regulators regarding energy and environmental markets and their regulation by the Commission.

Pursuant to the EEMAC's authorizing statute, the EEMAC must have nine members. In addition, the EEMAC Charter requires that the Committee have approximately 9–20 Associate Members. With several Associate Members' terms recently expiring, Commissioner Summer K. Mersinger, the EEMAC's Sponsor, seeks additional Associate Members of the EEMAC.

Accordingly, the Commission invites the submission of nominations for EEMAC Associate Members who represent a wide diversity of opinions and a broad spectrum of interests related to the energy and environmental markets and their regulation by the Commission. To advise the Commission effectively, EEMAC Associate Members must have a high level of expertise and experience in the energy and/or environmental markets and the Commission's regulation of such markets, including from a historical perspective. To the extent practicable, the Commission will strive to select members reflecting wide ethnic, racial, gender, and age representation. All EEMAC Associate Members must be willing to participate in a public forum.

Each nomination submission must provide relevant information about the proposed Associate Member: the individual's name, title, organizational affiliation and address, email address and telephone number, as well as information that supports the individual's qualifications to serve as an Associate Member of the EEMAC (*e.g.,* C.V. or resume). The submission must also include the name, email address, and telephone number of the person nominating the proposed Associate Member. Self-nominations are acceptable.

Submission of a nomination is not a guarantee of selection as an Associate Member of the EEMAC. As noted in the EEMAC's Charter, the CFTC identifies Associate Members of the EEMAC through a variety of methods. Such methods may include public requests for nominations for membership; recommendations from existing advisory committee members; consultations with knowledgeable persons outside the CFTC (industry, consumer groups, other state or federal government agencies, academia, etc.); requests to be represented received from individuals and organizations; and Commissioners' and CFTC staff's professional knowledge of those experienced in the energy and environmental markets. The office of the Commissioner primarily responsible for the EEMAC plays a primary, but not exclusive, role in this process and makes recommendations regarding membership to the Commission. The Commission, by vote, authorizes Associate Members to serve on the EEMAC.

Associate Members may be appointed as representatives, special government employees, or regular government employees. Associate Members serve at the pleasure of the Commission, and may be appointed to serve for one, two, or three-year terms. As required by the EEMAC Charter, Associate Members provide their reports and recommendations directly to the EEMAC and not the Commission. Associate Members do not have the right to vote on matters before the EEMAC and may not sign or otherwise formally approve reports or recommendations made by the EEMAC to the Commission. Associate Members do not receive compensation for their services, and are not reimbursed for travel and per diem expenses. The EEMAC meets at such intervals as are necessary to carry out its functions and must meet at least two times per year. Associate Members are expected to provide their advice and recommendations to EEMAC members during these meetings.

Paperwork Reduction Act

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subjected to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number. For this collection, OMB has issued control number 3038–0119.

Privacy Act of 1974

The information we collect about you is covered by the Privacy Act of 1974. The CFTC is providing this statement to you as required by 5 U.S.C. 552a(e)(3). We are authorized to collect information from you pursuant to the Federal Advisory Committee Act, 5 U.S.C. 1001 *et seq.,* and 7 U.S.C. 2(a)(15). The purpose of this collection is to maintain information on CFTC advisory committee and subcommittee applicants and members, and those who make recommendations for committee or subcommittee memberships or otherwise interact with the CFTC regarding its advisory committees and subcommittees. The CFTC will use the information primarily for the administration of its advisory committees and subcommittees, including as part of the member evaluation and selection process. The CFTC may also share your information externally as a ''routine use'' with, for example, committee and subcommittee Chairs and co-Chairs to conduct committee and subcommittee activities, the public as permitted or required to provide information about the committee or subcommittee and receive input regarding the work of the committee or subcommittee, and with other Federal agencies and entities as necessary for oversight, litigation, and breach response. For a complete list of routine uses, please see the CFTC's system of records notice CFTC–58 Advisory Committees, available at *https://www.cftc.gov/privacy* and 88 FR 20146. Providing the requested information is voluntary, but if you choose not to provide it, the CFTC may not be able to consider you for

membership on an advisory committee or subcommittee, or effectively administer its advisory committee or subcommittee activities.

(Authority: 7 U.S.C. 2(a)(15))

Dated: October 6, 2023.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2023–22577 Filed 10–11–23; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Department of the Army

Programmatic Environmental Impact Statement for Real Property Master Plan Implementation at Military Ocean Terminal Sunny Point, North Carolina

AGENCY: Department of the Army, DOD.

ACTION: Notice of intent.

SUMMARY: The Department of the Army (Army) announces its intent to conduct public scoping under the National Environmental Policy Act (NEPA) to gather information to prepare an Environmental Impact Statement (EIS) for proposed near-term real property actions and the update of the Real Property Master Plan (RPMP) for Military Ocean Terminal Sunny Point (MOTSU). MOTSU is a 16,435-acre installation located on the banks of the Cape Fear River between the towns of Boiling Spring Lakes and Southport, North Carolina. The scoping process will help identify reasonable alternatives, potential environmental impacts, and key issues of concern to be analyzed in the EIS. The Army intends to comply with the requirements of section 106 of the National Historic Preservation Act in parallel with this NEPA process and invites federally recognized Tribes and the State Historic Preservation Office (SHPO) of North Carolina to participate in the consultation process.

DATES: Scoping comments must be submitted/sent on or before November 11, 2023. There will be a public meeting, as discussed below.

ADDRESSES: Please send written comments to James A. Rupkalvis, Installation Manager, 6280 Sunny Point Road, Southport, NC 28461–7800 or via email to *james.a.rupkalvis.civ@army.mil*.

FOR FURTHER INFORMATION CONTACT: Stephen C Herring, Legislative Affairs Officer, Public and Congressional Affairs Office, Military Surface Deployment and Distribution Command; telephone (618) 220–6119; email: *stephen.c.herring.civ@army.mil*.

SUPPLEMENTARY INFORMATION: MOTSU is the Military Surface Deployment and Distribution Command's East Coast strategic ammunition port and is the Department of Defense's primary ammunition seaport supporting the European, African, and Middle Eastern areas of operation. The proposed action includes barricade safety, waterfront maintenance, Pleasure Island Explosive Safety Clear Zone security, linear infrastructure (*e.g.,* roads, rail, utilities, firebreaks), stormwater mitigation, and cantonment area infill. In addition to these projects planned for the fiscal year 2025 through 2031 timeframe, the proposed action includes modernizing operation areas and general repair and maintenance of infrastructure, to include facilities, wharves, roads, rail, utilities, and perimeter security. The purpose of the proposed action is to provide MOTSU a master plan that will guide installation-wide real property management and development. The need for the proposed action is to maintain and modernize MOTSU's infrastructure so its staff and assets are safe and secure and so its vital, long-term, trans-shipment mission is assured. The master plan allows for a coordinated approach to the maintenance and modernization of critical infrastructure.

The EIS will evaluate the potential impacts associated with implementing the proposed RPMP activities, to include analyzing Full-Plan Implementation, a Partial Implementation Alternative, and a No-Action Alternative. Any other reasonable alternatives identified during the scoping process will be considered for evaluation in the EIS. The EIS will assess the impacts of the alternatives on resources and identify mitigation measures. Resource areas to be addressed include land use and coastal zone management, cultural resources, socioeconomics and environmental justice, transportation and utilities infrastructure, hazardous materials, hazardous waste, toxic substances, and contaminated sites. The proposed action could result in significant adverse effects to endangered species, 100-year floodplains, wetlands, and waters of the Cape Fear River. Anticipated permits and other authorizations include findings of no practicable alternatives for actions proposed in floodplains and wetlands per Executive Orders 11988 and 11990 respectively, Endangered Species Act consultations and take permits, National Historic Preservation Act consultations, Clean Water Act section 401 water quality certifications and section 404 permits, Rivers and Harbors Act section 10 permits, Sediment Pollution Control Act permits, and North Carolina Coastal Area Management Act federal consistency determinations. Actual permits and other authorizations will be determined for each project following that project's final design.

Members of the public, federally recognized Native American Tribes, and Federal, state, and local agencies are invited to participate in the scoping process for the preparation of this EIS by attending the virtual public meeting and/or submitting written comments. The Army requests input on identification of potential alternatives, information, and analyses relevant to the proposed action.

Written comments must be sent within 30 days of publication of this NOI in the **Federal Register**. A virtual public meeting will be held during this period. The date and location of the meeting will be announced at least seven days in advance through local media, newspapers, and on the project's website. Materials, including posters, fact sheet(s), and comment forms will be made available on *https://www.sddc.army.mil/SitePages/Environmental%20Programs.aspx*.

James W. Satterwhite Jr.,

U.S. Army Federal Register Liaison Officer.

[FR Doc. 2023–22496 Filed 10–11–23; 8:45 am]

BILLING CODE 3711–02–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Strategic Environmental Research and Development Program Scientific Advisory Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)), Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Strategic Environmental Research and Development Program (SERDP) Scientific Advisory Board (SAB) will take place.

DATES: SERDP SAB will hold a meeting open to the public. Day 1—Wednesday, October 11, 2023 from 9:00 a.m. to 4:15 p.m. (EST). Day 2—Thursday, October 12, 2023 from 9:00 a.m. to 2:35 p.m. (EST). Day 3—Friday, October 13, 2023 from 9:00 a.m. to 11:45 a.m. (EST).

ADDRESSES: The meeting will be accessible in person or by videoconference. The in-person meeting will be held at the Hilton Garden Inn, Reagan National Airport, 2020 Richmond Highway, Arlington, VA 22202. Information for accessing the videoconference is provided in **SUPPLEMENTARY INFORMATION**, ''Meeting Accessibility''.

FOR FURTHER INFORMATION CONTACT: Dr. Kimberly Spangler, 571–372–6565 (voice), *kimberly.y.spangler.civ@mail.mil* (email). Mailing address is SERDP Office, 4800 Mark Center Drive, Suite 16F16, Alexandria, VA 22350–3605. Website: *https://serdp-estcp.org/about.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Designated Federal Officer, the Strategic Environmental Research and Development Program Scientific Advisory Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its October 11–13, 2023 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available on the *https://serdp-estcp.org/about.*

Purpose of the Meeting: The purpose of the meeting is for the SERDP SAB to make recommendations regarding technologies, research, projects, programs, activities, and, if appropriate, funding within the scope of SERDP Fiscal Year (FY) 2024.

Agenda

Wednesday, October 11, 2023

- 9:00 a.m. Convene
- 9:05 a.m. SAB Strategy Session
- 9:35 a.m.—Statement of Need Overview: Detection, Localization, Classification, and Remediation of Military Munitions Underwater
- 9:45 a.m.—Improving Advanced Geophysical Classification Performance in the Marine Environment—SAB Discussion and Vote
- 10:45 a.m.—Phenomenology Enriched Learning for Imaging and Classification of Underwater Military Munitions—SAB Discussion and Vote
- 11:30 a.m.—Continual Learning Machines for Robust Underwater UXO Classification—SAB Discussion and Vote
- 1:15 p.m.—Statement of Need Overview: Installation Resilience Research: Theoretical Frameworks for Compound Threats
- 1:25 p.m.—Predicting Impacts of Species Loss on Ecosystem Resilience: An Experimental Test of a Novel Theoretical Framework—SAB Discussion and Vote
- 2:10 p.m.—Statement of Need Overview: Development of Improved Concentration Technologies for Treatment of Matrices Impacted by Per- and polyfluoroalkyl substances (PFAS)
- 2:20 p.m.—Novel Functionalization of Conventional Sorbents for Enhanced Selectivity and Improved Concentration of Ultrashort- and Short-Chain PFAS—SAB Discussion and Vote
- 3:20 p.m.—Statement of Need Overview: Improved Understanding of Destructive Treatment Processes for PFAS in the Subsurface
- 3:30 p.m.—A Novel In Situ Subsurface PFAS Destruction Strategy that Uses Ligand-Coordinated Zero-Valent Metals at Ambient Conditions—SAB Discussion and Vote
- 4:15 p.m.—Public Comment Period
- 4:30 p.m.—Adjourn for the Day

Thursday, October 12, 2023

- 9:00 a.m.—Convene
- 9:05 a.m.—Statement of Need Overview: Sustainable Energetics Synthesis and Preparation
- 9:10 a.m.—Designing a High-throughput Cell-based Screen for N-Oxygenase Engineering—SAB Discussion and Vote
- 10:00 a.m.—Statement of Need Overview: Biological Impacts to DoD Coating Performance
- 11:00 a.m.—Coating Deterioration: Impacts of Multi-Domain Biofilms and Preventative Measures—SAB Discussion and Vote
- 12:55 p.m.—Statement of Need Overview: Self-Assembly Behavior of PFAS Found in Soil and Groundwater at Aqueous Film-Forming Foam-Impacted Sites
- 1:05 p.m.—Mechanistic Investigation of Assembly and Stability of Supramolecular forms of PFAS on Environmentally Relevant Surfaces and Development of Surface Analytical Protocols—SAB Discussion and Vote
- 1:50 p.m.—Self-assembly of PFAS Mixtures in the Presence of Inorganic Ions and Hydrocarbon Surfactants During Wetting and Drying—SAB Discussion and Vote
- 2:35 p.m.—Public Comment Period
- 2:50 p.m.—Adjourn for the Day

Friday, October 13, 2023

- 9:00 a.m.—Convene
- 9:05 a.m.—Statement of Need Overview: Advanced Wildland Fire Research to Improve Military Land Use Efficiency
- 9:15 a.m.—Linking Smoke to Fire: The Effect of Burn Conditions on Fuel Availability, Smoke Production, and Atmospheric Processing—SAB Discussion and Vote
- 10:00 a.m.—Developing Detailed Emission Source Terms for Next-Generation Wildland Fire and Smoke Modeling Tools Using Improved Near-field Fire Measurements—SAB Discussion and Vote
- 11:00 a.m.—From Fuel to Smoke: Measuring and Modeling the Chemistry and Composition of the Prescribed Fire Flame and Near-Field Plume—SAB Discussion and Vote
- 11:45 a.m.—Public Comment Period
- 12:00 p.m.—Adjourn

Public Comment Period: Just before the adjourning of each day the chair of the board will ask those in the room and in the virtual meeting if there are any oral public comments. If there are, the chair will call on each person to speak. The individual will have up to 5 minutes to address the board. After oral comments are given any written comments will be read by the Designated Federal Officer.

Meeting Accessibility: Pursuant to 5 U.S.C. 1009(a) and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public. The meeting will be held in person and via videoconference. The in-person meeting will be held at the Hilton Garden Inn, Reagan National Airport, 2020 Richmond Highway, Arlington, VA 22202. Seating is on a first-come basis. If you wish to attend by videoconference you must register at this link: (*https://www.zoomgov.com/meeting/register/vJIsdu2hqTIoHzPOyGGtXJoUg6vlLhw353c*). Once registered, the web address and audio number will be provided. For purposes of transparency and attendance reporting you will be required to use your actual first name and last name as your username.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Dr. Kimberly Spangler at (571) 372–6565 (voice) no later than Friday October 13, 2023 (by 5:00 p.m. EST) so

that appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140 and section 5 U.S.C. 1009(a)(3), interested persons may submit a written statement to the SERDP SAB. Individuals submitting a statement must submit their statement no later than 5:00 p.m. EST, Thursday, October 12, 2023 to *kimberly.y.spangler.civ@mail.mil* (email) or to (571) 372–6565 (voice). If a statement pertaining to a specific topic being discussed at the planned meeting is not received by Friday, October 13, 2023, prior to the meeting, then it may not be provided to, or considered by, the Committee during the October 11–13, 2023 meeting. The Designated Federal Officer, Dr. Kimberly Spangler will review all timely submissions with the SERDP SAB Chair and ensure such submissions are provided to the members of the SERDP SAB before the meeting.

Dated: October 10, 2023.

Natalie M. Ragland,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–22681 Filed 10–10–23; 4:15 pm]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2023–IES–0011]

Request for Information on Potential New Program, From Seedlings to Scale (S2S)

AGENCY: Institute of Education Sciences, Department of Education.

ACTION: Request for information.

SUMMARY: The National Center for Education Research (NCER), a center within the Institute of Education Sciences (IES), is seeking insight to guide its efforts to fund quick-turnaround high-reward, scalable solutions intended to improve education outcomes for all students.

DATES: We must receive your comments by November 13, 2023.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *regulations.gov.* However, if you require an accommodation or cannot otherwise submit your comments via *regulations.gov,* please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. The Department will not accept comments submitted after the comment period. To ensure that the Department does not receive duplicate copies, please submit your comments only once. Additionally, please include the Docket ID at the top of your comments.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on using *regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''FAQ'' tab.

Privacy Note: The Department's policy is generally to make comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available. We encourage, but do not require, that each respondent include their name, title, institution or affiliation, and the name, title, mailing and email addresses, and telephone number of a contact person for the institution or affiliation, if any.

FOR FURTHER INFORMATION CONTACT: Erin Higgins, Education Research Analyst, National Center for Education Research, Institute of Education Sciences, U.S Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–7240. Telephone: (202) 987–1531. You may also email your questions to *erin.higgins@ed.gov,* but as described above, comments must be submitted via the Federal eRulemaking Portal at *regulations.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Background

Our education system is tasked with helping Americans across their entire lifespan to successfully engage in civic activity and participate in an ever-evolving workforce, building the foundation for the Nation's future.

In the Explanatory Statement accompanying the fiscal year (FY) 2023 Consolidated Appropriations Act (P.L. 117–328), Congress directed IES to invest in quick-turnaround high-reward, scalable solutions intended to improve education outcomes for all students.[1] To fulfill this directive, IES's Accelerate, Transform, and Scale (ATS) initiative will support advanced education research and development (R&D) to create scalable solutions to improve education outcomes for all learners and eliminate persistent achievement and attainment gaps. Through this initiative, IES will invest in bold, innovative ideas that come from interdisciplinary, diverse teams that have the potential to make dramatic advances towards solving seemingly intractable problems and challenges in the education field.

ATS will pilot efforts modeled on the advanced research projects agencies (ARPAs) found throughout the Federal government. ARPAs leverage insights from traditional/basic research to develop and scale breakthrough solutions and capabilities in focused areas that research or industry do not traditionally support. Many domains of R&D are primed for breakthrough advances that can make inroads on long standing education goals, such as personalizing student and educator learning, dramatically increasing learners' motivation and engagement, transforming the implementation and usefulness of assessments, and supporting successful transitions from school to career and between careers.

To advance ARPA-style efforts in education, the ATS initiative will build on several existing IES investments, including the Leveraging Evidence to Accelerate Recovery Nationwide (LEARN) Research Network, the Small Business Innovation Research (SBIR) program, the Standards for Excellence in Educational Research (SEER) Research Network for Digital Learning Platforms, prize challenges, and the Transformative Research in the Education Sciences research program. ATS will also support new activities that emphasize creating scalable, high impact solutions, such as going from idea to prototype and preparing existing tools, techniques, and products with evidence of effectiveness for scaling.

This RFI is focused on a proposed new program within ATS we are calling ''From Seedlings to Scale'' (S2S). IES is considering a three-phase investment strategy for S2S to support transformative ideas as they grow from seedlings to scalable solutions. As proposed, S2S would focus on high quality research, robust product development, and sustainability and scaling in the education marketplace. The performance goals below highlight how, at a high-level, each of those elements could be combined into a successful project.

Across the three proposed phases of funding, the Department envisions that successful performers would:

- Develop a full product or a broadly-applicable, new capability.
- Foster collaboration between product developers, researchers, and

[1] United States Congress. Committee Print of the Committee on Appropriations, U.S. House of Representatives, on H.R. 2617/Public Law 117–328. 117th Congress, Second Session. Washington: US. Govt. Publishing Off. 2023.

educators who are highly-skilled in their respective disciplines and across disciplines.

- Challenge what is currently possible by pursuing breakthroughs, not incremental improvements or ''point solutions.''
- Maintain an unwavering focus on improving learner outcomes, continuous improvement, and rigorously evaluating performance.
- Define from the beginning a credible path to significant impact and commercial success (including free and open-source pathways).
- Catalyze new areas of interest and investment.

Through the specific questions in the next section, IES is soliciting public comment on the two topics described below, Focus Areas and Program Design, to inform the development of the S2S program.

Topic One: Proposed S2S Focus Areas

IES is currently considering four focus areas:

- Developing approaches that can be used to help learners build skills throughout their life spans to gain broadly applicable competencies and domain-specific skills in growing areas critical for international competitiveness in the jobs of the future.
- Creating tools and systems that can accurately identify and determine the unique needs of individual neurodiverse learners and propose a custom suite of instructional and technological supports to guide their learning.
- Creating next-generation tools for educators for feedback, recommendations, and supports that leverage artificial intelligence to augment teaching and planning. These efforts should support educators and coaches to reflect holistically on the elements of daily practice, including learning environment, instructional strategies, and student performance.
- Creating new techniques and approaches to help educators and learners implement strategies to support behavior and emotion regulation and to support learners' interactions with others in ways that build and maintain caring environments, strong relationships, and robust mental health.

We have also developed a list of potential cross-cutting areas that would be listed alongside the focus areas as ''additional topics of interest.'' We do not anticipate that these additional topics would become requirements for potential performers; rather, they would be strongly recommended as areas to consider. The additional topics of interest include:

- Data modernization (including transferability, interoperability, and common measures).
- Human-centered design for education innovation.
- Open, fair, and transparent research.
- Data privacy and security.

IES is *not* currently soliciting examples of ideas for breakthrough solutions under these categories, but we plan to announce more efforts in this area soon after the initial priority areas are solidified.

Topic Two: Proposed S2S Program Design

IES proposes to leverage a tiered investment model to spur R&D to accelerate the creation of tools, techniques, and products that can lead to breakthrough solutions for any stage of the education system: pre-K, K–12, postsecondary (including community colleges and technical training institutes), and adult education. We envision that this investment model will use a three-phase process to support developing transformative solutions. We offer a brief sketch of the proposed model below. Advancement from one stage to the next would not be automatic but would be contingent on performance and available funds. We anticipate that the timeline for completing all three phases would take an average of six years. However, it is possible that phase three awards focused on scaling may not follow-on directly from a phase two award if IES chooses to structure this phase similar to the Department of Energy's ARPA (ARPA–E) SCALEUP program (*https://arpa-e.energy.gov/technologies/scaleup*), which was launched by ARPA–E to provide funding for projects to continue scaling.

For the first phase of funding, teams would have approximately one year to demonstrate that their proposed solution could meet four essential milestones: (1) serve a set of education providers, educator, or learner needs; (2) define and refine the key performance indicators (KPIs) for the solution; (3) create a prototype that can demonstrate elements of the core functionality at a ''demo day''; and (4) conduct one or more successful studies providing evidence of the promise of the proposed solution for improving learner outcomes relative to traditional approaches, should the solution be fully developed.

Projects that demonstrate a compelling use case(s) and promising prototype would be able to move to the second phase. This stage would be approximately two years. The second phase would focus on rapid, iterative development to turn the prototype into a functional solution, answering key research questions about its design, establishing product-market fit, and gathering initial evidence of promise. In this second stage, awardees should also be looking for opportunities to forge strong external partnerships that can function together to improve learner outcomes.

The third phase of funding would last approximately three years. This stage would focus on leveraging strategic partnerships to support continuous improvement, expanding the user base, and independently and rigorously evaluating the impacts of the solutions that showed evidence of promise and strong product-market fit. In this stage, it would be critical to evaluate whether this new solution improves education outcomes and reduces persistent achievement and attainment gaps relative to existing solutions, and to determine cost, implementation ease, and other important measures that reflect both effectiveness and product-market fit. It is also possible that this phase may not follow directly from the previous two phases, allowing time to further develop the partnerships necessary for scaling.

This is a request for information only. This RFI is not a request for proposals (RFP), a request for applications (RFA), or a promise to issue an RFP or a notice inviting applications (NIA). This RFI does not commit the Department to contract for any supply or service whatsoever. Further, we are not seeking proposals and will not accept unsolicited proposals that align to this potential program. The Department will not pay for any information or administrative costs that you may incur in responding to this RFI. The documents and information submitted in response to this RFI will not be returned.

Solicitation of Comments: To assist in refining the topic areas and program design for the S2S program, we invite comments in response to the questions below:

(1) Are the focus areas and cross cutting topics described well suited to advanced development R&D?

(a) Are these areas already adequately covered by existing funding mechanisms? If not, why not?

(b) Are there other topics that you think would yield more promise for identifying and developing breakthrough solutions? If so, what do you find more compelling about that topic?

(2) To successfully develop products and ecosystems that make a major impact on learners' education outcomes, teams will need a variety of supports. IES may require support from private industry in areas such as providing consultation and coaching to teams, convening potential partners for research and scaling.

(a) What would an ideal team look like to maximize the likelihood of success? For example, what role would researchers, education agencies (at the state or local level), and private companies play in the team?

(b) How can we ensure community engagement and input?

(c) What kind of experience does your organization have with supporting ARPA-style R&D efforts, especially those related to the education sciences? What case studies can you share from your experience?

(d) Particularly in the areas of fair, open, and transparent research and data privacy and security, what kind of programing or resources would you recommend providing teams?

(3) With a focus on developing quick-turn around, high-reward and scalable solutions, what would you propose are the core activities and/or benchmarks for success for a project in each of the phases? What examples can you provide around past successes in social science domains or specifically related to education R&D?

(4) Could you provide any estimates of the costs, assets, and contributions required for a team to successfully complete each phase?

(5) As a part of this effort, IES may seek support in establishing a technical working group (TWG) to inform the activities that will guide research teams for the S2S competition. If we were to establish a TWG related to the S2S competition, what kind of expertise would you propose is essential to a TWG in this area? Are there specific organizations or individuals that you suggest be included in the TWG?

Accessible Format: By request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Mark Schneider,

Director, Institute of Education Sciences.

[FR Doc. 2023–22482 Filed 10–11–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA–345–C]

Application for Renewal of Authorization To Export Electric Energy; New Brunswick Energy Marketing Corporation

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: New Brunswick Energy Marketing Corporation (the Applicant or NBEMC) has applied for renewed authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before November 13, 2023.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov*.

FOR FURTHER INFORMATION CONTACT: Christina Gomer, (240) 474–2403, *electricity.exports@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export. (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE's Grid Deployment Office (GDO) by Delegation Order No. S1–DEL–S3–2023 and Redelegation Order No. S3–DEL–GD1–2023.

On December 5, 2008, DOE issued Order No. EA–345, authorizing NBEMC (f/k/a New Brunswick Power Generation Corporation) to transmit electric energy from the United States to Canada as a power marketer. This authority was renewed on December 6, 2013, (Order No. EA–345–A) and on December 5, 2018 (Order No. EA–345–B). On August 23, 2023, NBEMC filed an application with DOE (Application or App) for renewal of their export authority for an additional five-year term. App at 2.

In its Application, NBEMC states that it will purchase power to be exported to Canada from electric utilities in the U.S., federal power marketing agencies, qualifying cogeneration and small power production facilities, independent power producers, and other sellers. App. at 5. NBEMC notes it ''does not own any electric generation or transmission facilities and, as a power marketer, does not hold a franchise or service territory or native load obligation.'' *Id.* at 6. NBEMC also states it is not affiliated with an entity that holds a franchise or service territory in the U.S., and ''[t]hus, NBEMC has no transmission 'system' of its own on which its exports of power could have a reliability or stability impact.'' *Id.* NBEMC asserts DOE has recognized that power purchased by a power marketer is surplus to the needs of the selling entities, and exports of electricity under such circumstances would not impair the sufficiency of electric supply within the U.S. *Id.* at 7.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at *Electricity.Exports@hq.doe.gov*. Protests should be filed in accordance with Rule 211 of FERC's Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at *Electricity.Exports@hq.doe.gov* in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning NBEMC's Application should be clearly marked with GDO Docket No. EA–345–C. Additional copies are to be provided directly to Tyler S. Johnson, Bracewell LLP, 701 5th Avenue, Suite 3400, Seattle, Washington 98104, *tyler.johnson@bracewell.com*; Josh R. Robichaud, Bracewell LLP, 2001 M Street NW, Suite 900, Washington, DC 20036, *Josh.robichaud@bracewell.com*; Tracey L. Bradley, Bracewell LLP, 2001 M Street NW, Suite 900, Washington, DC 20036, *tracey.bradley@bracewell.com*; and John S. Bird, New Brunswick Energy Marketing Corporation, 515 King Street, 2nd Floor, P.O. Box 2040, Fredericton, New Brunswick, Canada E3B 5G4, *jbird@nbpower.com*.

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at *www.energy.gov/gdo/pending-applications-0* or by emailing *Electricity.Exports@hq.doe.gov*.

Signing Authority

This document of the Department of Energy was signed on October 6, 2023, by Maria Robinson, Director, Grid Deployment Office, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 6, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2023–22597 Filed 10–11–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA–461–A]

Application for Renewal of Authorization To Export Electric Energy; Saavi Energy Solutions, LLC

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: Saavi Energy Solutions, LLC (the Applicant or Saavi Energy Solutions) has applied for renewed authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before November 13, 2023.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov*.

FOR FURTHER INFORMATION CONTACT: Christina Gomer, (240) 474–2403, *electricity.exports@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export. (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE's Grid Deployment Office (GDO) by Delegation Order No. S1–DEL–S3–2023 and Redelegation Order No. S3–DEL–GD1–2023.

On November 19, 2018, DOE issued Order No. EA–461 authorizing Saavi Energy Solutions to transmit electric energy from the United States to Mexico as a power marketer. On August 18, 2023, Saavi Energy Solutions filed an application with DOE (Application or App.) for renewal of their export authority for an additional five-year term. App. at 1.

In its Application, Saavi Energy Solutions states that it ''does not own any electric generation or transmission facilities and, as a power marketer, does not hold a franchise or service territory or native load obligation.'' App. at 5. Moreover, the Applicant notes that none of its ''affiliates owns any electric transmission facilities other than the limited and discrete interconnection facilities described [in its Application], and Saavi Energy Solutions is not affiliated with an entity that holds a franchise or service territory.'' *Id.* Saavi Energy Solutions represents that it will ''export electricity purchased from electric utilities, qualifying small power production facilities, cogeneration facilities, federal power marketing agencies, and other sellers as those terms are defined in Sections 3(22), (17), (18) and (19) of the FPA.'' *Id.* Saavi Energy Solutions asserts DOE has recognized that power purchased by a power marketer is, by definition, surplus to the needs of the selling entities and with no native load obligations, the power marketer is free to sell its power portfolio on the open market domestically or as an export. Thus, the Applicant notes DOE has previously determined an export of electricity occurring under such circumstances will not impair the sufficiency of electric supply within the U.S. App. at 5–6.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at *Electricity.Exports@hq.doe.gov*. Protests should be filed in accordance with Rule 211 of FERC's Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at *Electricity.Exports@hq.doe.gov* in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning Saavi Energy Solutions' Application should be clearly marked with GDO Docket No. EA–461–A. Additional copies are to be provided directly to Daniel Delgado and Liliana Gonzalez, Saavi Energy Solutions, LLC, 24 Greenway Plaza, Suite 1205, Houston, Texas 77046, *daniel.delgado@saavienergia.com, Liliana.gonzalez@saavienergia.com,* and *mexcommgrp@saavienergia.com,* and Joshua R. Robichaud and Stephen C. Wald, Bracewell LLP, 2001 M Street NW, Suite 900, Washington, DC 20036, *josh.robichaud@bracewell.com* and *stephen.wald@bracewell.com*.

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, on the program website at */www.energy.gov/gdo/pending-applications-0* or by emailing *Electricity.Exports@hq.doe.gov*.

Signing Authority

This document of the Department of Energy was signed on October 6, 2023, by Maria Robinson, Director, Grid Deployment Office, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 6, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2023–22596 Filed 10–11–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA–459–A]

Application for Renewal of Authorization To Export Electric Energy; Mercuria Energy America, LLC

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: Mercuria Energy America, LLC (the Applicant or Mercuria) has applied for renewed authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before November 13, 2023.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov*.

FOR FURTHER INFORMATION CONTACT: Christina Gomer, (240) 474–2403, *electricity.exports@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export. (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE's Grid Deployment Office (GDO) by Delegation Order No. S1–DEL–S3–2023 and Redelegation Order No. S3–DEL–GD1–2023.

On November 19, 2018, DOE issued Order No. EA–459 authorizing Mercuria to transmit electric energy from the United States to Mexico as a power marketer. On August 18, 2023, Mercuria filed an application with DOE (Application or App.) for renewal of their export authority for an additional five-year term. App. at 1.

In its Application, Mercuria states that neither it ''nor any of its affiliates owns or controls any generation or transmission facilities.'' App. at 2. Further, the Applicant notes ''neither Mercuria nor any of its affiliates is a franchised utility or affiliated with any franchised utilities in North America.'' *Id.* Mercuria represents that it ''will acquire electricity on both a firm and interruptible basis from a variety of suppliers (*i.e.,* generators, electric utilities and other power marketers) that would enter into such transactions voluntarily, and therefore will be surplus of the selling entities.'' *Id.* at 4. Mercuria therefore asserts that ''as required by FPA Section 202(e), the proposed exports will not impair or tend to impede the sufficiency of electricity supplies in the United States or the regional coordination of electric utility planning or operations.'' *Id.*

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Attachment 1.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at *Electricity.Exports@hq.doe.gov*. Protests should be filed in accordance with Rule 211 of FERC's Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at *Electricity.Exports@hq.doe.gov* in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning Mercuria's Application should be clearly marked with GDO Docket No. EA–459–A. Additional copies are to be provided directly to Steven Bunkin, Mercuria Energy America, LLC, 33 Benedict Place, Greenwich, CT 06830, *sbunkin@mercuria.com,* and Jay Michals, Mercuria Energy America, LLC, 20 E Greenway Plaza, Ste. 650, Houston, TX 77046, *jmichaels@mercuria.com*.

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at *www.energy.gov/gdo/pending-applications-0* or by emailing *Electricity.Exports@hq.doe.gov*.

Signing Authority

This document of the Department of Energy was signed on October 6, 2023, by Maria Robinson, Director, Grid Deployment Office, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 6, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2023–22594 Filed 10–11–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2943–000]

Talen Keystone LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Talen Keystone LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 24, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: October 4, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–22475 Filed 10–11–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–15–000]

Nova Power, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Nova Power, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 24, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and

assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: October 4, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–22470 Filed 10–11–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2941–000]

Talen Conemaugh LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Talen Conemaugh LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 24, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: October 4, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–22473 Filed 10–11–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings # 1

Docket Numbers: EG24–2–000.

Applicants: Crow Creek Solar, LLC.

Description: Crow Creek Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/3/23.

Accession Number: 20231003–5181.

Comment Date: 5 p.m. ET 10/24/23.

Take notice that the Commission received the Compliance filings in EL Dockets:

Docket Numbers: EL24–2–000.

Applicants: EverBright, LLC.

Description: Petition for Declaratory Order of Everbright, LLC.

Filed Date: 10/3/23.

Accession Number: 20231003–5194.

Comment Date: 5 p.m. ET 10/31/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–736–005.

Applicants: System Energy Resources, Inc.

Description: Compliance filing: eTariff Compliance in Docket No. ER22–736 to be effective 3/1/2022.

Filed Date: 10/4/23.

Accession Number: 20231004–5002.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–15–000.

Applicants: Nova Power, LLC.

Description: Baseline eTariff Filing: Nova Power, LLC submits tariff filing per 35.12: Market-Based Rate Application and Request for Confidential Treatment to be effective 12/3/2023.

Filed Date: 10/3/23.

Accession Number: 20231003–5138.

Comment Date: 5 p.m. ET 10/24/23.

Docket Numbers: ER24–16–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Remove the Attachment AR Screening Study Processes to be effective 12/4/2023.

Filed Date: 10/4/23.

Accession Number: 20231004–5030.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–17–000.

Applicants: Public Service Company of New Hampshire.

Description: Tariff Amendment: Cancellation Great Lakes Hydro American LLC Large Generator Interconnect Agrmnt to be effective 10/5/2023.

Filed Date: 10/4/23.

Accession Number: 20231004–5062.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–18–000.

Applicants: Ridgeview Solar LLC.

Description: Ridgeview Solar LLC submits a Petition for Limited Prospective Waiver of Tariff Provision, or Alternatively for Remedial Relief, and Shortened Comment Period and Expedited Action.

Filed Date: 10/2/23.

Accession Number: 20231002–5380.

Comment Date: 5 p.m. ET 10/23/23.

Docket Numbers: ER24–19–000.

Applicants: Cottontail Solar 1, LLC.

Description: Baseline eTariff Filing: Reactive Power Compensation Baseline to be effective 1/15/2024.

Filed Date: 10/4/23.

Accession Number: 20231004–5065.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–20–000.

Applicants: Cottontail Solar 2, LLC.

Description: Baseline eTariff Filing: Reactive Power Compensation Baseline to be effective 12/4/2023.

Filed Date: 10/4/23.

Accession Number: 20231004–5069.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–21–000.

Applicants: Cottontail Solar 8, LLC.

Description: Baseline eTariff Filing: Reactive Power Compensation Baseline to be effective 12/15/2023.

Filed Date: 10/4/23.

Accession Number: 20231004–5078.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–22–000.

Applicants: Pennsylvania Electric Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Pennsylvania Electric Company submits tariff filing per 35.13(a)(2)(iii: Penelec Amends 10 ECSAs (6053 6137 6138 6141 6148 6287 6288 6289 6294 6295) to be effective 12/31/9998.

Filed Date: 10/4/23.

Accession Number: 20231004–5091.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–23–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL OATT Attachment M (LGIP) Appendix 7 Standard (LGIA) Preamble and Recitals to be effective 12/4/2023.

Filed Date: 10/4/23.

Accession Number: 20231004–5114.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–24–000.

Applicants: ISO New England Inc., Versant Power.

Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: ISO–NE/Versant Power; Local Service Agreement LSA/ISONE/VERSANT–23–01 to be effective 12/2/2022.

Filed Date: 10/4/23.

Accession Number: 20231004–5118.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–25–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: § 205(d) Rate Filing: 2023–10–5 GRE Century Sub-FSA 743–NSP to be effective 10/5/2023.

Filed Date: 10/4/23.

Accession Number: 20231004–5126.

Comment Date: 5 p.m. ET 10/25/23.

Docket Numbers: ER24–26–000.

Applicants: East Point Energy Center, LLC.

Description: Baseline eTariff Filing: East Point Energy Center, LLC Application for Market-Based Rate Authorization to be effective 12/4/2023.

Filed Date: 10/4/23.

Accession Number: 20231004–5131.

Comment Date: 5 p.m. ET 10/25/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: October 4, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–22471 Filed 10–11–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4334–017]

EONY Generation Limited; Notice of Waiver Period for Water Quality Certification Application

On September 29, 2023, EONY Generation Limited submitted to the Federal Energy Regulatory Commission (Commission) a copy of its application for a Clean Water Act section 401(a)(1) water quality certification filed with New York State Department of Environmental Conservation (New York DEC), in conjunction with the above captioned project. Pursuant to 40 CFR 121.6 and section 4.34(b)(5) of the Commission's regulations,[1] we hereby notify the New York DEC of the following:

Date of Receipt of the Certification Request: September 26, 2023.

Reasonable Period of Time to Act on the Certification Request: One year (September 26, 2024).

If New York DEC fails or refuses to act on the water quality certification request on or before the above date, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: October 4, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–22478 Filed 10–11–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–523–000]

ANR Pipeline Company; Notice of Schedule for the Preparation of an Environmental Assessment for the Oak Grove Enhancement Project

On August 1, 2023, ANR Pipeline Company (ANR) filed an application in Docket No. CP23–523–000 requesting a Certificate of Public Convenience and Necessity pursuant to section 7(c) and Authorization pursuant to section 7(b) of the Natural Gas Act to construct, operate, and abandon certain natural gas pipeline facilities. The proposed project is known as the Oak Grove Enhancement Project (Project). The Project would include construction of 34.1 miles of new 30-inch-diameter natural gas pipeline to replace 33.6 miles of existing 30-inch-diameter natural gas pipeline in Richland and West Carroll Parishes, Louisiana. According to ANR, its project would improve the integrity and reliability of ANR's system by replacing vintage pipeline facilities installed in the 1950's with new pipeline facilities.

On August 11, 2023, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization

[1] 18 CFR 4.34(b)(5).

within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.[1]

Schedule for Environmental Review

Issuance of EA—March 1, 2024
90-day Federal Authorization Decision Deadline [2]—May 30, 2024

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Oak Grove Enhancement Project would consist of the following facilities:

- Installation of 34.1 miles of new 30-inch-diameter segment of natural gas pipeline, which will begin at ANR's existing Delhi Compressor Station (CS) in Richland Parish, Louisiana and primarily parallel the existing Line 0–501, 1–501, and 2–501 pipelines before the new segment ties into the existing route just south of State Route 586 in West Carroll Parish, Louisiana at the terminus of the existing Line 0–501 segment to be abandoned.
- Abandonment in place and by removal of 33.6 miles of existing 30-inch-diameter natural gas pipeline, which begins at ANR's existing Delhi CS in Richland Parish and terminates just south of State Route 586 in West Carroll Parish. Approximately one percent (0.25 mile) of the existing Line 0–501 segment would be abandoned by removal, while the remaining existing pipeline segments (totaling 33.35 miles) would be abandoned in place.

The Oak Grove Enhancement Project would not increase or reduce service to any existing ANR customer and no changes to system capacity are proposed. ANR's Project design would allow the existing segment to remain in operation until the replacement pipeline is placed into service.

Background

On August 23, 2023, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Oak Grove Enhancement Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the Notice of Scoping, the Commission received one comment from the Louisiana Department of Wildlife and Fisheries regarding impacts on wildlife habitats. All substantive comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP23–523), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: October 4, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–22481 Filed 10–11–23; 8:45 am]

BILLING CODE 6717–01–P

[1] 40 CFR 1501.10 (2020).

[2] The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Tuesday, October 17, 2023 at 10:30 a.m. and its continuation at the conclusion of the open meeting on October 19, 2023.

PLACE: 1050 First Street NE, Washington, DC and virtual (this meeting will be a hybrid meeting).

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Investigatory records compiled for law enforcement purposes and production would disclose investigative techniques.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceedings or arbitration.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Vicktoria J. Allen,

Deputy Secretary of the Commission.

[FR Doc. 2023–22685 Filed 10–10–23; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the

standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than October 27, 2023.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, IL 60690–1414. Comments can also be sent electronically to *Comments.applications@chi.frb.org:*

1. *George B. Bley II, Palm Harbor, Florida, individually, and acting in concert with the Bley Family Control Group;* to retain voting shares of Petefish, Skiles Bancshares, Inc., and thereby indirectly retain voting shares of Petefish, Skiles & Company, both of Virginia, Illinois.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–22582 Filed 10–11–23; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 13, 2023.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *State Holding, Inc., Richmond, Missouri;* to become a bank holding company by acquiring The State Bank, Richmond, Missouri.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2023–22590 Filed 10–11–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Documentation Burden

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submission.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Documentation Burden,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before November 13, 2023.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions: Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Documentation Burden.* AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Documentation Burden.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/documentation-burden/protocol.*

This is to notify the public that the EPC Program would find the following information on *Documentation Burden* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements, if relevant: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index

outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Guiding Questions

Description/Overview of Measurements of Documentation Burden

(1) What metrics of documentation burden that have been developed or used (including metrics broadly—quantitative and qualitative)?

(a) For which settings, populations, and intended uses were the metrics developed?

(b) How have these metrics been applied?

(c) Is there published information available on validity of the metrics?

(d) What are the key strengths and weaknesses of different metrics that have been used?

(2) What are the different perspectives on the appropriateness of different metrics of documentation burden that have been applied/proposed (*e.g.,* scalability, resource intensiveness to collect, equitable across populations)?

(3) What are the perceptions of documentation burden from the perspective of people in different clinical roles (*e.g.,* doctor, nurse, etc.) and patients/caregivers?

Factors Influencing Documentation Burden

(4) What is the role of patients in documentation burden?

(5) What is the role of setting (*i.e.,* rural vs. urban, hospital, outpatient, academic institution, etc.) in documentation burden?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Settings)

PICOTS elements	Inclusion criteria	Exclusion criteria
Population	Healthcare professionals, including but not limited to: • Physicians. • Nurses. • Other professionals.	• Any healthcare professional without direct patient contact.
Interventions (Exposure)	• EHR. • Electronic prescribing. • Electronic patient portals. • Computerized physician order entry.	• None.
Comparators	• None	• None.
Outcomes	Metrics of documentation burden, including but not limited to: • WOW. • Time on Inbox. • Time on Encounter Note Documentation. • Excessive workload. • Time on EHR. • Administrative tasks. • Fragmentation of workflow. • Physician-patient interaction.	• None.
Timing	• All	• None.
Settings	• Any clinical settings	• None.
Study design	• RCTs. • Comparative observational studies. • Surveys. • Qualitative studies. • Mixed-method studies. • Systematic review or meta-analysis.	• In vitro studies. • Erratum. • Editorials. • Letters. • Case studies/case reports. • Narrative reviews.
Publications	• Studies published in English as peer reviewed full-text articles • Published after the year 2000	• Foreign language studies. • Conference abstracts.

Abbreviations: EHR = electronic health record; RCT = randomized clinical trials; WOW = Work Outside of Work.

Dated: October 5, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–22503 Filed 10–11–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or us) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 13, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0037. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers—21 CFR 108.25 and 108.35, and 21 CFR Parts 113 and 114

OMB Control Number 0910–0037—Extension

Section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342) deems a food to be adulterated, in part, if the food bears or contains any poisonous or deleterious substance that may render it injurious to health. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. Under section 404 of the FD&C Act (21 U.S.C. 344), our regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit us to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum.* The spores of *C. botulinum* need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(1) (21 CFR 108.25(c)(1) and 108.35(c)(1)). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Forms FDA 2541d, FDA 2541e, and FDA 2541f for all methods except aseptic processing, or Form FDA 2541g for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (21 CFR 113.87(a)).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms also must document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§ 113.60(c) (thermally processed low-acid foods) and § 114.80(b) (acidified foods)).

The records of processing information are periodically reviewed during factory inspections by FDA to verify fulfillment of the requirements in parts 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

As described in FDA regulations, processors may obtain the paper version of Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g at *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm.* Processors mail completed paper forms to us. However, processors who are subject to § 108.25 and/or § 108.35 have an option to submit Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g electronically.

Although we encourage commercial processors to use the electronic submission system for plant registration and process filing, we will continue to make paper-based forms available. To standardize the burden associated with process filing, regardless of whether the process filing is submitted electronically or using a paper form, we are offering the public the opportunity to use four forms, each of which pertains to a specific type of commercial processing and is available both on the electronic submission system and as a paper-based form. The electronic submission system

and paper-based form ''mirror'' each other to the extent practicable. The four process filing forms are as follows:

- Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method);
- Form FDA 2541e (Food Process Filing for Acidified Method);
- Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method); and
- Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems).

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers.

In the **Federal Register** of March 21, 2023 (88 FR 16990), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
108.25(c)(1) and 108.35(c)(2); Food canning establishment registration.	2541	1,218	1	1,218	0.17 (10 minutes)	207
108.25(c)(2); Food process filing for acidified method.	2541e	2,078	7	14,546	0.33 (20 minutes)	4,800
108.35(c)(2); Food process filing for low-acid retorted method.	2541d	842	7	5,894	0.33 (20 minutes)	1,945
108.35(c)(2); Food process filing for water activity/formulation control method.	2541f	111	4	444	0.33 (20 minutes)	147
108.35(c)(2); Food process filing for low-acid aseptic systems.	2541g	168	11	1,848	0.75 (45 minutes)	1,386
108.25(d), 108.35(d) and (e); Report of any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce.	N/A	1	1	1	4	4
Total						8,489

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates in table 1 on registrations, process filings, and reports received. The estimates for hours per response are based on our experience with similar programs and information received from industry.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
113.100 and 114.100	10,392	1	10,392	250	2,598,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. No burden has been estimated for the third-party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Since the publication of the 60-day notice we have adjusted our burden estimate. Our estimated burden for the information collection reflects an increase of 3,606 total burden hours and a corresponding increase of 10,141 total annual responses. This increase corresponds with data obtained from past submissions.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22461 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–P–1344 and FDA–2023–P–2655]

Determination That CYTOXAN (Cyclophosphamide) for Injection (Sterile Dry Powder Excipient-Free Formulation), 500 Milligrams/Vial, 1 Gram/Vial, and 2 Grams/Vial, and CYTOXAN (Cyclophosphamide) for Injection (Sterile Dry Powder With Sodium Chloride Formulation), 500 Milligrams/Vial, 1 Gram/Vial, and 2 Grams/Vial, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined that the sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection, 500 milligrams (mg)/vial, 1 gram (g)/vial, and 2 g/vial, and the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the sterile dry powder excipient-free formulation or the sterile dry powder with sodium chloride formulation of these drug products, and it will allow FDA to continue to approve ANDAs that refer to these formulations of CYTOXAN as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Tereza Hess, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993–0002, 202–768–5659, *Tereza.Hess@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made: (1) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that referred to the listed drug have been approved and (2) prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CYTOXAN (cyclophosphamide) for Injection (sterile dry powder with sodium chloride formulation), with the 500 mg/vial, initially approved on May 4, 1964, the 1 g/vial, initially approved on August 30, 1982, and the 2 g/vial, initially approved on August 30, 1982, are the subjects of NDA 012142, held by Baxter Pharmaceuticals. Subsequently, CYTOXAN (cyclophosphamide) for Injection (lyophilized powder with mannitol) was also approved under NDA 012142, with the 500 mg/vial approved on January 4, 1984; the 1 g/vial approved on September 24, 1985; and the 2 g/vial approved on December 10, 1985. On November 7, 2003, the lyophilized powder with mannitol formulation in 500 mg/vial, 1 g/vial, and 2 g/vial strengths was reformulated and approved as a sterile dry powder excipient-free formulation under Supplement 107 to NDA 012142. On March 31, 2012, the CYTOXAN (cyclophosphamide) for Injection, sterile dry powder with sodium chloride formulation in 500 mg/vial, 1 g/vial, and 2 g/vial strengths was reformulated and approved as a lyophilized powder with mannitol formulation under Supplement 113. CYTOXAN is indicated for treatment of malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma, multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, breast carcinoma, and minimal change nephrotic syndrome in pediatric patients.

FDA previously determined that certain CYTOXAN (cyclophosphamide) for Injection formulations and strengths were not discontinued from sale for reasons of safety or effectiveness, but these determinations did not address all previously approved formulations and strengths. In the **Federal Register** of March 1, 2004 (69 FR 9630), FDA issued a determination that CYTOXAN (cyclophosphamide) for Injection (non-lyophilized formulation), 2 g/vial, was not withdrawn from sale for reasons of safety or effectiveness. In the **Federal Register** of August 5, 2013 (78 FR 47321), FDA issued a determination that CYTOXAN (cyclophosphamide) for Injection (lyophilized formulations), 100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial, and 2 g/vial, and CYTOXAN (cyclophosphamide) for Injection (non-lyophilized formulations), 100 mg/vial and 200 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. Neither of the previous **Federal Register** notices expressly indicate that the determinations were made for the sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection in the 500 mg/vial, 1 g/vial, and 2 g/vial strengths or the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial.

The sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, and the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, are discontinued.

Lachman Consultant Services, Inc., submitted a citizen petition dated May 5, 2020 (Docket No. FDA–2020–P–1344), under 21 CFR 10.30, requesting that the Agency determine whether discontinued formulations of all strengths of CYTOXAN (cyclophosphamide) for Injection approved under NDA 012142, including the sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, were withdrawn from sale for reasons of safety or effectiveness. Epic Pharma,

LLC submitted a citizen petition dated June 27, 2023 (Docket No. FDA–2023–P–2655), also requesting that the Agency determine whether the sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petitions did not specifically address the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, this formulation also has been discontinued. We have also determined whether the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, was withdrawn for safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CYTOXAN (cyclophosphamide) for Injection (sterile dry powder excipient-free formulation), 500 mg/vial, 1 g/vial, and 2 g/vial, and CYTOXAN (cyclophosphamide) for Injection (sterile dry powder with sodium chloride formulation), 500 mg/vial, 1 g/vial, and 2 g/vial, were not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that the sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, or the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of the sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, and the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency has determined that the sterile dry powder excipient-free formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, and the sterile dry powder with sodium chloride formulation of CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial, drug products have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that have the sterile dry powder excipient-free formulation or the sterile dry powder with sodium chloride formulation. ANDAs that refer to CYTOXAN (cyclophosphamide) for Injection, 500 mg/vial, 1 g/vial, and 2 g/vial may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22494 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 13, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0769. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

OMB Control Number 0910–0769—Extension

This information collection supports the voluntary submission of allegations of regulatory misconduct to FDA's Center for Devices and Radiological Health (CDRH). An allegation of regulatory misconduct is a claim that a medical device manufacturer or individuals marketing medical devices or electronic products regulated by CDRH may be doing so in a manner that violates the law. Reporting these allegations can help make FDA aware of regulatory concerns it may not learn of otherwise. This information can help FDA identify the potential risks to patients and determine whether further investigation is warranted, as well as any steps needed to address or correct a potential violation. Anyone may file a complaint reporting an allegation of regulatory misconduct. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

Allegations of regulatory misconduct may include failure to register and list a medical device, marketing uncleared or unapproved products, failure to follow quality system requirements, or misleading promotion.

You can submit an allegation through the Allegations of Regulatory Misconduct Form (*https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form*), by email, or by regular mail.

FDA published a 60-day notice for public comment in the **Federal Register** of June 12, 2023 (88 FR 38061) and received comments. While one comment appeared to question the purpose of the information collection, another comment supported FDA activities regarding the reporting of information covered by the collection. No comment suggested that we revise our burden estimate.

We also received suggestions on how our submission form might be improved. In response to this comment, we are revising the submission form using asterisks to more clearly indicate which fields are required for submission versus non-required fields. The form also has been updated to allow submission of the company's website.

Similarly, one comment noted that current procedures do not allow for complete anonymity when submitting allegations of regulatory misconduct to FDA. The comment suggests changing the submission process to allow submission of attachments to the form, rather than via separate email. While we have not made changes regarding the submission process at this time, we appreciate these suggestions and continue to consider enhancements and updates to our systems as our limited resources permit. We recognize that confidentiality is an important concern. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1–9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

Finally, one comment expressed concern regarding verification by FDA of the accuracy and validity of the information (allegations) submitted. Allegations of regulatory misconduct related to medical devices are reviewed by CDRH. CDRH prioritizes the review of allegations based on the level of potential risks, within the context of an overall benefit-risk profile, to patients, and takes responsive action accordingly. We note, however, that subsequent questions or inquiry intended to clarify information submitted is not considered a collection of information under the PRA (see 5 CFR 1320.3(h)(9)) subject to OMB review and approval. To learn more about CDRH's process for handling allegations, please visit: *https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct.*

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of voluntary allegations to CDRH.	2,500	1	2,500	0.25 (15 minutes)	625

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We recently consolidated the intake of allegations across CDRH Offices. This has improved our estimate and we have adjusted the number of responses accordingly. The number of responses is based on the voluntary allegations received by CDRH in 2022. The adjusted estimated burden for the information collection reflects an increase of 900 responses and a corresponding increase of 225 hours.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22463 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3848]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information in the regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

DATES: Submit either electronic or written comments on the collection of information by December 11, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 11, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the

public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3848 for ''Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring—21 CFR Part 315

OMB Control Number 0910–0409—Extension

This information collection supports our regulations in part 315 (21 CFR part 315) that require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of: (1) a new diagnostic radiopharmaceutical or (2) a new indication for use of an approved diagnostic radiopharmaceutical. Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables us to properly evaluate the safety and effectiveness profiles of such radiopharmaceuticals.

The information, which is usually submitted as part of a new drug application (NDA) or biologics license application or as a supplement to an approved application typically includes, but is not limited to: (1) nonclinical and clinical data on the pharmacology; (2) toxicology; (3) adverse events; (4) radiation safety assessments; and (5) chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50) and have been approved under OMB control number 0910–0001.

In table 1, row 1, we estimate the annual reporting burden for preparing the safety and effectiveness sections of an application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that three submissions will be received annually from three applicants and that 2,000 hours would be spent preparing the portions of the application that would be affected by this information collection. We further estimate the total time needed to prepare complete applications for diagnostic radiopharmaceuticals as approximately 6,000 hours. This information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001. In fact, clarification of our criteria for the

evaluation of diagnostic radiopharmaceuticals in this information collection is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles by enabling manufacturers to tailor information submissions and avoid unnecessary clinical trials.

In table 1, row 2, we estimate the annual reporting burden for preparing the safety and effectiveness sections of a supplement to an approved application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that one submission will be received annually. We estimate the total time needed to prepare complete applications for supplements to new applications for diagnostic radiopharmaceuticals as approximately between 500 and 1,000 hours. We calculated the median of this estimate to arrive at approximately 750 hours. We further estimate that the total time needed to prepare the portions of the application that would be affected by this information collection as 750 hours. As previously stated, this information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 750 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR NDAS AND SUPPLEMENTS TO APPROVED NDAS FOR DIAGNOSTIC RADIOPHARMACEUTICALS [1]

Manufacturers' activity (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
NDAs (§§ 315.4, 315.5, and 315.6)	3	1	3	2,000	6,000
Supplements to Approved NDAs (§§ 315.4, 315.5, and 315.6)	1	1	1	750	750
Total					6,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since our last OMB approval, our estimated burden for the information collection reflects an overall decrease of 11 responses with a corresponding decrease of 12,000 burden hours. We attribute this adjustment to a decrease in the number of submissions for NDAs for diagnostic radiopharmaceuticals and new indication supplements for diagnostic radiopharmaceuticals we received over the past few years.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22460 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3768]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adherence Potential and Patient Preference in Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Adherence Potential and Patient Preference in Prescription Drug Promotion.''

DATES: Either electronic or written comments on the collection of information must be submitted by December 11, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as

well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3768 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Adherence Potential and Patient Preference in Prescription Drug Promotion.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAstaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adherence Potential and Patient Preference in Prescription Drug Promotion

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality.

Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our home page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research,* which includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

This study builds on OPDP's portfolio of research on market claims and disclosures to explore the influence of statements around patient adherence and preference in prescription drug promotion. Previous FDA-funded research has shown that market claims that advertise drug characteristics unrelated to medicinal properties, such as ''#1 Prescribed,'' influence consumer and provider perceptions about a drug's efficacy (Ref. 1). In the same study, results of a tradeoff analysis suggested that patients prefer a drug over a

competitor when this type of claim is present, and a drug without this claim required at least 1.23 percent greater efficacy to be chosen over a drug with this claim (Ref. 2). Treatment preferences may also be influenced by other drug characteristics, including its impact on quality of life, complexity of dosage regimens, administration mode, and cost to family and self (Refs. 3–5).

It is not known how claims that appeal to the possibility for greater adherence or to social norms around what other patients or healthcare providers prefer influence perceptions of a drug. A related question is whether including a disclosure stating the uncertainty around such claims (*e.g.,* there is no conclusive research on whether DRUG A results in better adherence) can mitigate any misleading perceptions or influence preferences. Some evidence suggests that disclosures in prescription drug promotion are typically noticed and may help consumers and healthcare providers understand information (Refs. 2 and 6), but this topic has not been investigated in the context of adherence claims.

The present research is designed to complement previous research by experimentally examining the role of adherence and patient preference claims in prescription drug promotion. We have the following specific questions:

Research questions:

1. Does the presence or absence of an implied-adherence claim affect consumers' behavioral intentions or risk, benefit, and adherence perceptions?

2. Does the presence or absence of an adherence-related patient preference claim affect consumers' behavioral intentions or risk, benefit, and adherence perceptions?

3. Does the presence of both types of claims (adherence and preference) have a cumulative impact on consumers' behavioral intentions or risk, benefit, and adherence perceptions?

4. Does a disclosure of information to the effect that there is no conclusive research on whether the drug results in better adherence mitigate consumers' behavioral intentions or risk, benefit, and adherence perceptions?

To complete this research, we will show participants a website for a fictitious prescription drug product for type 2 diabetes. We propose the design in table 1, which varies based on whether the fictitious prescription drug promotional communication includes a claim about:

- implied adherence;
- patient preference; and
- a disclosure that there is no conclusive research on adherence.

TABLE 1—DESIGN 2 (IMPLIED ADHERENCE CLAIM) × 2 (PATIENT PREFERENCE CLAIM) × 2 (DISCLOSURE)

		With disclosure [1]		Without disclosure	
		Patient preference claim		Patient preference claim	
		Yes	No	Yes	No
Implied Adherence Claim	Yes.				
	No.				

[1] *E.g.,* "There is no conclusive research to suggest better adherence to Drug X compared with Drug Y."

Recruitment will occur by email through an internet panel, and participant eligibility will be determined with a screener at the beginning of the online survey. For the pretest, we expect to screen 253 consumers and 294 primary care physicians (PCPs) to reach our desired number of completed surveys. We will conduct complete pretest surveys with 160 consumers who self-identify as having been diagnosed with diabetes and 160 PCPs who treat diabetes (both obtained from a web-based research vendor) to ensure that the questionnaire programming works as expected. For the main study, we expect to screen 566 consumers and 660 PCPs to reach our desired number of completed surveys. Thus, for the main study final sample, we will recruit 360 adult voluntary participants aged 18 years or older who self-identify as having been diagnosed with diabetes and 360 voluntary participants who are employed as PCPs who treat diabetes. We will exclude individuals who work in healthcare settings, employees of the Department of Health and Human Services, and individuals who work in the marketing, advertising, or pharmaceutical industries.

The total annual estimated burden imposed by this collection of information is 520 hours (table 2). These estimates account for over-recruitment of 10 percent to account for survey incompletes. As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage.

Each participant will see one of eight versions of a consumer web page for a fictitious prescription diabetes treatment, as reflected in table 1. They will answer a questionnaire designed to take no more than 20 minutes regarding benefit and risk perceptions, adherence perceptions, behavioral intentions, adherence claim retention, and patient preference claim retention. The survey is available upon request at *DTCresearch@fda.hhs.gov.*

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Pretest:					
Consumers: pretest screener completes (assumes 70% eligible).	253	1	253	0.08 (5 min.)	20
Consumers: number of completes, pretest	176	1	176	0.33 (20 min.)	58
PCPs: pretest screener completes (assumes 60% eligible).	294	1	294	0.08 (5 min.)	24
PCPs: number of completes, pretest	176	1	176	0.33 (20 min.)	58

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Main Study:					
Consumers: number of main study screener completes (assumes 70% eligible).	566	1	566	0.08 (5 min.)	45
Consumers: number of completes, main study	396	1	396	0.33 (20 min.)	131
PCPs: number of main study screener completes (assumes 60% eligible).	660	1	660	0.08 (5 min.)	53
PCPs: number of completes, main study	396	1	396	0.33 (20 min.)	131
Total (rounded)	.....	.....	.....	.....	520

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Aikin, K.J., K.R. Betts, A. Keisler, and K.S. Ziemer, ''Market Claims and Efficacy Information in Direct-to-Consumer Prescription Drug Print Advertisements,'' *Psychology & Marketing,* 36(8), 747–757, 2019a.
2. Aikin, K.J., K.R. Betts, K.S. Ziemer, and A. Keisler, ''Consumer Tradeoff of Advertising Claim Versus Efficacy Information in Direct-to-Consumer Prescription Drug Ads,'' *Research in Social and Administrative Pharmacy,* 15(12), 1484–1488, 2019b.
3. Arroyo, R., A.P. Sempere, E. Ruiz-Beato, D. Prefasi, et al. ''Conjoint Analysis To Understand Preferences of Patients With Multiple Sclerosis for Disease-Modifying Therapy Attributes in Spain: A Cross-Sectional Observational Study,'' *BMJ Open,* 7(3), e014433, 2017.
4. Fraenkel, L., L. Suter, C.E. Cunningham, and G. Hawker, ''Understanding Preferences for Disease-Modifying Drugs in Osteoarthritis,'' *Arthritis Care Research,* 66(8), 1186–1192, 2014.
5. Wouters, H., G.A. Maatman, L. Van Dijk, M.L. Bouvy, et al. ''Trade-Off Preferences Regarding Adjuvant Endocrine Therapy Among Women With Estrogen Receptor-Positive Breast Cancer,'' *Annals of Oncology,* 24(9), 2324–2329, 2013.
6. Betts, K.R., V. Boudewyns, K.J. Aikin, C. Squire, et al. ''Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements,'' *Research in Social and Administrative Pharmacy,* 14(10), 951–963, 2018.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22586 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations for Voting Members for the Digital Health Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for voting members, excluding consumer and industry representatives, to serve on the Digital Health Advisory Committee (the Committee) in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies effective with this notice. FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before December 11, 2023 will be given first consideration for membership on the Committee. Nominations received after December 11, 2023 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal (*https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm*) and selecting Academician/Practitioner from the dropdown menu (regardless of whether Academician/Practitioner accurately describes the nominee), or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: James Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–796–6313, *James.Swink@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill current vacancies on the Digital Health Advisory Committee. This notice does not include consumer and industry representative nominations. The Agency will publish two separate notices announcing the vacancy of a representative of consumer interests and a vacancy of representatives of interests of the device manufacturing industry.

I. General Description of the Committee Duties

The Committee provides advice on complex scientific and technical issues related to Digital Health Technologies (DHTs). This also may include advice on the regulation of DHTs, and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring,

and software, may be considered by the Committee. The Committee advises the Commissioner of Food and Drugs (Commissioner) on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, use of DHTs in clinical trials for medical products, cybersecurity, DHT user experience, and Agency policies and regulations regarding these technologies. The Committee provides relevant expertise and perspective to improve Agency understanding of the benefits, risks, and clinical outcomes associated with use of DHTs. The Committee performs its duties by providing advice and recommendations on new approaches to develop and evaluate DHTs and to promote innovation of DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established Agency policy or regulation for topics related to DHTs.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in the fields of digital health, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, software development, user experience, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, cybersecurity, and implementation in clinical practice of and patient experience with digital health, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this Committee will serve either as Special Government Employees or nonvoting representatives. Federal members will serve as Regular Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with and represent industry interests.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee with the exception of the following: Individuals who are not U.S. citizens or nationals cannot be appointed as Advisory Committee Members (42 U.S.C. 217(a)) in the FDA. Self-nominations are also accepted. Nominations must include a cover letter; a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22569 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–1795]

Determination That MEKINIST (Trametinib Dimethyl Sulfoxide) Tablets, 1 Milligram, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined that MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 milligram (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for trametinib dimethyl sulfoxide tablets, 1 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3601, *Nicole.Mueller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, is the subject of NDA 204114, held by Novartis Pharmaceuticals Corp., and initially approved on May 29, 2013. MEKINIST is a kinase inhibitor indicated as a single agent for the treatment of BRAF-inhibitor treatment-naïve patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.

MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Apotex Inc., submitted a citizen petition dated May 4, 2023 (Docket No. FDA–2023–P–1795), under 21 CFR 10.30, requesting that the Agency determine whether MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22464 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations of Individuals and Consumer Organizations for the Digital Health Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for a voting consumer representative to serve on the Digital Health Advisory Committee. FDA is also requesting that any consumer organizations interested in participating in the selection of a voting consumer representative to serve on the Digital Health Advisory Committee notify FDA in writing. Nominees recommended to serve as a voting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for the current vacancy effective with this notice. FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting member to represent consumer interests on the Digital Health Advisory Committee may send a letter or email stating that interest to FDA (see **ADDRESSES**) by November 27, 2023 for vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by November 27, 2023. Nominations will be accepted for current vacancy.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to *ACOMSSubmissions@fda.hhs.gov* or by mail to Advisory Committee and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT:

For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002, 301–796–8220, *Kimberly.Hamilton@fda.hhs.gov.*

For questions relating to the Digital Health Advisory Committee: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301 796–6313, *James.Swink@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a voting consumer representative on the Digital Health Advisory Committee. Elsewhere in this **Federal Register**, FDA is publishing separate documents regarding:

1. Digital Health Advisory Committee; Notice of Establishment
2. Request for Nominations for Voting Members on a Public Advisory Committee: Digital Health Advisory Committee
3. Request for Nominations of Individuals and Industry Organizations for the Digital Health Advisory Committee

I. Function and General Description of the Committee Duties

Digital Health Advisory Committee

The Committee provides advice on complex scientific and technical issues related to Digital Health Technologies (DHTs). This also may include advice on the regulation of DHTs, and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, and software, may be considered by the Committee. The Committee advises the Commissioner on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data,

interoperability, personalized medicine/genetics, decentralized clinical trials, use of DHTs in clinical trials for medical products, cybersecurity, DHT user experience, and Agency policies and regulations regarding these technologies. The Committee provides relevant expertise and perspective to improve Agency understanding of the benefits, risks, and clinical outcomes associated with use of DHTs.

II. Criteria for Members

Persons nominated for membership as a consumer representative on this committee should meet the following criteria: (1) demonstrate an affiliation with and/or active participation in in consumer or community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 45 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or résumé. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Digital Health Advisory Committee with the exception of the following: individuals who are not U.S. citizens or nationals cannot be appointed as Advisory Committee Members (42 U.S.C. 217(a)) in FDA. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available; a signed copy of the Acknowledgment and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee for which the nominee is recommended. In addition, nominations must also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. After selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22567 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations of Individuals and Industry Organizations for the Digital Health Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for temporary nonvoting industry representatives to be included in a pool of individuals to serve on the Digital Health Advisory Committee. FDA is also requesting that industry organizations interested in participating in the selection of a pool of nonvoting industry representatives to serve as temporary nonvoting members on the Digital Health Advisory Committee (the Committee) in the Center for Devices and Radiological Health notify FDA in writing. Nominees recommended to serve as a temporary nonvoting industry representative may either be self-nominated or nominated by an industry organization. This position may be filled by representatives of different medical device areas based on areas of expertise relevant to the topics being considered by the Committee. Nominations will be accepted for current vacancies effective with this notice. FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest, must send a letter stating that interest to the FDA by *November 13, 2023,* (see sections I and II of this document for details). Concurrently, nomination materials for prospective candidates should be sent to FDA by *November 13, 2023.*

ADDRESSES: All statements of interest from interested industry organizations interested in participating in the selection process of a pool of nonvoting industry representatives should be sent electronically to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA

Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993–0002, 301–796–5960, email: *margaret.ames@fda.hhs.gov.*

For questions relating to the Digital Health Advisory Committee, contact James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Room 5211, Silver Spring, MD 20993–0002, 301–796–6313, *James.swink@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a pool of nonvoting industry representatives for the Digital Health Advisory Committee (this position may be filled by representatives of different medical device areas based on areas of expertise relevant to the topics being considered by the Advisory Committee).

Elsewhere in this **Federal Register**, FDA is publishing separate documents regarding:

1. Digital Health Advisory Committee; Notice of Establishment
2. Request for Nominations for Voting Members for the Digital Health Advisory Committee
3. Request for Nominations of Individuals and Consumer Organizations for the Digital Health Advisory Committee

I. General Description of the Committee's Duties

The Committee provides advice on complex scientific and technical issues related to Digital Health Technologies (DHTs). This also may include advice on the regulation of DHTs, and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, and software, may be considered by the Committee. The Committee advises the Commissioner on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, use of DHTs in clinical trials for medical products, cybersecurity, DHT user experience, and Agency policies and regulations regarding these technologies. The Committee provides relevant expertise and perspective to improve Agency understanding of the benefits, risks, and clinical outcomes associated with use of DHTs. The Committee performs its duties by providing advice and recommendations on new approaches to develop and evaluate DHTs and to promote innovation of DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established Agency policy or regulation for topics related to DHTs.

II. Qualifications

Persons nominated for the Digital Health Advisory Committee should be full-time employees of firms that manufacture medical device products, or consulting firms that represent manufacturers or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest must send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 45 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes or *curriculum vitae.* The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate or candidates (to serve in a pool of individuals, with varying areas of expertise), to represent industry interest for the committee, within 60 days after the receipt of the FDA letter. The interested organizations are not bound by the list of nominees in selecting a candidate or candidates. However, if no individual is selected within 60 days, the Commissioner will select temporary nonvoting members (or pool of individuals) to represent industry interests.

IV. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a temporary nonvoting industry representative. Nominations must include a cover letter and a current, complete résumé or *curriculum vitae* for each nominee, including current business and/or home address, telephone number, and email address if available; and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**). Nominations should specify the advisory committee for which the nominee is recommended within 30 days of publication of this document (see **DATES**). Nominations should also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Only interested industry organizations participate in the selection process. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22568 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4181]

Agency Information Collection Activities; Proposed Collection; Comment Request; Cattle Materials Prohibited From Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in

response to the notice. This notice solicits comments on the reporting and recordkeeping requirements for cattle materials prohibited from use in animal food or feed.

DATES: Either electronic or written comments on the collection of information must be submitted by December 11, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–4181 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Cattle Materials Prohibited From Use in Animal Food or Feed.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Cattle Materials Prohibited From Use in Animal Food or Feed—21 CFR 589.2001

OMB Control Number 0910–0627—Extension

This information collection supports implementation of Agency statutory and regulatory requirements regarding substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. Our regulation at § 589.2001 (21 CFR 589.2001) is designed to safeguard against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These

materials are referred to as ''cattle materials prohibited in animal feed'' or CMPAF. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements on renderers that process cattle materials, including reporting and recordkeeping requirements. The reporting and recordkeeping requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know whether the cattle material meets the requirements of our regulation.

Under our regulations, we may designate a country from which cattle materials are not considered CMPAF. A country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine, including certain required information. We use the information provided to determine whether to grant a request for designation and to impose conditions if a request is granted. Additionally, designated countries will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries at any time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate. We use the information to ensure their designations remain appropriate.

Renderers that receive, manufacture, process, blend, or distribute CMPAF, or products that contain or may contain CMPAF, must take measures to ensure that the materials are not introduced into animal feed, including maintaining adequate written procedures specifying how such processes are to be carried out.

Description of Respondents: Respondents to this information collection are foreign governments seeking designation under § 589.2001(f) and rendering facilities that process cattle materials.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
589.2001(f); Process for designating countries to request exemption from the requirements of this regulation	1	1	1	40	40
589.2001(f); response to request for review by FDA	1	1	1	26	26
Total					66

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information the country is required to submit includes information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in § 589.2001(b)(1).

Since the last renewal, we have reduced the request for designation burden from 80 hours to 40 hours. This reduction is because respondents are required to provide this information to other entities in order to comply with international standards and therefore will have already compiled the necessary information.

Our estimate of the reporting burden for designation under § 589.2001(f) is based on estimates found in our final rule. Since the rule's effective date in 2009, only two requests for designation have been received; however, we retain our current estimate of one to permit such requests for designation by respondents and to permit related responses to FDA.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2001(c)(2)(ii), 589.2001(c)(2)(vi) and (c)(3)(i), and 589.2001(c)(3)(i)(A) and (B); Rendering facilities maintain written procedures and records, and certification or documentation from the supplier	145	1	145	45	6,525

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden we attribute to recordkeeping activities is assumed to be distributed among the individual elements and averaged among respondents. The total number of recordkeepers contains a subset of 50 recordkeepers who maintain written procedures and records specifically required by 21 CFR 589.2001(c).

We have adjusted our recordkeeping burden estimate in Table 2, which results in a decrease of 2,525 hours. This is based primarily on consolidation within the industry and a decrease in the estimated number of respondents subject to recordkeeping requirements.

Based on our review since the last OMB approval, there is an overall adjustment decrease of 2,565 burden hours. The adjustment is attributable to decreases in the average reporting burden time and in respondent subject to recordkeeping requirements.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22495 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3941]

Advisory Committee; Digital Health Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of establishment.

SUMMARY: Under the Federal Advisory Committee Act, the Food and Drug Administration (FDA or Agency) is announcing the establishment of the Digital Health Advisory Committee. The Commissioner of Food and Drugs (Commissioner) has determined that it is in the public interest to establish such a committee. Duration of this committee is 2 years from the date the Charter is filed, unless the Commissioner formally determines that renewal is in the public interest.

DATES: Either electronic or written comments on the notice must be submitted by December 11, 2023. FDA is establishing a docket for public comment on this document. The docket number is FDA–2023–N–3941. The docket will close on December 11, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3941 for ''Advisory Committee; Digital Health Committee; Establishment.'' Received comments, those filed in a timely manner, will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: James Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993, 301–796–6313, *James.Swink@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Digital Health Advisory Committee (Committee) provides advice to the Commissioner or designee, on complex scientific and technical issues related to digital health technologies (DHTs). This also may include advice on the regulation of DHTs, and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning (AI/ML), augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, and software, may be considered by the Committee. The Committee advises the Commissioner on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, use of DHTs in clinical trials for medical products, cybersecurity, DHT user experience, and Agency policies and regulations regarding these technologies. The Committee provides relevant expertise and perspective to improve Agency understanding of the benefits, risks, and clinical outcomes associated with use of DHTs. The Committee performs its duties by providing advice and recommendations on new approaches to develop and evaluate DHTs and to promote innovation of DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established Agency policy or regulation for topics related to DHTs.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are

selected by the Commissioner or designee from among authorities knowledgeable in the fields of digital health, such as AI/ML, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, software development, user experience, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, cybersecurity, and implementation in clinical practice of and patient experience with digital health, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve either as special government employees or non-voting representatives. Federal members will serve as regular government employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as non-voting members who are identified with and represent industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

In announcing the establishment of this Advisory Committee under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*), FDA is also soliciting public feedback on potential topics for this committee to discuss and upon which to advise the Agency. The following topics may include, but are not limited to:

- Transparency and bias management considerations, including promoting health equity in DHTs
- Augmented reality and virtual reality technical and clinical questions
- Transparency and labeling considerations for ''opaque box'' algorithms
- Digital therapeutics
- AI/ML
- Input on regulation of AI/ML-enabled devices
- Real-world data and real-world evidence
- Patient-generated health data
- Postmarket monitoring considerations for a total product lifecycle approach to DHTs
- Interoperability
- Personalized medicine/genetics
- Wearables, remote patient monitoring, and internet of things
- Postmarket monitoring of DHTs
- Technologies to enable decentralized clinical trials
- Cybersecurity best practices in software development for cloud-based software

Elsewhere in this issue of the **Federal Register**, FDA is publishing separate documents regarding: (1) Digital Health Advisory Committee: Request for Nominations for Voting Members on a Public Advisory Committee: Digital Health Advisory Committee; (2) Request for Nomination of Individuals and Consumer Organizations for the Digital Health Advisory Committee; and (3) Request for Nomination of Individuals and Industry Organizations for the Digital Health Advisory Committee.

FDA intends to publish in the **Federal Register** a final rule adding the Digital Health Advisory Committee to 21 CFR 14.100.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22566 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Commission on Childhood Vaccines (ACCV) will hold public meetings for the 2024 calendar year (CY). Information about ACCV, agendas, and materials for these meetings can be found on the ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.*

DATES: ACCV meetings will be held on March 7, 2024, 10:00 a.m.–4:00 p.m. Eastern Time (ET); March 8, 2024, 10:00 a.m.–4:00 p.m. ET; September 5, 2024, 10:00 a.m.–4:00 p.m. ET; September 6, 2024, 10:00 a.m.–4:00 p.m. ET.

ADDRESSES: Meetings may be held in-person or by Zoom webinar. For updates on how the meeting will be held, visit the ACCV website meeting page included below 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will be posted. In-person ACCV meetings will be held at 5600 Fishers Lane, Rockville, MD 20857. For meeting information updates, go to the ACCV website meeting page at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 8W–25A, Rockville, MD 20857; 800–338–2382; or *ACCV@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACCV provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other issues related to implementation of the National Vaccine Injury Compensation Program and concerning other matters as described under section 2119 of the Public Health Service Act (42 U.S.C. 300aa–19).

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2024 meetings, agenda items may include, but are not limited to: updates from the Division of Injury Compensation Programs, Department of Justice, Office of Infectious Disease and HIV/AIDS Policy (HHS), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics Evaluation and Research (Food and Drug Administration). Refer to the ACCV website listed above for all current and updated information concerning the CY 2024 ACCV meetings, including draft agendas and meeting materials that will be posted 5 calendar days before the meeting.

These meetings are open to the public. Meetings held by Zoom webinar will require registration. Registration details will be provided on our ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.* All registrants will be asked to provide their name, affiliation, and email address. After registration, individuals will receive personalized Zoom information via email.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACCV should

be sent to Pita Gomez using the contact information listed above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Pita Gomez using the contact information listed above at least 10 business days before the meeting(s) they wish to attend. Since all in-person meetings will occur in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–22584 Filed 10–11–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Thursday, November 2, 2023, and Friday, November 3, 2023. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Thursday, November 2, 2023, from 10:00 a.m. to 4:00 p.m. Eastern Time (ET) and Friday, November 3, 2023, from 10:00 a.m. to 2:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html* by the deadline of 12:00 p.m. ET on November 1, 2023. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

During the November 2–3, 2023, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) An update on the Krabbe disease expedited evidence review update;

(2) An update on the Duchenne Muscular Dystrophy evidence review update;

(3) An update by the ACHDNC Decision Matrix ad hoc topic group and potential vote on revisions to the ACHDNC Decision Matrix;

(4) A presentation and discussion on the ACHDNC's conflict of interest procedures;

(5) Ad hoc topic group updates; and

(6) A possible presentation on the National Academies of Sciences, Engineering, and Medicine Workshop on Next Generation Screening.

ACHDNC will not vote on recommending conditions for inclusion in the Recommended Uniform Screening Panel during this meeting; however, Krabbe disease and Duchenne Muscular Dystrophy evidence review updates along with a discussion and a potential vote on revisions to the ACHDNC Decision Matrix may inform such potential future recommendations. Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is available on the ACHDNC website.

Members of the public will have the opportunity to provide comments on any or all of the above agenda items. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Members of the public registered to provide oral public comments on all other newborn screening related topics are tentatively scheduled to provide their statements on Thursday, November 2, 2023. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Friday, October 20, 2023. Written comments will be shared with the Committee, so that they have an opportunity to consider them prior to the meeting.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–22493 Filed 10–11–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory

Committee on Infant and Maternal Mortality (ACIMM) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES: December 5, 2023, 10 a.m. to 5 p.m. Eastern Time and December 6, 2023, 9:30 a.m. to 2 p.m. Eastern Time.

ADDRESSES: This meeting will be held in person at HRSA Headquarters (5600 Fishers Lane, Room 5W07, Rockville, MD, 20857) and virtually via webinar. *The webinar link and log-in information will be available at the ACIMM website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, MD 20857; 301–443–0543; or *SACIM@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of the Federal Advisory Committee Act (5 U.S.C. Chapter 10), as amended.

ACIMM advises the Secretary of Health and Human Services (Secretary) on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality, and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, maternal health, as well as influence similar efforts in the private and voluntary sectors. The Committee provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The agenda for the December 5–6, 2023, meeting is being finalized and may include the following topics: an update on the recommendations submitted to the Secretary on improving birth outcomes among American Indian/Alaska Native mothers and infants; updates on the federal Healthy Start program; Committee workgroup discussions on rural health/systems issues, social determinants of health, and preconception/interconception care and reproductive health; federal updates; and Committee operations. Agenda items are subject to change as priorities dictate. Refer to the ACIMM website listed above for any updated information concerning the meeting.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to ACIMM should be sent to Vanessa Lee, using the email address above at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing *SACIM@hrsa.gov.* Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or a reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–22509 Filed 10–11–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002; Internal Agency Docket No. FEMA–B–2376]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov*; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer

of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Colorado:						
Adams	City of Aurora (22–08–0618P).	The Honorable Mike Coffman, Mayor, City of Aurora, 15151 East Alameda Parkway, Aurora, CO 80012.	Public Works Department, 15151 East Alameda Parkway, Suite 3200, Aurora, CO 80012.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	080002
Adams	Unincorporated areas of Adams County, (22–08–0618P).	Steve O'Dorisio, Chair, Adams County Board of Commissioners, 4430 South Adams County Parkway, Brighton, CO 80601.	Adams County Community and Economic Development, Department, 4430 South Adams County Parkway, Brighton, CO 80601.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 202	080001
Broomfield	City and County of Broomfield (22–08–0513P).	The Honorable Guyleen Castriotta, Mayor, City and County of Broomfield, 1 DesCombes Drive, Broomfield, CO 80020.	Engineering Department, 1 DesCombes Drive, Broomfield, CO 80020.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 2, 2024	085073
Douglas	Town of Castle Rock, (22–08–0671P).	The Honorable Jason Gray, Mayor, Town of Castle Rock, 100 North Wilcox Street, Castle Rock, CO 80104.	Water Department, 175 Kellogg Court, Castle Rock, CO 80194.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 13, 2023	080050
Douglas	Unincorporated areas of Douglas County, (22–08–0671P).	Abe Laydon, Chair, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Department of Public Works/Engineering, 100 3rd Street, Castle Rock, CO 80104.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 13, 2023	080049
Jefferson	City of Golden (22–08–0756P).	The Honorable Laura Weinberg, Mayor, City of Golden, 911 10th Street, Golden, CO 80401.	Public Works Department, 1445 10th Street, Golden, CO 80401.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	080090
Jefferson	Unincorporated areas of Jefferson County, (22–08–0610P).	Andy Kerr, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Suite 5550, Golden, CO 80419.	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 1, 2023	080087
Jefferson	Unincorporated areas of Jefferson County, (22–08–0756P).	Andy Kerr, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Suite 5550, Golden, CO 80419.	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	080087
Connecticut: Hartford.	City of New Britain, (22–01–1075P).	The Honorable Erin E. Stewart, Mayor, City of New Britain, 27 West Main Street, New Britain, CT 06051.	Public Works Department, 27 West Main Street, Room 501, New Britain, CT 06051.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 4, 2023	090032
Delaware: New Castle.	Unincorporated areas of New Castle County, (23–03–0218P).	Matthew Meyer, New Castle County Executive, 87 Reads Way, New Castle, DE 19720.	New Castle County Land Use Department, 87 Reads Way, New Castle, DE 19720.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 28, 2023	105085
Florida:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Broward	City of Deerfield Beach, (23–04–4228P).	The Honorable Bill Ganz, Mayor, City of Deerfield Beach, 150 Northeast 2nd Avenue, Deerfield Beach, FL 33441.	Environmental Services Department, 200 Goolsby Boulevard, Deerfield Beach, FL 33442.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 30, 2023	125101
Lee	City of Bonita Springs, (23–04–1949P).	The Honorable Rick Steinmeyer, Mayor, City of Bonita Springs, 9101 Bonita Beach Road, Bonita Springs, FL 34135.	Community Development Department, 9220 Bonita Beach Road, Suite 111, Bonita Springs, FL 34135.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	120680
Miami-Dade	City of Miami (23–04–1745P).	The Honorable Francis Suarez, Mayor, City of Miami, 444 Southwest 2nd Avenue, Miami, FL 33130.	Building Department 444 Southwest 2nd Avenue, Miami, FL 33130.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 3, 2024	120650
Monroe	Village of Islamorada, (23–04–4107P).	The Honorable Joseph Buddy Pinder III, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 1, 2023	120424
Monroe	Village of Islamorada, (23–04–4211P).	The Honorable Joseph Buddy Pinder III, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 11, 2023	120424
Palm Beach	City of Westlake, (23–04–0749P).	The Honorable JohnPaul O'Connor, Mayor, City of Westlake, 4001 Seminole Pratt Whitney Road, Westlake, FL 33470.	City Hall, 4001 Seminole Pratt Whitney Road, Westlake, FL 33470.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 8, 2024	120018
Palm Beach	City of West Palm Beach, (22–04–5604P).	The Honorable Keith James, Mayor, City of West Palm Beach, P.O. Box 3366, West Palm Beach, FL 33402.	Building Department, 401 Clematis Street, West Palm Beach, FL 33401.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	120229
Pasco	Unincorporated areas of Pasco County, (23–04–1176P).	Jack Mariano, Chair, Pasco County Board of Commissioners, 8731 Citizens Drive, New Port Richey, FL 34654.	Pasco County Building Construction Services Department, 8731 Citizens Drive, Suite 230, New Port Richey, FL 34654.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 4, 2024	120230
Pasco	Unincorporated areas of Pasco County, (23–04–2545P).	Jack Mariano, Chair, Pasco County Board of Commissioners, 8731 Citizens Drive, New Port Richey, FL 34654.	Pasco County Building Construction Services Department, 8731 Citizens Drive, Suite 230, New Port Richey, FL 34654.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 4, 2024	120230
Pasco	Unincorporated areas of Pasco County, (23–04–2692P).	Jack Mariano, Chair, Pasco County Board of Commissioners, 8731 Citizens Drive, New Port Richey, FL 34654.	Pasco County Building Construction Services Department, 8731 Citizens Drive, Suite 230, New Port Richey, FL 34654.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 28, 2023	120230
Louisiana: Tangipahoa.	Unincorporated areas of Tangipahoa Parish, (23–06–0213P).	Robby Miller, Tangipahoa Parish President, P.O. Box 215, Amite City, LA 70422.	Tangipahoa Parish Government Building, 206 East Mulberry Street, Amite City, LA 70422.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	220206
Pennsylvania: Blair	Township of Frankstown, (23–03–0118P).	George W. Henry, Jr., Chair, Township of Frankstown Board of Supervisors, 2122 Frankstown Road, Hollidaysburg, PA 16648.	Township Hall, 2122 Frankstown Road, Hollidaysburg, PA 16648.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 13, 2023	421387
Texas:						
Caldwell	Unincorporated areas of Caldwell County, (22–06–2389P).	The Honorable Hoppy Haden, Caldwell County Judge, 110 South Main Street, Room 101, Lockhart, TX 78644.	Caldwell County Main Historic Courthouse, 110 South Main Street, Room 201, Lockhart, TX 78644.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 22, 2023	480094
Collin	City of Celina (23–06–0639P).	The Honorable Ryan Tubbs, Mayor, City of Celina, 142 North Ohio Street, Celina, TX 75009.	City Hall, 142 North Ohio Street, Celina, TX 75009.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 2, 2024	480133

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Dallas	City of Garland (22–06–0934P).	The Honorable Scott LeMay, Mayor, City of Garland, 200 North 5th Street, Garland, TX 75040.	Engineering Department, 800 Main Street, 3rd Floor, Garland, TX 75040.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 4, 2023	485471
Denton	Unincorporated areas of Denton County, (23–06–0647P).	The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208.	Denton County Hall, 1 Courthouse Drive, Denton, TX 76208.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 17, 2023	480774
Grayson	City of Tioga, (23–06–0305P).	The Honorable Craig Jezek, Mayor, City of Tioga, P.O. Box 206, Tioga, TX 76271.	City Hall, 600 Main Street, Tioga, TX 76271.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 16, 2024	481624
Harris	Unincorporated areas of Harris County, (22–06–2777P).	The Honorable Lina Hidalgo, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Engineering Department, 1001 Preston Street, 7th Floor, Houston, TX 77002.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 20, 2023	480287
Medina	Unincorporated areas of Medina County, (23–06–0919P).	The Honorable Keith Lutz, Medina County Judge, 1300 Avenue M, Room 250, Hondo, TX 78861.	Medina County Old Jail Building, 1502 Avenue K, Hondo, TX 78861.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 12, 2024	480472
Tarrant	City of Fort Worth, (23–06–0280P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	T/PW Engineering Vault, 200 Texas Street, Fort Worth, TX 76102.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 1, 2023	480596
Waller	Unincorporated areas of Waller County, (22–06–2777P).	The Honorable Carbett ''Trey'' J. Duhon, III, Waller County Judge, 836 Austin Street, Suite 203, Hempstead, TX 77445.	Waller County Engineering Department, 775 Business Highway 290 East, Hempstead, TX 77445.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 20, 2023	480640
Utah:						
Davis	City of Farmington, (23–08–0529P).	The Honorable Brett Anderson, Mayor, City of Farmington, 160 South Main Street, Farmington, UT 84025.	City Hall, 160 South Main Street, Farmington, UT 84025.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 20, 2023	490044
Salt Lake	City of Herriman City, (22–08–0795P).	Nathan Cherpeski, Manager, City of Herriman City, 5355 West Herriman Main Street, Herriman, UT 84096.	City Maps (GIS) Department, 5355 West Herriman Main Street, Herriman, UT 84096.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	490252
Salt Lake	City of Murray, (22–08–0780P).	The Honorable Brett A. Hales, Mayor, City of Murray, 10 East 4800 South, 3rd Floor, Murray, UT 84107.	Geographic Information Systems Division, 10 East 4800 South, Murray, UT 84107.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 14, 2023	490103
Washington	Town of Virgin (23–08–0208P).	The Honorable Jean Krause, Mayor, Town of Virgin, P.O. Box 790008, Virgin, UT 84779.	Planning and Zoning Department, 114 South Mill Street, Virgin, UT 84779.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 30, 2023	490181
Vermont: Chittenden.	Town of Essex, (23–01–0198P).	Greg Duggan, Town of Essex Manager, 81 Main Street, Essex Junction, VT 05452.	Town Clerk's Office (Land Records), 81 Main Street, Essex Junction, VT 05452.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 24, 2023	500034

[FR Doc. 2023–22592 Filed 10–11–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports,

currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alabama: Madison (FEMA Docket No.: B–2361).	City of Huntsville (23–04–2057P).	The Honorable Thomas Battle Jr., Mayor, City of Huntsville, 308 Fountain Circle, 8th Floor, Huntsville, AL 35801.	City Hall, 308 Fountain Circle, Huntsville, AL 35801.	Oct. 5, 2023	010153
Colorado:					
Gilpin (FEMA Docket No.: B–2361).	City of Black Hawk (22–08–0228P).	The Honorable David D. Spellman, Mayor, City of Black Hawk, P.O. Box 68, Black Hawk, CO 80422.	Community Planning and Development Department, 211 Church Street, Black Hawk, CO 80422.	Sep. 22, 2023	080076
Gilpin (FEMA Docket No.: B–2361).	City of Central City (22–08–0228P).	The Honorable Jeremy Fey, Mayor, City of Central City, P.O. Box 249, Central City, CO 80427.	City Hall, 141 Nevada Street, Central City, CO 80427.	Sep. 22, 2023	080077
Florida:					
Lake (FEMA Docket No.: B–2361).	City of Leesburg (22–04–3930P).	Al Minner, Manager, City of Leesburg, P.O. Box 490630, Leesburg, FL 34749.	Public Works Department, 501 West Meadow Street, Leesburg, FL 34748.	Sep. 25, 2023	120136
Lake (FEMA Docket No.: B–2361).	Unincorporated areas of Lake County (22–04–3930P).	Jennifer Barker, Lake County Manager, P.O. Box 7800, Tavares, FL 32778.	Lake County Public Works Department, 323 North Sinclair Avenue, Tavares, FL 32778.	Sep. 25, 2023	120421
Manatee (FEMA Docket No.: B–2361).	Unincorporated areas of Manatee County (23–04–0814P).	Lee Washington, Manatee County Administrator, 1112 Manatee Avenue West, Bradenton, FL 34205.	Manatee County Administration Building, 1112 Manatee Avenue West, Bradenton, FL 34205.	Sep. 25, 2023	120153
Orange (FEMA Docket No.: B–2361).	Unincorporated areas of Orange County (21–04–3684P).	The Honorable Jerry L. Demings, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801.	Orange County Public Works Department, Stormwater Management Division, 4200 South John Young Parkway, Orlando, FL32839.	Sep. 22, 2023	120179
Pinellas (FEMA Docket No.: B–2361).	City of Clearwater (23–04–0224P).	The Honorable Brian Aungst, Sr., Mayor, City of Clearwater, 600 Cleveland Street, 6th Floor, Clearwater, FL 33756.	City Hall, 100 South Myrtle Avenue, Clearwater, FL 33756.	Sep. 28, 2023	125096
Sumter (FEMA Docket No.: B–2361).	City of Wildwood (22–04–4208P).	The Honorable Ed Wolf, Mayor, City of Wildwood, 100 North Main Street, Wildwood, FL 34785.	Sumter County Service Center, 7375 Powell Road, Wildwood, FL 34785.	Sep. 22, 2023	120299
Sumter (FEMA Docket No.: B–2361).	Unincorporated areas of Sumter County (22–04–4208P).	Bradley Arnold, Sumter County Administrator, 7375 Powell Road, Wildwood, FL 34785.	Sumter County Service Center, 7375 Powell Road, Wildwood, FL 34785.	Sep. 22, 2023	120296
Georgia: DeKalb (FEMA Docket No.: B–2361).	Unincorporated areas of DeKalb County (23–04–0174P).	Michael L Thurmond, Chief Executive Officer, DeKalb County, 1300 Commerce Drive, 6th Floor, Decatur, GA 30030.	DeKalb County Roads and Drainage Department, 727 Camp Road, Decatur, GA 30032.	Sep. 22, 2023	130065
Maryland: Montgomery (FEMA Docket No.: B–2361).	Unincorporated areas of Montgomery County (22–03–0958P).	Marc Elrich, Montgomery County Executive, 101 Monroe Street, 2nd Floor, Rockville, MD 20850.	Montgomery County Department of Permitting Services, 2425 Reedie Drive, 7th Floor, Wheaton, MD 20902.	Sep. 25, 2023	240049

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Montana: Gallatin (FEMA Docket No.: B–2352).	Unincorporated areas of Gallatin County (23–08–0301P).	Zach Brown, Chair, Gallatin County Commission, 311 West Main Street, Room 306, Bozeman, MT 59715.	Gallatin County Department of Planning and Community Development, 311 West Main Street, Room 108, Bozeman, MT 59715.	Sep. 18, 2023	300027
South Carolina: Berkeley (FEMA Docket No.: B–2361).	Unincorporated areas of Berkeley County (22–04–5274P).	Johnny Cribb, Berkeley County Supervisor, 1003 Highway 52, Moncks Corner, SC 29461.	Berkeley County Planning and Zoning Department, 1003 Highway 52, Moncks Corner, SC 29461.	Sep. 21, 2023	50029
Texas:					
Bexar (FEMA Docket No.: B–2361).	Unincorporated areas of Bexar County (22–06–2152P).	The Honorable Peter Saki, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78205.	Sep. 25, 2023	480035
Denton (FEMA Docket No.: B–2361).	City of Fort Worth (23–06–0297P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	T/PW Engineering Vault, 200 Texas Street, Fort Worth, TX 76102.	Sep. 25, 2023	480596
Ellis (FEMA Docket No.: B–2361).	City of Grand Prairie (22–06–2534P).	The Honorable Ron Jensen, Mayor, City of Grand Prairie, P.O. Box 534045, Grand Prairie, TX 75053.	City Hall, 300 West Main Street, Grand Prairie, TX 75050.	Sep. 14, 2023	480798
Ellis (FEMA Docket No.: B–2361).	Unincorporated areas of Ellis County (22–06–2534P).	The Honorable Todd Little, Ellis County Judge, 101 West Main Street, Waxahachie, TX 75165.	Ellis County Courts and Administration, 109 South Jackson Street, Waxahachie, TX 75165.	Sep. 14, 2023	480798
Hays (FEMA Docket No.: B–2361).	Unincorporated areas of Hays County (23–06–0307P).	The Honorable Ruben Becerra, Hays County Judge, 111 East San Antonio Street, Suite 300, San Marcos, TX 78666.	Hays County Development Services Department, 2171 Yarrington Road, Suite 100, Kyle, TX 78640.	Sep. 28, 2023	480321
Kaufman (FEMA Docket No.: B–2361).	Unincorporated areas of Kaufman County (23–06–0527P).	The Honorable Jakie Allen, Kaufman County Judge, 1902 East U.S. Highway 175, Kaufman, TX 75142.	Kaufman County Development Services Department, 106 West Grove Street, Kaufman, TX 75142.	Sep. 29, 2023	480411
Tarrant (FEMA Docket No.: B–2361).	City of Arlington (23–06–0354P).	The Honorable Jim Ross, Mayor, City of Arlington, P.O. Box 90231, Arlington, TX 76004.	Public Works and Transportation Department, 101 West Abram Street, Arlington, TX 76004.	Sep. 18, 2023	485454
Tarrant (FEMA Docket No.: B–2361).	City of Fort Worth (23–06–0306P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Transportation and Public Works Department, Engineering Vault, 200 Texas Street, Fort Worth, TX 76102.	Sep. 18, 2023	480596
Tarrant (FEMA Docket No.: B–2361).	City of Fort Worth (23–06–0361P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Transportation and Public Works Department, Engineering Vault, 200 Texas Street, Fort Worth, TX 76102.	Sep. 25, 2023	480596
Tarrant (FEMA Docket No.: B–2361).	City of Haltom City (23–06–0193P).	The Honorable An Truong, Mayor, City of Haltom City, 5024 Broadway Avenue, Haltom City, TX 76117.	Public Works Department, 4200 Hollis Street, Haltom City, TX 76111.	Sep. 18, 2023	480599
Tarrant (FEMA Docket No.: B–2361).	Unincorporated areas of Tarrant County (23–06–0306P).	The Honorable Tim O'Hare, Tarrant County Judge, 100 East Weatherford Street, Suite 501, Fort Worth, TX 76196.	Tarrant County Administration Building, 100 East Weatherford Street, Fort Worth, TX 76196.	Sep. 18, 2023	480582
Wise (FEMA Docket No.: B–2361).	City of New Fairview (23–06–0882P).	The Honorable John R. Taylor, Mayor, City of New Fairview, 999 Illinois Lane, New Fairview, TX 76078.	Public Works Department, 999 Illinois Lane, New Fairview, TX 76078.	Sep. 22, 2023	481629
Wise (FEMA Docket No.: B–2361).	Unincorporated areas of Wise County (23–06–0882P).	The Honorable J.D. Clark, Wise County Judge, 101 North Trinity Street, Decatur, TX 76234.	Wise County Public Works Department, 2901 South F.M. 51, Building 100, Decatur, TX 76234.	Sep. 22, 2023	481051

[FR Doc. 2023–22591 Filed 10–11–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002; Internal Agency Docket No. FEMA–B–2374]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before January 10, 2024.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2374, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400

C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Harper County, Kansas and Incorporated Areas Project: 23–07–0011S Preliminary Date: June 23, 2023	
City of Anthony	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Attica	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Bluff City	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Danville	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Harper	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
City of Waldron	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.
Unincorporated Areas of Harper County	Harper County Courthouse, 201 North Jennings Avenue, Anthony, KS 67003.

[FR Doc. 2023–22593 Filed 10–11–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[OMB Control Number 1653–0051]

Agency Information Collection Activities; Extension of a Currently Approved Collection: Standards To Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995 the Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance. This information collection was previously published in the **Federal Register** on August 3, 2023, allowing for a 60-day comment period. ICE received no comments. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until November 13, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of the publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: If you have questions related to this collection please contact: Chelsea Dennis, ICE/OIPE, (202) 423–7456, *chelsea.y.dennis@ice.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the

functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Standards to Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities.

(3) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households. DHS sets standards for the prevention, detection, and response to sexual abuse in its confinement facilities. For DHS facilities and as incorporated in DHS contracts, these standards require covered facilities to retain and report to the agency certain specified information relating to sexual abuse prevention planning, responsive planning, education and training, and investigations, as well as to collect, retain, and report to the agency certain specified information relating to allegations of sexual abuse within the covered facility.

(4) *An estimate of the total number of respondents:* 1,376,754.

(5) *An estimate of the total public burden (in hours) associated with the collection:* 117,267 annual burden hours.

Dated: October 4, 2023.

Scott Elmore,

ICE PRA Clearance Officer, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2023–22445 Filed 10–11–23; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Quarterly Narrative Progress Report, Employment and Training Supplemental Budget Request Activities

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Quarterly Narrative Progress Report, Employment and Training Supplemental Budget Request Activities.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by December 11, 2023.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Jennifer Garrett by telephone at (415) 910–2585, TTY 1–877–889–5627 (these are not toll-free numbers), or by email at *Garrett.Jennifer.L@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, 200 Constitution Avenue NW, Room S–4524, Washington, DC 20210; by email: *Garrett.Jennifer.L@dol.gov;* or by fax 202–693–3229.

FOR FURTHER INFORMATION CONTACT: Jennifer Garrett by telephone at 415–910–2585 (this is not a toll-free number) or by email at *Garrett.Jennifer.L@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The ETA National and Regional Offices use the Quarterly Narrative Progress Report, Employment and Training Supplemental Budget Request Activities, to monitor the progress of State Workforce Agencies (SWAs) in implementing supplemental grant projects. ETA provides supplemental grants for SWAs to prevent and detect improper benefit payments, improve state performance, and address outdated information technology (IT) system infrastructures. ETA implements these projects through Unemployment Insurance (UI) Supplemental Budget Request (SBR) grants, Reemployment Services and Eligibility Assessments (RESEA) grants, and Dislocated Worker Grants (DWGs) to states for demonstration and special projects such as Reemployment and Systems Integration (RSI). This information collection includes the funded project/activity, the targeted start and completion dates for the project/activity, and the quarterly implementation status. These data are needed for budget preparation and control; program planning and evaluation; program monitoring, oversight, and performance accountability; actuarial and program research; and for accounting to Congress and the public. Title III, Section 303(a)(6) of the Social Security Act authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention 1205–0517.

Submitted comments will also be a matter of public record for this ICR and

posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Extension without Changes.

Title of Collection: Quarterly Narrative Progress Report, Employment and Training Supplemental Budget Request Activities.

Form: ETA 9178.

OMB Control Number: 1205–0517.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 57.

Frequency: Quarterly.

Total Estimated Annual Responses: 228.

Estimated Average Time per Response: 5 hours.

Estimated Total Annual Burden Hours: 1,140 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Brent Parton,

Principal Deputy Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2023–22500 Filed 10–11–23; 8:45 am]

BILLING CODE 4510–FW–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–472, OMB Control No. 3235–0531]

Proposed Collection; Comment Request; Extension: Rule 0–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 350l *et seq.*), the Securities and Exchange Commission (''Commission'') plans to submit to the Office of Management and Budget a request for extension of the previous approved collection of information discussed below.

The Investment Company Act of 1940 (the ''Act'') [1] establishes a comprehensive framework for regulating the organization and operation of investment companies (''funds''). A principal objective of the Act is to protect fund investors by addressing the conflicts of interest that exist between funds and their investment advisers and other affiliated persons. The Act places significant responsibility on the fund board of directors in overseeing the operations of the fund and policing the relevant conflicts of interest.[2] Rule 0–1 (17 CFR 270.0–1), as amended, provides definitions for the terms used by the Commission in the rules and regulations it has adopted pursuant to the Act. The rule also contains a number of rules of construction for terms that are defined either in the Act itself or elsewhere in the Commission's rules and regulations. Finally, rule 0–1 defines terms that serve as conditions to the availability of certain of the Commission's exemptive rules. More specifically, the term ''independent legal counsel,'' as defined in rule 0–1, sets out conditions that funds must meet in order to rely on any of ten exemptive rules (''exemptive rules'') under the Act.[3]

If the board's counsel has represented the fund's investment adviser, principal underwriter, administrator (collectively, ''management organizations'') or their ''control persons'' [4] during the past two years, rule 0–1 requires that the board's independent directors make a determination about the adequacy of the counsel's independence. A majority of the board's independent directors are required to reasonably determine, in the exercise of their judgment, that the counsel's prior or current representation of the management organizations or their control persons was sufficiently limited to conclude that it is unlikely to adversely affect the counsel's professional judgment and legal representation. Rule 0–1 also requires that a record for the basis of this determination is made in the minutes of the directors' meeting. In addition, the independent directors must have obtained an undertaking from the counsel to provide them with the information necessary to make their determination and to update promptly that information when the person begins to represent a management organization or control person, or when he or she materially increases his or her representation. Generally, the independent directors must re-evaluate their determination no less frequently than annually.

Any fund that relies on one of the exemptive rules must comply with the requirements in the definition of ''independent legal counsel'' under rule 0–1. We assume that approximately 2,909 funds rely on at least one of the exemptive rules annually.[5] We further assume that the independent directors of approximately one-third (970) of those funds would need to make the required determination in order for their counsel to meet the definition of independent legal counsel.[6] We estimate that each of these 970 funds would be required to spend, on average, 0.75 hours annually to comply with the recordkeeping requirement associated with this determination, for a total annual burden of approximately 727.5 hours. Based on this estimate, the total annual cost for all funds' compliance

[1] 15 U.S.C. 80a.

[2] For example, fund directors must approve investment advisory and distribution contracts. *See* 15 U.S.C. 80a–15(a), (b), and (c).

[3] The relevant exemptive rules are: rule 10f–3 (17 CFR 270.10f–3), rule 12b–1 (17 CFR 270.12b–1), rule 15a–4(b)(2) (17 CFR 270.15a–4(b)(2)), rule 17a–7 (17 CFR 270.17a–7), rule 17a–8 (17 CFR 270.17a–8), rule 17d–1(d)(7) (17 CFR 270.17d–1(d)(7)), rule 17e–1(c) (17 CFR 270.17e–1(c)), rule 17g–1 (17 CFR 270.17g–1), rule 18f–3 (17 CFR 270.18f–3), and rule 23c–3 (17 CFR 270.23c–3).

[4] A ''control person'' is any person—other than a fund—directly or indirectly controlling, controlled by, or under common control, with any of the fund's management organizations. *See* 17 CFR 270.01(a)(6)(iv)(B).

[5] Based on statistics compiled by Commission staff, we estimate that there are approximately 3,232 funds that could rely on one or more of the exemptive rules. Of those funds, we assume that approximately 90 percent (2,909) actually rely on at least one exemptive rules annually.

[6] We assume that the independent directors of the remaining two-thirds of those funds will choose not to have counsel, or will rely on counsel who has not recently represented the fund's management organizations or control persons. In both circumstances, it would not be necessary for the fund's independent directors to make a determination about their counsel's independence.

with this rule is approximately $194,485. To calculate this total annual cost, the Commission staff assumed that approximately two-thirds of the total annual hour burden (485 hours) would be incurred by a compliance manager with an average hourly wage rate of $360 per hour,[7] and one-third of the annual hour burden (242.5 hours) would be incurred by compliance clerk with an average hourly wage rate of $82 per hour.[8]

The estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. These estimates are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by December 11, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: October 6, 2023.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 2023–22580 Filed 10–11–23; 8:45 am]

BILLING CODE 8011–01–P

[7] The estimated hourly wages used in this PRA analysis were derived from the Securities Industry and Financial Markets Association's Reports on Management and Professional Earnings in the Securities Industry (2013) (modified to account for an 1,800-hour work year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead) (adjusted for inflation), and Office Salaries in the Securities Industry (2013) (modified to account for an 1,800-hour work year and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead) (adjusted for inflation).

[8] (485 × $360/hour) + (242.5 × $82/hour) = $194,485.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–316, OMB Control No. 3235–0359]

Proposed Collection; Comment Request; Extension: Form N–17f–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form N–17f–1 (17 CFR 274.219) is entitled ''Certificate of Accounting of Securities and Similar Investments of a Management Investment Company in the Custody of Members of National Securities Exchanges.'' The form serves as a cover sheet to the accountant's certificate that is required to be filed periodically with the Commission pursuant to rule 17f–1 (17 CFR 270.17f–1) under the Act, entitled ''Custody of Securities with Members of National Securities Exchanges,'' which sets forth the conditions under which a fund may place its assets in the custody of a member of a national securities exchange. Rule 17f–1 requires, among other things, that an independent public accountant verify the fund's assets at the end of every annual and semi-annual fiscal period, and at least one other time during the fiscal year as chosen by the independent accountant. Requiring an independent accountant to examine the fund's assets in the custody of a member of a national securities exchange assists Commission staff in its inspection program and helps to ensure that the fund assets are subject to proper auditing procedures. The accountant's certificate stating that it has made an examination, and describing the nature and the extent of the examination, must be attached to Form N–17f–1 and filed with the Commission promptly after each examination. The form facilitates the filing of the accountant's certificates, and increases the accessibility of the certificates to both Commission staff and interested investors.

Commission staff estimates that it takes: (i) 1 hour of clerical time to prepare and file Form N–17f–1; and (ii) 0.5 hour for the fund's chief compliance officer to review Form N–17f–1 prior to filing with the Commission, for a total of 1.5 hours. Each fund is required to make 3 filings annually, for a total annual burden per fund of approximately 4.5 hours.[1] Commission staff estimates that an average of 21 funds currently file Form N–17f–1 with the Commission 3 times each year, for a total of 64 responses annually.[2] The total annual hour burden for Form N–17f–1 is therefore estimated to be approximately 95 hours.[3]

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Compliance with the collections of information required by Form N–17f–1 is mandatory for funds that place their assets in the custody of a national securities exchange member. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by December 11, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

[1] This estimate is based on the following calculation: (1.5 hours × 3 responses annually = 4.5 hours).

[2] This estimate is based on a review of Form N–17f–1 filings made with the Commission over the last three years.

[3] This estimate is based on the following calculations: (4.5 hours × 21 funds = 94.5 total hours).

Dated: October 6, 2023.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 2023–22578 Filed 10–11–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold an Open Meeting on Friday, October 13, 2023 at 9:30 a.m. (ET).

PLACE: The meeting will be webcast on the Commission's website at *www.sec.gov*.

STATUS: This meeting will begin at 9:30 a.m. (ET) and will be open to the public via webcast on the Commission's website at *www.sec.gov*.

MATTERS TO BE CONSIDERED:

1. The Commission will consider whether to adopt a rule under the Securities Exchange Act of 1934 (''Exchange Act'') to increase the transparency and efficiency of the securities lending market.

2. The Commission will consider whether to adopt a rule under the Exchange Act that is designed to provide greater transparency to investors and other market participants by increasing the public availability of short sale-related data and whether to approve a proposed amendment to the national market system plan governing the consolidated audit trail (''CAT'') created pursuant to the Exchange Act to require a CAT reporting firm that is reporting short sales to indicate whether such firm is asserting use of the bona fide market making exception under Rule 203(b) of Regulation SHO.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

(Authority: 5 U.S.C. 552b)

Dated: October 6, 2023.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 2023–22619 Filed 10–10–23; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–177, OMB Control No. 3235–0177]

Proposed Collection; Comment Request; Extension: Rule 6e–2 and Form N–6EI–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 6e–2 (17 CFR 270.6e–2) under the Investment Company Act of 1940 (''Act'') (15 U.S.C. 80a) is an exemptive rule that provides separate accounts formed by life insurance companies to fund certain variable life insurance products, exemptions from certain provisions of the Act, subject to conditions set forth in the rule.

Rule 6e–2 provides a separate account with an exemption from the registration provisions of section 8(a) of the Act if the account files with the Commission Form N–6EI–1 (17 CFR 274.301), a notification of claim of exemption.

The rule also exempts a separate account from a number of other sections of the Act, provided that the separate account makes certain disclosure in its registration statements (in the case of those separate accounts that elect to register), reports to contractholders, proxy solicitations, and submissions to state regulatory authorities, as prescribed by the rule.

Since 2008, there have been no filings of Form N–6EI–1 by separate accounts. Therefore, there has been no cost or burden to the industry since that time. The Commission requests authorization to maintain an inventory of one burden hour for administrative purposes.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by December 11, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: October 6, 2023.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 2023–22579 Filed 10–11–23; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 12217]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Monet and His Modern Legacy'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition ''Monet and his Modern Legacy'' at the Nelson-Atkins Museum of Art, Kansas City, Missouri; the Cleveland Museum of Art, Cleveland, Ohio; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order

12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2023–22462 Filed 10–11–23; 8:45 am]

BILLING CODE 4710–05–P

TENNESSEE VALLEY AUTHORITY

Allen Aeroderivative Generation Project

AGENCY: Tennessee Valley Authority.

ACTION: Notice of Intent.

SUMMARY: The Tennessee Valley Authority (TVA) intends to prepare an environmental assessment (EA) or environmental impact statement (EIS) to address the potential environmental impacts associated with the proposed installation and operation of six new aeroderivative combustion turbine (CT) units at the Allen Combustion Turbine (ACT) site, located in Shelby County, Tennessee, southwest of the City of Memphis. The new aeroderivative units would generate approximately 200 Megawatts (MW) of power to help meet the growing system demand. The units would provide flexible and dispatchable transmission grid support and facilitate the integration of renewable generation onto the TVA bulk transmission system, consistent with TVA's 2019 Integrated Resource Plan (IRP). TVA is inviting public comment concerning the scope of the review, alternatives being considered, and environmental issues that should be addressed.

DATES: The public scoping period begins with the publication of this Notice of Intent in the **Federal Register**. To ensure consideration, comments must be postmarked, submitted online, or emailed no later than November 13, 2023. To facilitate the scoping process, TVA will hold an in-person public open house meeting; see *https://www.tva.gov/NEPA* for more information on the meeting.

ADDRESSES: Written comments should be submitted by email to *NEPA@tva.gov* or online at *https://www.tva.gov/NEPA*. Comments may also be mailed to Matthew Higdon, NEPA Specialist, 400 West Summit Hill Drive #WT11B, Knoxville, Tennessee 37902.

FOR FURTHER INFORMATION CONTACT: Matthew Higdon by email to *nepa@tva.gov,* by phone at (865) 632–8051, or by mail at the address above.

SUPPLEMENTARY INFORMATION: This notice is provided in accordance with the Council on Environmental Quality's Regulations (40 CFR parts 1500 to 1508) and TVA's procedures for implementing the National Environmental Policy Act (NEPA). TVA is an agency and instrumentality of the United States, established by an act of Congress in 1933, to foster the social and economic welfare of the people of the Tennessee Valley region and to promote the proper use and conservation of the region's natural resources. One component of this mission is the generation, transmission, and sale of reliable and affordable electric energy.

Preliminary Proposed Action and Alternatives

TVA anticipates that the scope of the EA or EIS will evaluate an Action Alternative and a No Action Alternative. Under the Action Alternative, TVA would install and operate six new aeroderivative combustion turbine units generating approximately 200 MW of power at ACT. TVA would also continue to operate two existing CT units which would provide an additional 120 MW of power. The new units would support fast-start dispatching and have synchronous condensing capabilities to improve grid stability. Four of the units would have black-start capabilities. Under the proposal, TVA would implement the best available control technologies to mitigate air emissions. Construction would occur over a one-year timeframe (approximately) beginning in 2025 or 2026, with construction activities taking place within previously disturbed areas at ACT and adjacent properties. Commercial operations would begin in 2025 or 2026.

Under the No Action Alternative, TVA would not install new aeroderivative CT units at the ACT, and TVA would retire all existing units. The No Action alternative provides a baseline for comparing against the Action Alternative.

Background

In the 2019 IRP, TVA evaluated six scenarios (plausible futures) and five strategies (potential TVA responses to those plausible futures) and identified a range of potential resource additions and retirements throughout the TVA power service area, which encompasses approximately 80,000 square miles. The target supply mix adopted by the TVA Board through the 2019 IRP included the addition of up to 5,200 MW of simple cycle capacity by 2028 to facilitate the integration of solar onto the TVA bulk power system.

Investments in adding aeroderivative CTs to the peaking fleet aligns with the direction in the IRP, which recommended enhancing system flexibility to integrate renewables and distributed resources, with substantial solar additions over the next two decades. As the amount of solar generation on the TVA generation portfolio continues to increase, flexibility of the remainder of the fleet becomes even more important. For instance, cloud patterns that temporarily block the sun and reduce solar generation require other generating units to respond to continue to reliably supply power to customers. Aeroderivative CTs are inherently well-suited to provide flexibility, enabling the remainder of the system to better integrate renewables.

Since the completion of the IRP, TVA has seen a strong increase in electric demand. Population has increased in the TVA service region by 1.5 percent since 2019. TVA expects continued strong growth in annual electric demand through the middle of this decade. Forecasted electric demand is expected to grow more than one percent per year on average between 2023–2026. Current system modeling shows that with increased residential migration and commercial development, TVA must add capacity to the system to maintain adequate operating reserves.

In 2019, TVA also completed a CT Modernization Study to evaluate the condition of its existing CT units and form recommendations for investments to ensure a reliable and flexible peaking fleet into the future. The results of the study identified the ACT units as the ''most challenged'' based on their age and material condition and recommended that they be replaced. The CT Modernization Study also recommended adding new aeroderivative CTs to enhance system flexibility, integrate increasing renewable capacity, and provide dispatchable capacity. The proposed action would also be consistent with the findings and recommendations of this study.

In June 2021, TVA issued an environmental assessment (EA) addressing the retirement of the CT units at Allen. At that time, TVA issued the Paradise and Colbert Combustion Turbine EA and an associated finding of no significant impact, in which TVA

addressed the retirement of all 20 CT units at its Allen and Johnsonville plants and the replacement of the capacity lost with new CT units at its Paradise and Colbert plants. Under the current proposal, TVA is considering the continual operation of existing Units 19 and 20 at ACT, previously identified for retirement.

In December 2022, during Winter Storm Elliott, 16 of the units at ACT failed to start, impacting the TVA system position by 240 MWs. Since this event, these 16 units at Allen have ceased operations. Only two units at ACT (Units 19 and 20) are operable.

Project Purpose and Need

The purpose of the proposed action is to increase the flexibility and reliability of TVA power system by improving TVA's transmission system stability in western Tennessee and providing new, dispatchable generation to support the continued system load growth experienced in the TVA power service area over the past few years. These improvements would help TVA to expand and integrate renewable energy resources onto its transmission grid, which would allow TVA to advance its decarbonization goals.

TVA has identified the need to improve the stability of its transmission system in the western portion of Tennessee. In this area, additional resources are needed to ensure that adequate transmission voltages are maintained within the desired limits. In addition, as identified in the 2019 IRP, TVA needs flexible, dispatchable power that can successfully integrate increasing amounts of renewable energy sources while ensuring it can meet required year-round generation and maximum capacity system demands and planning reserve margin targets.

Anticipated Environmental Impacts

The EA or EIS will include an evaluation of the environmental, social, and economic impacts associated with implementing the proposed action. Because all ground disturbing activities associated with the proposal would occur within previously disturbed areas of TVA's Allen facility, TVA anticipates that the primary issues to be addressed in the EA or EIS will be impacts to air quality, climate change, environmental justice, and transportation. Other resource issues, including socioeconomics and surface water quality, will be addressed. Measures to avoid, minimize, and mitigate adverse effects will be identified and evaluated in the EA or EIS. TVA seeks input from the public during the scoping period on other relevant issues that should be considered and potential mitigation measures.

Anticipated Permits and Other Authorizations

TVA anticipates seeking required permits or authorizations, as appropriate. TVA's proposed action may require issuance of an air permit under the Clean Air Act; an Individual or Nationwide Permit under Section 404 of the Clean Water Act; Section 401 Water Quality Certification; conformance with Executive Orders on Environmental Justice (12898), Wetlands (11990), Floodplain Management (11988), Migratory Birds (13186), and Invasive Species (13112); and compliance with Section 106 of the National Historic Preservation Act, Section 7 of the Endangered Species Act, and other applicable Local, Federal, and State regulations.

Public Participation and Scoping Process

Scoping, which is integral to the process for implementing NEPA, provides an early and open process to ensure that issues are identified early and properly studied; issues of little significance do not consume substantial time and effort; the draft EA or EIS is thorough and balanced; and delays caused by an inadequate EA or EIS are avoided. TVA seeks comment and participation from all interested parties for identification of potential alternatives, information, and analyses relevant to the proposed action in this EA or EIS. Public comments received during the scoping period will assist TVA in determining the appropriate level of NEPA review.

Information about this project is available at *https://www.tva.gov/NEPA,* which includes a link to an online public comment page. Comments must be received or postmarked no later than November 13, 2023. Federal, state, local agencies, and Native American Tribes are also invited to provide comments. Please note that any comments received, including names and addresses, will become part of the project administrative record and will be available for public inspection. TVA plans to have an open house meeting during the scoping period. Visit *https://www.tva.gov/NEPA* to submit comments and obtain more information about the open house meeting.

EA or EIS Preparation and Schedule

TVA will consider comments received during the scoping period and develop a scoping report which will be published online. The scoping report will summarize public and agency comments that were received and identify the projected schedule for completing the environmental review process. TVA will post a draft EA or EIS for public review and comment on the project web page. TVA anticipates holding a public open house after releasing the draft EA or EIS. TVA expects to release the draft EA or EIS in Spring or Summer 2024 and a final EA or EIS in late 2024. If an EIS is prepared, TVA would publish a Record of Decision at least 30 days after the release of the final EIS.

Authority: 40 CFR 1501.9.

Rebecca Tolene,

Vice President, Environment and Sustainability.

[FR Doc. 2023–22517 Filed 10–11–23; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–0754; Summary Notice No. 2023–40]

Petition for Exemption; Summary of Petition Received; Global Aviation Technologies

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before November 1, 2023.

ADDRESSES: Send comments identified by docket number FAA–2023–0754 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in

Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, AIR–646, Federal Aviation Administration, phone (206) 231–3187, email *deana.stedman@faa.gov.* This notice is published pursuant to 14 CFR 11.85.

Issued in Los Angeles, California, on October 3, 2023.

Thuan Nguyen,

Acting Manager, Technical Writing Section.

Petition for Exemption

Docket No.: FAA–2023–0754.

Petitioner: Global Aviation Technologies.

Section(s) of 14 CFR Affected: §§ 23.807(d)(1)(i); 23.811(b) and (c); and 23.812.

Description of Relief Sought: The petitioner requests relief from § 23.807(d)(1)(i), which is a commuter category airplane safety requirement, that requires an airplane with a total passenger seating capacity of 15 or fewer to have an emergency exit on each side of the cabin (as defined in § 23.807(b)) in addition to the passenger entry door.

The petitioner also requests relief from § 23.811(b) and (c), which are commuter category airplane safety requirements for emergency exit marking, that require exits and doors to be internally marked with the word ''exit'' by a sign that meets a specific size, color, and illumination as stated in those regulations.

The petitioner also requests relief from § 23.812, which contains the safety requirements for commuter category airplanes for emergency lighting.

The requested relief is for the Textron Model 390 airplane, Type Certificate A00010WI, which was certified as normal category. The petitioner's project would increase the gross weight of the airplane which would necessitate compliance with the requirements for commuter category airplanes.

[FR Doc. 2023–22448 Filed 10–11–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–0741; Summary Notice No. 2023–39]

Petition for Exemption; Summary of Petition Received; Global Aviation Technologies

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before November 1, 2023.

ADDRESSES: Send comments identified by docket number FAA–2023–0741 using any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.

• *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, AIR–646, Federal Aviation Administration, phone (206) 231–3187, email *deana.stedman@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Los Angeles, California, on October 3, 2023.

Thuan Nguyen,

Acting Manager, Technical Writing Section.

Petition for Exemption

Docket No.: FAA–2023–0741.

Petitioner: Global Aviation Technologies.

Section(s) of 14 CFR Affected: § 23.783(f)(1).

Description of Relief Sought: The petitioner has requested relief from § 23.783(f)(1), which requires that, for commuter category airplanes, each passenger entry door must qualify as a floor level emergency exit. This exit must have a rectangular opening of not less than 24 inches wide by 48 inches high, with corner radii not greater than one-third the width of the exit. The requested relief is for the Textron Model 390 airplane, Type Certificate A00010WI, which was certified as normal category. The petitioner's project would increase the gross weight of the airplane which would necessitate compliance with the requirements for commuter category airplanes.

[FR Doc. 2023–22446 Filed 10–11–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–0753; Summary Notice No. 2023–41]

Petition for Exemption; Summary of Petition Received; Global Aviation Technologies

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before November 1, 2023.

ADDRESSES: Send comments identified by docket number FAA–2023–0753 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, AIR–646, Federal Aviation Administration, phone (206) 231–3187, email *deana.stedman@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Los Angeles, California, on October 3, 2023.

Thuan Nguyen,

Acting Manager, Technical Writing Section.

Petition for Exemption

Docket No.: FAA–2023–0753.

Petitioner: Global Aviation Technologies.

Section(s) of 14 CFR Affected: § 23.775(h)(1).

Description of Relief Sought: The petitioner has requested relief from § 23.775(h)(1), which requires that, for commuter category airplanes, windshield panes and their supporting structures must withstand, without penetration, the impact of a two-pound bird when the velocity of the airplane (relative to the bird along the airplane's flight path) is equal to the airplane's maximum approach flap speed. The requested relief is for the Textron Model 390 airplane, Type Certificate A00010WI, which was certified as normal category. The petitioner's project would increase the gross weight of the airplane which would necessitate compliance with the requirements for commuter category airplanes.

[FR Doc. 2023–22447 Filed 10–11–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0209]

Women of Trucking Advisory Board (WOTAB); Notice of Public Meeting

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting of the WOTAB.

DATES: The meeting will be held on Thursday, October 26, 2023, from 10 a.m. to 4:30 p.m. ET. Requests for accommodations for a disability must be received by Friday, October 21. Requests to submit written materials for consideration during the meeting must be received no later than Friday, October 21.

ADDRESSES: The meeting will be held virtually for its entirety. Please register in advance of the meeting at *www.fmcsa.dot.gov/wotab.* Copies of WOTAB task statements and an agenda for the entire meeting will be made available at *www.fmcsa.dot.gov/wotab* at least 1 week in advance of the meeting. Once approved, copies of the meeting minutes will be available at the website following the meeting. You may visit the WOTAB website at *www.fmcsa.dot.gov/wotab* for further information on the committee and its activities.

FOR FURTHER INFORMATION CONTACT: Ms. Shannon L. Watson, Designated Federal Officer, WOTAB, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 360–2925, *wotab@dot.gov.* Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

WOTAB was created under the Federal Advisory Committee Act (FACA) in accordance with section 23007(d)(1) of the Bipartisan Infrastructure Law (BIL) (Pub. L. 117–58), which requires the Federal Motor Carrier Safety Administration (FMCSA) to establish WOTAB. WOTAB will review and report on policies that provide education, training, mentorship, and outreach to women in the trucking industry and identify barriers and industry trends that directly or indirectly discourage women from pursuing and retaining careers in trucking.

WOTAB operates in accordance with FACA under the terms of the WOTAB charter, filed February 11, 2022.

II. Agenda

WOTAB will begin consideration of Task 23–4: Examining ways in which trucking companies, nonprofit organizations, training, and education providers, and trucking associations may coordinate functions to facilitate support for women pursuing careers in trucking. For this and all topics considered by the committee, FMCSA will include presentations by Agency experts and those in the field under discussion.

III. Public Participation

The meeting will be open to the public via virtual platform. Advance

registration via the website is required by Friday, October 21.

DOT is committed to providing equal access to this meeting for all participants. If you need alternative formats or services due to a disability, such as sign language interpretation or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section by Friday, October 21.

Oral comments from the public will be heard during designated comment periods at the discretion of the WOTAB chair and Designated Federal Officer. To accommodate as many speakers as possible, the time for each commenter may be limited. Speakers are requested to submit a written copy of their remarks for inclusion in the meeting records and for circulation to WOTAB members. All prepared remarks submitted on time will be accepted and considered as part of the record. Any member of the public may present a written statement to the committee at any time.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–22477 Filed 10–11–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment Request, Qualified Personal Residence Trust

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden associated with the information collection requirements related to the sale of residence from qualified personal residence trust.

DATES: Written comments should be received on or before December 11, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please include, ''OMB Number: 1545–1485—Public Comment Request Notice'' in the Subject line.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Sale of Residence from Qualified Personal Residence Trust.

OMB Number: 1545–1485.

Form Project Number: TD 8743.

Abstract: Internal Revenue Code section 2702(a)(3) provides special favorable valuation rules for valuing the gift of a personal residence trust. Regulation section 25.2702–5(a)(2) provides that if the trust fails to comply with the requirements contained in the regulations, the trust will be treated as complying if a statement is attached to the gift tax return reporting the gift stating that a proceeding has been commenced to reform the instrument to comply with the requirements of the regulations.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and households.

Estimated Number of Responses: 300.

Estimated Time per Respondent: 2 Hrs., 5 Min.

Estimated Total Annual Burden Hours: 625.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: October 4, 2023.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2023–22483 Filed 10–11–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the National Research Advisory Council

AGENCY: Department of Veterans Affairs.

ACTION: Notice of solicitation for nominations.

SUMMARY: The Department of Veteran Affairs (VA) Office of Research and Development (ORD) is committed to having a diverse and inclusive membership on its National Research Advisory Council (NRAC or the Council). The NRAC is seeking nominations for its 2024 membership cycle of qualified candidates who promote racial and ethnic diversity, as well as sex, geographic, religious, disability/mobility, and prior military service diversity in membership.

DATES: Nominations for membership on NRAC must be received by November 15, 2023 no later than 4 p.m., Eastern Standard Time. Submission of an application does not guarantee selection.

ADDRESSES: All nomination packages should be emailed to Rashelle Robinson: *Rashelle.Robinson@va.gov*.

FOR FURTHER INFORMATION CONTACT: Allison Williams ND Ph.D. RN at *Allison.williams3@va.gov* or

727.204.1903 A copy of NRAC charter and list of the current membership can also be obtained by contacting Dr. Williams.

SUPPLEMENTARY INFORMATION: The Council provides advice to the Secretary of Veterans Affairs (Secretary) and the Under Secretary for Health (USH) and makes recommendations on the nature and scope of research and development sponsored and/or conducted by the Veterans Health Administration (VHA) to include:

(1) the policies and projects of the Office of Research and Development (ORD);

(2) the focus of research on the high priority health care needs of Veterans;

(3) the balance of basic, applied, and outcomes research;

(4) the scientific merit review process;

(5) the appropriate mechanisms by which ORD can leverage its resources to enhance the research financial base;

(6) the rapid response to changing health care needs, while maintaining the stability of the research infrastructure; and

(7) the protection of human subjects of research.

Authority: NRAC was established by the directive of the Secretary of VA, in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. Ch. 10.

Membership Criteria and Qualification: The Council will be comprised of not more than 12 members. Members will be selected from knowledgeable VA- and non-VA experts, and Veterans' community representatives with special qualifications and competencies to deal effectively with research and development issues in the VA. Interested individuals must be a U.S. citizen and hold an M.D., Ph.D., or equivalent doctoral degree. NRAC is looking for individuals with primary expertise that includes:

a. basic biomedical research;

b. rehabilitation research and development;

c. health services research and development;

d. clinical research;

e. geriatric care;

f. primary care;

g. special Veterans population health issues;

h. occupational and environmental health research;

i. mental health and behavioral research; and

j. surgery.

In addition, the NRAC will have at least one Veteran as a member to ensure an important perspective on the health problems of Veterans.

Membership Requirements: NRAC meets three times a year either virtually, hybrid or in-person. Lobbyists serving as members of advisory boards and commissions or federally-registered lobbyists are prohibited from serving on Federal advisory committees in an individual capacity. In accordance with Federal Travel Regulation, VA will cover travel expenses—to include per diem—for all members of the Council, for any travel associated with official Council duties. Non-VA Council members also may be authorized to receive a stipend for their services.

To the extent possible, the Secretary seeks members who have diverse professional and personal qualifications including but not limited to subject matter experts in the areas described above. We ask that nominations include any relevant experience information so that VA can ensure diverse Council membership.

Requirements for Nomination Submission: Nominations should be 12-point font typed (one nomination per nominator). Self-nominations are acceptable. Nomination package should include:

(1) A cover letter that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes that qualify the nominee for service in this capacity), and a statement from the nominee indicating the willingness to serve as a member of the Council;

(2) The nominee's contact information, including name, mailing address, telephone numbers, and email address;

(3) The nominee's curriculum vitae that shows all relevant professional, publications, Veterans service involvement and/or work experience;

(4) A summary of the nominee's experience and qualifications relative to the membership consideration described above; and

(5) A statement confirming that the nominee is not a federally-registered lobbyist.

Packages will be reviewed by ORD Leadership staff and individuals selected for appointment to the Council will be notified via email.

The Department makes every effort to ensure that the membership of VA Federal advisory committees is diverse in terms of points of view represented and the committee's capabilities. Appointments to this Council shall be made without discrimination because of a person's race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability or genetic information. Nominations must state that the nominee is willing to serve as a member of the Council and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: October 5, 2023.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–22522 Filed 10–11–23; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 88 Thursday,
No. 196 October 12, 2023

Part II

Securities and Exchange Commission

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the DTC Operational Arrangements (Necessary for Securities To Become and Remain Eligible for DTC Services); Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98604; File No. SR–DTC–2023–010]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the DTC Operational Arrangements (Necessary for Securities To Become and Remain Eligible for DTC Services)

DATES: September 28, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 27, 2023, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been primarily prepared by the clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rules 19b–4(f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of modifications to the DTC Operational Arrangements (Necessary for Securities to Become and Remain Eligible for DTC Services) (''OA'')[5] to clarify and update provisions relating to the processing of securities eligibility requests and servicing of assets on Deposit at DTC, as described in greater detail below.[6]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The OA is designed to maximize the number of issues of securities that may be made eligible for DTC services, providing for the orderly processing of such securities and timely payments to Participants. DTC's experience demonstrates that when Participants, Issuers, Underwriters, Agents (as such terms are defined in the Rules[7] or in the OA),[8] and their counsel are aware of DTC's requirements, those requirements can be readily met in most instances. The purpose of this rule change is to revise the text of the OA to update and clarify DTC's processes in this regard. Additionally, some ministerial changes, changes to methods of notification, and clarifying language have been introduced to provide a more concise description of OA procedures. In this regard, the proposed rule change would revise the text of the OA as set forth in the respective sections as described below:

OA section	Revision
I.A.1. (Submission of an Eligibility Request)	Pursuant to Rule 5, DTC shall accept a Security as an Eligible Security only, among other requirements, upon a determination by the Corporation that it has the operational capability and can obtain information regarding the Security necessary to permit it to provide its services to Participants and Pledgees when such Security is Deposited.[9] Timely confirmation of details relating to a security is an important part of making an eligibility determination. Therefore, pursuant to the proposed rule change, the OA would be revised to add new text to this subsection that requires the agent for a security to confirm an issue's features and attributes once the underwriter of the security has submitted the issue for eligibility. In this regard, new text would be added to this subsection which would state: ''As Agent for a new security qualifying for DTC eligibility, Agent must complete the Agent Confirmation supplied by DTC's Underwriting Department to confirm a new issue's features and attributes based on the security type. The agreement of the information supplied by the underwriter, the Agent Confirmation, and the offering document ensure the accuracy of the asset servicing of the security. This confirmation must be provided by the Agent via email at least three (3) business days prior to the Closing Date of the issue.''
Section I.B.5 (Instruction Letters Regarding the Expiration of a Restrictive Period).	The proposed rule change would enhance instructions relating to existing forms and requirements for Issuers and Agents to request the processing of exchanges relating to CUSIPs for securities that were originally restricted pursuant to Rule 144A and/or Regulation S and which have become unrestricted. In this regard, the proposed rule change would add three subsections to respectively provide instructions for the three types of exchange processes that may occur in this regard, namely (a) an optional exchange process, (b) a voluntary exchange process, and (c) a mandatory exchange process. The processes for (a) and (b) relate to exchanges where a Participant has an option to exchange existing 144A shares to unrestricted shares, with the difference between an optional exchange and a voluntary exchange being described functionally in terms of, (i) with respect to (a), the agent for the issue facilitating the exchange through DTC's Deposit/Withdrawal at Custodian (''DWAC'') function and (ii) with respect to (b) being conducted using DTC's Automated Tender Offer Program (''ATOP''). Under a mandatory exchange, the issuer requires the Participant to receive the unrestricted shares in exchange for any144A shares the Participant holds.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] *Available at http://www.dtcc.com/~/media/Files/Downloads/legal/issue-eligibility/eligibility/operational-arrangements.pdf.*

[6] Each term not otherwise defined herein has its respective meaning as set forth in the Rules, By-Laws and Organization Certificate of DTC (the ''Rules''), *available at http://www.dtcc.com/legal/rules-and-procedures.aspx* and the OA, *supra* note 5.

[7] *See supra* note 6.

[8] *See supra* note 5.

OA section	Revision
	The text added with respect to (a) above would include a heading named ''Optional Exchange Process (Agent Facilitates via Deposit/Withdrawal at Custodian ''DWAC''))'' for a new subsection a. under I.B.5. The new subsection a. would state: ''To request DTC to provide for the ability to have the Issuer's Agent facilitate via DWAC the exchange on an optional basis for Participants to request to exchange restricted Securities represented by a restricted CUSIP number for new unrestricted Securities of the same issue represented by an unrestricted CUSIP, Issuer will complete and submit the instruction letter along with a copy of the form of each unrestricted Security (without effective restrictive legends) bearing the new unrestricted CUSIP to DTC's Underwriting Department no later than 10 business days prior to the effective date or exchange date (*i.e.,* date of the end of the restrictive period and/or distribution compliance period imposed under such exemptions has elapsed) or the date Agent will begin acknowledging Participants' DWAC requests. Receipt of the instruction letter must be in conjunction with the DTC Participant eligibility request via UW SOURCE for the new unrestricted Securities. (*Refer* to Section I (A)(1), Submission of an Eligibility Request to DTC.)'' Subsection a. would also incorporate existing text that provides an internet link to the applicable form for optional exchanges. This existing text also previously referred to voluntary exchanges, however, the reference to voluntary exchanges would be deleted and instead be included in a new subsection relating to voluntary exchanges as described below. The internet link would be updated to reflect that the link uses a Hypertext Transfer Protocol Secure (https:) format rather than a Hypertext Transfer Protocol (http:) format. The text added with respect to (b) above would include a heading named ''Voluntary Exchange Process (Use of DTC's Automated Tender Offer Program ''ATOP))'' for a new subsection b. under I.B.5. The new subsection b. would state: ''Issuer and Agent acknowledges that any such exchange of restricted Securities for Securities of a CUSIP that is unrestricted will be made in accordance with the rules and procedures of DTC's Automated Tender Offer Program (''ATOP'') including that Agent is required to approve and adhere to all requirements represented in the Letter of Agreement (''LOA'') for each exchange processed through ATOP, (*Refer* to Section VI(D)(5)(a), Tender/Exchange Processing). To request DTC to process a voluntary exchange of restricted Securities represented by a restricted CUSIP number for new unrestricted Securities of the same issue represented by an unrestricted CUSIP, Issuer will complete and submit the instruction letter along with a copy of the form of each unrestricted Security (without effective restrictive legends) bearing the new unrestricted CUSIP no later than 10 business days prior to the effective date or exchange date (*i.e.,* date of the end of the restrictive period and/or distribution compliance period imposed under such exemptions has elapsed) to both DTC's Underwriting Department and Reorganization Voluntary Announcements Department by email at *uwcorplor@dtcc.com* and *voluntaryreorgannouncements@dtcc.com*. The form of instruction letter and related requirements for Issuers and Agents with respect to such exchanges to be made voluntary for Participants are available at: *https://www.dtcc.com/~/media/Files/Downloads/legal/issue-eligibility/special-letters/Optional-Process-Instruction-Letter.pdf*.'' The text added with respect to (c) above would include a heading named ''Mandatory Exchange Process'' for a new subsection b. under I.B.5. The new subsection c. would state: ''To request DTC to process a mandatory exchange of restricted Securities represented by a restricted CUSIP number for new unrestricted Securities of the same issue represented by an unrestricted CUSIP, Issuer will complete and submit the instruction letter along with a copy of the form of each unrestricted Security (without effective restrictive legends) bearing the new unrestricted CUSIP no later than 10 business days prior to the effective date or exchange date (*i.e.,* date of the end of the restrictive period and/or distribution compliance period imposed under such exemptions has elapsed) to both DTC's Underwriting Department and Reorganization Mandatory Announcements Department by email at *uwcorplor@dtcc.com* and *mandatoryreorgannouncements@dtcc.com*. Issuer and Agent acknowledges that any such exchange of restricted Securities for Securities of a CUSIP that is unrestricted will be made in accordance with the DTC Rules concerning mandatory exchanges.'' The new subsection c. would also incorporate existing text that provides internet links for documentation relating to mandatory exchanges. However, these links would be updated to indicate that they utilize a Hypertext Transfer Protocol Secure (https:) format rather than a Hypertext Transfer Protocol (http:) format.
Section I.C.6. (Certificated Securities with Short-Term Maturities).	This subsection provides in its first of two paragraphs that DTC, at its sole discretion, may make eligible a certificated security maturing within 60 calendar days of its closing date, on an exception basis subject to processing considerations. However, this provision relates to securities that are not in DTC's money market instrument program (''MMI Program'') and the MMI Program does facilitate the eligibility and processing of such short-term securities.[10] The MMI Program operates using an automated platform providing MMI Issuing and Paying Agents[11] (each, an ''IPA'') with the ability to issue, service, and settle Securities that are money market instruments (''MMI Securities'') that are processed in the MMI Program[12] that they introduce into the marketplace through DTC.

OA section	Revision
	DTC believes that, given efficiencies for the processing of short-term securities that have been built into the MMI Program, directing short term securities to the MMI Program would promote the prompt and accurate processing of such securities. In addition, pursuant to the Rules, DTC maintains sole discretion with respect to accepting any security as eligible for DTC services on a non-discriminatory basis;[13] and therefore the existing text relating to DTC's exercise discretion in this regard is redundant. Therefore, DTC would revise the OA text to delete the substance of the text reflecting the provision described above relating to DTC's discretion with regard to accepting for eligibility a security maturing within 60 days of its closing date and replace it with text that would state that a security that is scheduled to mature in 30 calendar days or less from the issuance date or DTC eligibility date will not be made eligible as a Non-MMI Security. The added text would also include a cross-reference to the OA Section I(A)(2) (Special Rules and Processes for Money Market Instruments) for more information relating to special rules and processes for MMI Securities. Also, a reference to referring to a short-term security as a ''bond'' would be changed to ''security'' to make the reference consistent with DTC's terminology for MMI whereby MMI are referred to as MMI Securities in its Rules.[14]
	In addition, the second paragraph of this subsection which relates specifically to monthly optional redemptions would be designated as a new subsection I.C.7., as described below.
I.C.7. Monthly Optional Redemptions (New Subsection).	The proposed rule change would break out the last paragraph of subsection I.C.6. into a separate subsection under the heading ''Monthly Optional Redemptions.'' The paragraph describes eligibility requirements for debt securities that have provisions allowing an issuer the option to make monthly redemptions of securities. The paragraph is broken out as the requirements are not specific to short-term securities. The text of the newly broken out subsection would be revised for technical changes, including (i) clarifying that the securities subject to the subsection are debt securities, (ii) change references to ''issue'' and ''issuance'' to ''security, and (iii) remove text that the security will be considered for eligibility if it is a new issuance that is registered under the Securities Act of 1933 (''Securities Act'') and replace it with a cross-reference to the OA's eligibility requirements.
II.A.1. (CUSIP Number Assignment)	This subsection describes DTC's requirements for issuers to obtain CUSIP Numbers as part of the eligibility process.
	The second paragraph states that certain corporate actions on existing securities may require the issuer to obtain a new CUSIP Number. This paragraph will be revised for technical wording changes.
	In this regard, the text currently states: ''DTC may require the Issuer or Agent to obtain a new CUSIP number from Standard & Poor's CUSIP Service Bureau to facilitate the adequate processing of a corporate action events, (*e.g.,* reverse stock split, interest payment). An example of such a requirement for a new CUSIP for an interest payment is when the additional issuance of debt securities carries an interest accrual date or period that is different than the original issuance.'' Pursuant to the proposed rule change (i) ''in order to'' would be shortened to ''to'', (ii) the ''a'' between ''processing of'' and ''corporate action'' will be deleted and replaced with ''certain'', and (iii) and the word ''event'' will be changed to the plural ''events'' and a comma will be added after the word.
	In addition, ''Standard & Poor's CUSIP Service Bureau'' would be shortened to ''CUSIP Service Bureau''. Standard & Poor's recently transferred the CUSIP Service Bureau to a different entity and therefore the reference to Standard & Poor's is outdated. However, since there is only one CUSIP Service Bureau, DTC believes it is unnecessary for the OA to include the name of the owner of the CUSIP Service Bureau in the OA.
II.B.2. (Balancing Securities)	This section contains several subsections that describe DTC's FAST program of which balancing, referred to in the current title of the section, is a component. The title of the section will be changed from ''Balancing Securities'' to ''FAST Program'' to better reflect the nature of the content.
II.B.2.b. FRAC	This subsection describes requirements relating to the use of the FRAC function by issuers' agents for confirmation or rejection of balances or transfers of securities in DTC's FAST program.[15] Pursuant to the OA, FAST Agents shall reconcile and confirm to DTC the amount of the Securities reflected by such Balance Certificate and recorded in the name of Cede & Co. daily, or other periodic basis as DTC may reasonably request. The subsection that describes the FRAC process provides details on confirmation and rejection requirements relating to the closing date of a new issuance or secondary offering. DTC would like to clarify the process requiring a FAST Agent to confirm or reject balance transfers associated with the presentation, by adding the following text to this subsection:
	''FRAC is to also be used by the FAST Agent to confirm or reject balances or transfers associated with the presentation, by DTC, of securities for a corporate action event for the drawdown of the FAST position on the target security and/or an add-to-balance of position when the entitlement security will be FAST. Balances are to be confirmed by the FAST Agent upon receipt of the SCL instruction from DTC on the effective date or the DTC allocation date of the corporate action or as soon as practicable thereafter. It is the obligation of the FAST Agent to use FRAC to confirm the Cede &Co. FAST Balance and process the event according to the electronic SCL instructions presented.''[16]

OA section	Revision
	In addition, a sentence in the first paragraph of this subsection would be revised for clarity. The sentence states: ''*Under no circumstances will a Participant's account be credited unless DTC's Underwriting Department receives closing information from the underwriter and the Agent.*'' Alt text: It is necessary that the closing information provided to DTC, by each the issuer and the agent, agree. In this regard, the following text would be added to the end of the sentence (after ''Agent'' and before the period): '', and the closing information is in agreement''.
II.B.2.c. DWAC	The text of this section will be revised to create a defined term to clarify that the term ''ADRs'' refers to American Depositary Receipts.
II.B.4.c. (Termination of Transfer Agent Services).	In compliance with Rule 17Ad–16 of the Act, all registered transfer agents are required to provide written notice (''17Ad–16 Notice'') to DTC when ceasing to perform or assuming transfer agent services on behalf of an Issuer or when the transfer agent is changing its name or address. Subsection II.B.4.c. lists information to be included on termination notices, as required by DTC. Pursuant to the proposed rule change, the OA would be revised for technical and clarifying changes to (i) change references to ''Transfer Agent'' to ''transfer agent,'' (ii) remove text indicating that the agent must list issues for which the transfer agent will no longer be responsible, and replace the text with a more succinct statement that the notice include the issuer's name, (iii) modify text stating ''The name of each issuer . . .'' to instead state ''The name and description of each Issuer's Security . . .''.
II.B.4.g. (Other Notices Delivered by Transfer Agents for Posting to LENS).	This subsection describes the delivery requirements for certain notices that an Agent forwards to DTC to post to LENS. Two existing sentences will be revised for clarity. These sentences state: ''In order to be posted to LENS, the notice must be sent to *TAServices@dtcc.com*. Hard copy notices will not be posted to LENS.'' In order to clarify the text which is intended to describe how notices must be sent by email, these sentences would be revised to: (i) delete ''In order for'' and replace it with ''For a notice'', (ii) add ''an email with'' between ''LENS,'' and ''the notice'', (iii) add ''attached as a PDF file'' between ''the notice attached as a PDF file'' and ''must'' and (iv) add ''and/or notices embedded in the body of the email'' between ''Hard copy notices'' and ''will not be posted''.
III.B. (Notices)	This section sets forth requirements for Issuers and Agents provision of notices to DTC for distribution to Participants. In addition to describing the information required to be included in a notice, it provides that the information may be delivered to DTC by secure means such as registered or certified mail, overnight delivery, or email. DTC believes that due to the time sensitive nature of such notices and risks of delay in delivery and transmittal via hard copy, for purposes of timeliness and processing efficiency relating to such notices, all such notices should be sent to DTC electronically. Therefore, the proposed rule change would delete provisions for hard copy delivery and instead provide that such notices should be sent via email or other electronic transmission (*i.e.,* BMA5 or REDCAL) and remove all references to transmittal by telecopy.[17]
	DTC would also revise a sentence that states: ''If the party sending the notice by telecopy or email does not receive a telecopy or email receipt from DTC confirming that the notice has been received, such party shall telephone the respective DTC department to confirm their receipt of the notice.'' The proposed change would change ''shall'' after ''party'' and before ''telephone'' with ''may (in addition to removing references to telecopy notice as mentioned above).''
	The proposed rule change would also delete a parenthetical cross-reference at the end of this subsection that states: ''(*See* Exhibit C for a summary of important notices and required time frames for income, redemption and maturity, and reorganization payments.)'' Exhibit C does not exist, and any applicable timeframes are included within the main text of the OA.
III.C. (Payment Instructions)	This section states, among other things, that all payments must be received by DTC in immediately available funds and must equal the full amount due on payable date. However, occasionally payments are tied to an ''effective date.'' Also, for Reorganization events, a payment date or effective date may not be specified, but the funds are made available for payment at a certain time in accordance with the timing of a specific transaction. To account for such varying terminology and timing of payments, the proposed rule change would clarify this section to add text to, in addition to requiring immediate payment on ''payable date'', payments should be made in immediately available funds on the full amount due on the ''effective date'' or the date on which funds are first made available for payment for Reorganization events, as applicable.
III.C.1. (Income Payment Standards)	This subsection describes how income payments must be made to DTC. The section would be revised for technical and grammatical changes. It would also be revised to (i) change a reference to ''same day funds'' to ''immediately available funds'' as part of the description on how income payments must be made, for consistency with terminology used in III.C. (Payment Instructions) and (ii) remove text indicating that DTC may allow for special arrangements in exception to the requirement to make payment in immediate available funds via Fedwire. DTC believes that accepting a special arrangement in exception to these standards, such as payment by check, would introduce risk to DTC's ability to timely pass income through to its Participants.
III.C.2. (Redemption and Maturity Payment Standards).	Redemption and maturity payments include cash payments of principal proceeds due to redemptions and maturities (''Redemption and Maturity Payments''). Such payments must be made to DTC's Redemption Deposit Account in accordance with the Procedures set forth in this subsection.

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	The second paragraph of this subsection includes a paragraph that states: ''DTC must receive CUSIP-specific detail of payments, no later than 2:50 p.m. ET. The dollar amount associated with such detail must correspond with the actual dollar payment received by 3:00 p.m. ET. All Redemption and Maturity Payments must be paid in same-day funds prior to 3:00 p.m. ET on the payable date. Failure to provide timely payment to DTC could jeopardize the same-day distribution of these payments to Participants and beneficial holders.'' To clarify text relating to the required timing of payments to DTC, the proposed rule change would delete ''by'' in the second sentence after the word ''received'' and before ''3:00 p.m.'' with ''prior to.'' In addition, the proposed rule change would make clarifying changes to the third sentence of the paragraph. Funds paid to DTC in accordance with this subsection are paid via Fedwire. Fedwire funds are immediately available. Therefore, the third sentence as shown above would be revised to instead state: ''All Redemption and Maturity Payments must be delivered to Cede & Co., as nominee of DTC, in immediately available funds prior to 3:00 p.m. ET on the payable date.'' The proposed rule change would remove text indicating that DTC may allow for special arrangements in exception to the requirement to make payment in immediate available funds via Fedwire. DTC believes that accepting a special arrangement in exception to these standards, such as payment by check, would introduce risk to DTC's ability to timely pass income through to its Participants. The proposed rule change would make technical and conforming changes to the third paragraph of the subsection by (i) replacing ''payments'' with ''Redemption and Maturity Payments,'' (ii) enhancing readability by moving the phrase ''via Fedwire'' from one place to another in a sentence describing how payments should be made and (iii) change a reference from ''same-day'' funds to ''immediately available'' funds. Finally, a reference in the final paragraph of the subsection to the ''Customer Service Hotline'' would be changed to ''Client Support Line.'' In addition, all other references to ''Customer Service Hotline'' to ''Client Support Line'' would be changed throughout the OA.
II.C.3. (Reorganization Payment Standards)	As with a change described for the subsection directly above, this subsection would be revised to change references from ''same-day'' funds to ''immediately available'' funds. The subsection would also be revised for other stylistic and descriptive purposes without altering the substance of the text as well as updating an email address supplied for submission of inquiries relating to wire instructions and payment information. The proposed change would also remove text indicating that DTC may allow for special arrangements in exception to the requirement to make payment in immediate available funds via Fedwire. DTC believes that accepting a special arrangement in exception to these standards, such as payment by check, would introduce risk to DTC's ability to timely pass income through to its Participants.
III.D. (Additional Payment Arrangements/Policies/Procedures).	This subsection includes a statement that ''no fees, such as wire fees, may be deducted from any payment due to DTC, its nominee, Cede & Co., or its assigns.'' Because such payments are passed through to the beneficial owners that are entitled to the entirety of the payment, it is not appropriate for an agent to charge DTC any fee in this regard. Therefore, DTC would clarify this provision by replacing the word ''deducted'' with ''charged to DTC; this includes invoicing DTC a fee or deducting a fee.'' Also, text relating to making inquiries directs the reader to email addresses further above in the OA text. However, the referenced text also includes phone information. Therefore, the proposed rule change would revise the reference to email addresses to instead refer to ''contact information.''
III.D.3. (Post-Payable Income Adjustments)	This would be added as a new subsection to describe DTC's existing practices regarding post-payable income adjustments. Adjustments can result from (but are not limited to) changes in rate, record date, accrual period or payable date and any activity tracking for stock loans, repos and due bill fail tracking. The subsection would provide that DTC will agree to Agents' requests for the reallocation of certain misapplied, misdirected, or miscalculated income payments resulting in post-payable adjustment to DTC Participants under the following conditions: • Agent's notice to DTC where the adjustment request will result in a credit to DTC Participants must be received by DTC no later than one calendar year from the initial payment date; • Agent's notice to DTC for any adjustment request which will cause a debit-only, or there is a portion of the adjustment that will result in a debit, must be received by DTC no later than 90 calendar days from the initial payment date; • Agent's notice to DTC for the adjustment request is to include the root cause adjustment code and information identifying issuance date, instrument, issuer, servicer, and calculating agent. DTC will not process any post-payable adjustments missing these key details; and • In the event the Agent's adjustment request (*e.g.,* rate change) resulted in an overpayment of funds and requires DTC to charge back funds from DTC Participants' accounts, in order to receive the collect funds the Agent is to refer to Section III(D)(4)(b) *Processing Errors,* and contact DTC's P&I Event Reconciliation and Support (PIERS) Department via email at *returnofoverpayments@dtcc.com* for further details.

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	Issuers and/or Agents wishing to modify certain income payments beyond the time period that DTC will process the adjustments may do so by obtaining a ''P&I Allocation Register'' by emailing *AnnouncementsRateChangeRequests@dtcc.com* and making payment arrangements directly with the affected DTC participants. For adjustments resulting from Agent's requests to DTC to revise rates, record dates, or payable dates, DTC will notify Participants at least one day prior to processing the adjustment to Participants' accounts when the adjustment will be processed within 30 days of the original allocation, and DTC will notify Participants at least three days prior to processing the adjustment to Participants' accounts when the adjustment will be processed 30 days or more after the original allocation.
III.D.4. (Requests for Return-of Funds)	This subsection provides introductory text for provisions that apply to instances where the Paying Agent and/or Issuer request the return of funds made to DTC. The proposed rule change would clarify that this subsection applies to such requests as they relate to income, redemption, or maturity payments, as applicable. A cross-reference to related text in Section VI.E. (Chargeback of Reorganization Payments) would also be added.
III.D.4.b. (Processing Errors)	This subsection provides instructions for agents and issuers on how to request returns of erroneous payments made to DTC. The proposed rule change would clarify that in addition to erroneous payments, the instructions also apply to overpayments made to DTC. The subsection states that a return of payment will only be made to the account from which the payment was received. While this provision is intended to prevent the return of a payment to the wrong location, occasionally, an issuer or agent may request that the payment be returned to an account other than the one that originally sent the payment. In these instances, DTC will send the payment to an account designated by the agent or issuer in a signed ''Account Designation Letter.'' For security reasons, DTC believes it should receive such a signed letter with respect to all such accounts to which payments are sent to an issuer or agent. Therefore, DTC would replace the reference to payments being sent only to the account from which the payment was originally made, to state that the payment will be sent to the account named in the Account Designation Letter from the issuer or agent that DTC has on file. In addition, it is DTC's experience that the return of payments under $100 is not cost effective for DTC or the applicable issuer or agent, as the cost of processing the return could be equal to or exceed the amount of the erroneous payment. Therefore, DTC would add text to this subsection to state that DTC will only process claims of $100.00 or greater.
III.d.4.c. (DWAC Deposit and Income Payments)	A new subsection III.D.4.c. (DWAC Deposit Income Payments) will be added to clarify to Agents' their existing responsibilities relating to DWAC deposits made between a record date and payment date. Failure by Agents to fulfill these responsibilities may cause processing errors requiring remediation in accordance with III.d.4.b. In this regard, the text of this new subsection would read as follows: ''Agent is to pay DTC income payments on payment date for record date position. Agent is responsible when approving a DWAC deposit after a record date and before the payment date to ensure the deposited position is not included in the Cede & Co. captured record date position when funding DTC on the payment date, and Agent will make the income payment due the depositing participant directly to the participant. DTC has no responsibility to make the payment to the participant. Agent is responsible when approving a DWAC deposit to ensure the deposited position has all the same attributes of the security into which the deposit is being made, (*e.g.,* accrual date or period, record date, payment date, payment cycle, interest rate, call feature, put feature, maturity date). Refer to Section II A. 1. *CUSIP Number Assignment.* Failure by Agent to follow the above procedures could result in an overpayment by Agent to DTC and jeopardize the timely and accurate payment to DTC and the same-day distribution of these payments to Participants and beneficial holders. See also Section b., *Processing Errors,* above.''
IV.A. (Dividend and Income Payment Details) ...	The title of this section will be revised to remove the words ''Dividend and'', so that the section will be named ''Income Payment Details'', because dividends are a form of income and including ''Dividend'' in the title is redundant. A reference to the text of the section to dividends and income would also be revised to delete the word ''dividends.''. Text would also be added to describe that income payments include cash dividends, interest, and periodic principal distributions paid to holders of record. The section text provides that an Issuer or Agent shall provide a notice of dividend and income payment information to DTC electronically, as previously arranged by Issuer or Agent and DTC, as soon as the information is available. However, if DTC does not receive such information by a certain time prior to when the payment is to be made it is possible that that payment will not be processed within the timeframe requested by the Issuer or Agent. Therefore, DTC would revise the text to remove the reference that the notice should be provided as soon as the information is available, and instead include a specific timeframe such that the notice must be provided to facilitate timely processing. Specifically, the changed text would state that the notice should be received by DTC prior to the payable date, but in no event later than 3 a.m. on the payable date, which is consistent with a timeframe already noted in IV.A.1 of the OA with respect to notices relating to structured securities. In addition, DTC will add text requiring that the electronic notification mentioned above must be provided either via automated files (DCN/BMA/RedCal) or the standard spreadsheet files (DCNLite/BMALite/RedCalLite).

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	In addition, because the text requires that notice be sent via electronic submission, DTC would remove outdated references to an email address and a physical mailing address.
IV.A.1. (Structured Securities)	This subsection includes the specific information DTC requires to be in a notice for DTC to process a payment relating to structured securities. The specified information would be revised to delete ''coupon rate, expressed as a percentage'' as this information is not needed by DTC to process the payment. Also, an item requiring the notice to include the payment classification (*e.g.,* Interest, Principal, Premium, and Special Distribution) would be added as this information is necessary to accurately designate the payment type in DTC's system.
IV.A.3. (Defaulted Issues)	DTC would add a new subsection to describe information needed to process payments on issues that are currently in a defaulted payment status. The additional text would read as follows: ''3. Defaulted Issues Agent shall provide DTC with a notice of payments on defaulted issues. After establishing the amount of any payment to be made on such Securities, Agent shall send such notice to DTC's Announcements Department via email to *dividenddefaultpayments@dtcc.com,* preferably five but no fewer than two business days prior to the payable or distribution date. Such notice shall include the following information: • Security description and CUSIP number; • record date; • payable date; and • dividend (rate per share) or interest rate (per $1,000 principal amount) and the potential tax liability, including but not limited to capital gains, liquidations, and any cash liquidating distributions.''
IV.B. (Currency Payment Provisions)	This section describes requirements relating to currency payments, including that all income payments must be made in U.S. dollars or Canadian dollars, as applicable. The section also states that payments in other currencies must be made directly by the Agent. The proposed rule change would clarify that such payments must be made directly by the Agent to the DTC Participants.
IV.B.2.a. (Securities Denominated in a Non-U.S. Currency with an Option for U.S Dollar Payments).	This subsection provides terms for Issues and Agents making payments in currencies other than U.S. dollars. The proposed rule change clarifies that any payment in non-U.S. currency should be made in the currency designated in an offering document provided to DTC. The non-U.S. currency would be defined as the ''Initial Currency and/or Designated Currency.'' Because this subsection is intended to apply to payments relating to equity and debt instruments, DTC would change references to such payments from describing them as income, redemption and maturity, and reorganization payments and instead refer to them as principal, interest and dividends payments, as the latter more broadly captures both payment types. The text currently provides that the Agent is authorized by the Issuer to make payments on its behalf. For the purpose of confirming that the Issuer is fully authorized to act on behalf of the Agent in this regard, DTC would add text to this subsection whereby the Agent represents that it has been appointed by Issuer to receive and convert designated portions of payments into U.S. dollars. The subsection provides, among other things, that (i) absent any other arrangements, any beneficial owners that do not elect payments in a non-US currency shall receive U.S. dollar payments by DTC payment to the Participants holding on their behalf and, (ii) unless the Agent is notified by DTC of any election to receive non-U.S. currency payments, all payments will be made in U.S. dollars. To provide for enhanced clarity in this regard, DTC would revise the text to move the latter statement (ii) so that it appears in a sentence directly after the former statement (i) as opposed to further down the text as is currently the case. If payments are made by the Agent outside of DTC, then DTC is not part of such payment process and is unable to confirm if the applicable Participants have been paid. To provide for enhanced clarity, the proposed rule change would add the following text in this regard: ''Agent accepts responsibility for the Non-U.S. currency payment made to DTC Participants, including confirming directly to the DTC Participants that payment has been made. The Agent acknowledges that DTC is unable to, and will not, confirm whether such payments were made to or received by DTC Participants.'' The proposed rule change would also make changes related to updating terminology to align defined terms and modify text for grammar and readability.
IV.B.2.b. (Securities with Payments Made in Canadian Dollars and/or U.S. Dollars).	This subsection relates to Securities that may make payments in Canadian and/or U.S. Dollars. DTC accepts and passes through income payments in U.S. Dollars and will also process payments in Canadian Dollars to the extent the Security is eligible for DTC's Canadian-Link Service. The proposed rule change would revise the text of this subsection to consolidate language relating to the responsibilities of DTC, Issuers and Agents in this regard, as well as the acceptable denominations for payment on applicable Securities, namely U.S. Dollars and Canadian Dollars. The proposed rule change also provides clarification relating to the form and method of payments made to DTC (depending on whether payments are to be made in Canadian Dollars or U.S. Dollars), details on tax withholding to reflect existing arrangements where CDS serves as DTC's Tax Withholding Agent, and notifications and related deadlines.

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	DTC maintains an account at the CDS Clearing and Depository Services Inc. (''CDS'') in Canada and Securities credited to DTC by CDS are onward credited by DTC to Participants. As Securities may transfer between CDS and DTC regularly, it is necessary that the records of the Agent and DTC agree on record date so that the DTC position in the Security is in balance with the records of the Agent. In this regard, the proposed rule change would add text relating to the applicable process necessary for such balancing to occur timely. Specifically, the added text would state that the Agent must confirm via FRAC the Securities Control Listing (SCL) by 6:00 p.m. ET on the record date or the date requested by DTC.
IV.B.2.b.3. (Securities Denominated in a Non-U.S. Currency without an Option for U.S. Dollar Payments).	DTC does not process non-U.S. currency (other than Canadian). This subsection provides requirements on how such payments should be made by the Agent outside of DTC. The proposed rule change would clarify the text relating to the obligations for the Agent in this regard and clarifying that the Agent is solely responsible to ensure such payments are made to Participants. This proposed change would provide that DTC shall bear no responsibility with respect to such Non-U.S. currency payments, and note that DTC is unable to confirm whether such payments were made to or received by DTC Participants.
IV.C.2. (Reduction of Payment on Treasury Shares or Repurchased Debt Securities (for Cash Dividend or Interest Payment).	This subsection provides that a Participant that holds treasury shares or repurchased debt securities (*i.e.,* issuer buy-back) at DTC on the record date for a cash dividend or interest payment shall submit an instruction through the Corporate Actions Web (''CA Web'') to reduce its entitlement to the payment by the amount attributable to such treasury shares or repurchased securities. If the Participant does not submit such instruction within a designated timeframe, then the Agent shall provide to DTC a notice of reduction in the dividend or interest payment amount due DTC because of treasury shares or repurchased debt securities held on deposit by DTC on the record date. With respect to each Participant with a reduced entitlement, the Agent is responsible to ensure that the applicable Participants submit a confirmation letter providing details relating to the reduction. The proposed rule change would clarify, that while it is the Agent's responsibility to ensure that each Participant submits a confirmation letter, it is the responsibility of the Participant to provide the letter to DTC. For the sake of clarity, the proposed rule change would also consolidate a list of the contents and requirements that relate to the required letter.
IV.D.1.a. (Voluntary Dividend Reinvestment and Securities with an Automatic Dividend Reinvestment (with an option to elect a cash dividend).	This subsection describes conditions for an Issuer's securities to participate in the DTC Dividend Reinvestment Program. The DTC Dividend Reinvestment Program allows Participants to reinvest income payments for additional securities. The DTC Dividend Reinvestment Program also includes an opt-out feature, where income payments on certain issues have been automatically reinvested into securities and Participants could instruct to receive cash instead. For an issue to participate, the Issuer's Agent, acting as the Issuer's Dividend Reinvestment Plan Administrator, must complete and sign DTC's Dividend Reinvestment Letter of Agreement (reprinted on Agent's letterhead). This Dividend Reinvestment Letter of Agreement details the terms agreed upon by the Agent for the processing of reinvestment instructions through DTC. The subsection includes the following statement: ''The Agent must provide a written request to DTC for all Securities to be included in DTC's DRP. *DTC may refuse to make eligible certain issues if Agent has a record of failing to comply with such arrangements.*'' DTC proposes to delete this statement as it is redundant because the provision of the letter of agreement constitutes the writing, and it is intuitive that an Agent would need to comply with the agreement for its issues to be added to the program. The text would also be modified to remove a reference to right fax as a method for Agents to submit dividend reinvestment instructions.
IV.D.2. (Stock/Pay-in-Kind (''PIK'') Distributions to Holders of Record).	This subsection contains information and requirements relating to a PIK, which is a distribution that pays additional shares of a security that the payment relates to. Text in this subsection relating to stock distributions would be revised for technical and clarifying changes for readability without altering its substance or meaning. A sentence in the text relating to a PIK on a bond issue currently states: ''If the new denomination of the new bond is different from the denomination of the Original Bond (*i.e.,* the minimum denomination and/or the increment), then the Original Bond denomination (*e.g.,* $1,000 by $1,000) is to be changed to reflect the denomination of the new bonds (*e.g.,* $1000 by $1.00) for the remainder of the Original Bond's term.'' The proposed rule change would modify this sentence to add the following words at the end of this sentence before the period: ''or until all baby bond positions are eliminated.'' This sentence will also be moved to another paragraph in the text for enhanced clarity and flow. In addition, text will be modified for consistency with respect to defined terms.

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IV.D.2.a. (Fractional Entitlements in Cash or Additional Roundup Shares).	This subsection discusses the processing of fractional entitlements on a stock distribution such as a stock split, stock dividend, or pay-in-kind distribution. The section states that DTC does not support the distribution of fractional shares of securities and lists the acceptable forms of fractional entitlements that may be processed through DTC, namely cash-in-lieu of fractions (''CIL'') and roundup shares. CIL pays the cash value of fractional shares that would otherwise be distributed. Roundup shares provide for issuers and their agents to round the amounts of shares distributed to the next whole number. The section provides those fractional entitlements are to be computed by the agent at the Participant level or beneficial owner level and provides instructions relating to providing DTC with such payments. Pursuant to the proposed rule change, the OA text would add a clarification that such information on fractional entitlements should not be calculated at the Cede & Co. level only. An issuer and their Issuer and their Agent when paying CIL of fractions or additional roundup shares are to calculate and pay such entitlement down to the beneficial owner level when the event notification specifically refers to fractional entitlements being calculated at the shareholder/beneficial owners level, however, if the timing of the event precludes providing the opportunity for participants to identify and receive payment calculated at the beneficial owner level, or it is not specified in the event, then calculations can be done at the DTC participant level. Fractional entitlements should not be calculated at the Cede & Co. level only. The proposed rule change would also make technical and clarifying changes to the text of this subsection relating to Participant instructions collected at the beneficial owner level and update a mailing address.
IV.D.2.b. (Restricted Distribution Shares Issued)	This subsection would be modified to remove a cross-reference to ''Section VI(A), *Standards for Voluntary and Mandatory Reorganizations Notices* for notice instructions.)'' This reference is misplaced and not relevant to the subsection.
IV.D.3. (Reduction of Payment on Treasury Shares (for Stock Dividend Payments).	Treasury shares are owned by the issuer and not entitled to receive distributions. If a Participant holds any Treasury shares, the Participant must notify DTC via a confirmation letter regarding the treasury shares it holds so that the Participant's entitlement will be reduced in relation to the treasury shares it holds. The proposed rule change would revise the text to clarify that the confirmation letter is only required of ''applicable Participants'' and that an agent will facilitate obtaining the letter from Participants. The proposed change would also consolidate a list of information required to be included in such letters so that all the elements of the letter are included in one list rather than two, as the OA currently reads. The change would also remove a requirement that the Participant affix its medallion signature guarantee stamp to the letter. Text would also be added to refer the reader to an email address to contact to obtain a template of the confirmation letter.
V.A. (Redemptions, Advance Refundings, and Calls Inclusive of Sinking Funds and Mandatory Redemptions).	This section sets forth certain requirements relating to redemptions of securities. An issuer may conduct its redemptions pro-rata (distributed as an equal percentage across all holders) or by lottery (whereby DTC randomly selects holders whose securities will be redeemed). Once an issuer uses either a pro-rata process or the lottery process, future redemptions must be made using the same process. Pursuant to the proposed rule change, this section would be clarified by adding the following text after a sentence that states that DTC cannot support pro-rata lottery redemptions: ''In addition, once a security starts paying principal via lottery or pro-rata pass-through of principal, future principal payments must be made using the same payment method. Securities must not use both lottery and pro-rata pass through methods of paying principal. Pro-rata pass-through of principal must not be used for securities that offer ''pay-in-kind'' distributions.'' The proposed rule change would move text relating to eligibility of new issues that contain provisions for monthly optional redemptions from this Section to a new subsection I.C.7. (Monthly Optional Redemptions). The specific text to be moved states: ''DTC will consider for eligibility a new issue of securities where the issuance is registered under the Securities Act and containing provisions for monthly optional redemptions by the Issuer only if the issue is in book-entry ''BEO'' format and DTC has received an executed LOR prior to closing. (*See* Section (I)(B), *Documentation*).'' This text is a more logical fit to be included under Section I. of the OA as Section I. covers securities eligibility. Text would also be revised to delete a provision relating to notifications under this subsection that states that a ''second'' redemption notice shall be sent to DTC in a secure fashion within 60 calendar days if action is required and if DTC has not acted on the first notice, as it would be redundant to require such a second notice to be sent. The text would also be revised to delete text that states that an Agent's receipt of securities and redemption presentment documentation from DTC may be confirmed to DTC by using DTC's Participant Browser Service (''PBS'') function Redemption Payment Summary Return. Paying agents on the PWP program shall send their confirmations via email at *fastpay@dtcc.com* using the format provided by DTC. This confirmation verifies receipt of the redemption presentment and confirms intent to pay DTC, on the payable date by 3:00 p.m. ET, the value stated in the presentment documentation, provided the item is funded. Agent shall notify DTC immediately via email at *rpsdiscrepancies@dtcc.com* when discrepancies between the securities and redemption presentment documentation and the Agent's records are identified. This text is unnecessary as such information is delivered electronically and as such a confirmation would not be required.

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	The proposed rule change would also clarify that in addition to other methods described in this section, instructions relating to redemptions may be sent to DTC using a supported automated feed, such as REDCAL, DCN or BMA, or using an appropriate DTC formatted Microsoft Excel spreadsheet.[18] Finally, the subsection would be revised to for other technical and clarifying changes to the text.
V.A.1. (Notice of Recission)	From time to time, an issuer will seek to rescind a redemption event. DTC requests information and documentation to process the recission. To enhance clarity relating to this process, DTC would add a new subsection V.A.1. (Notice of Recission) that sets forth the information and documentation that DTC needs to be able to process the recission. In this regard, the new subsection would state: ''To notify DTC of a rescinded redemption event, Issuer or Agent must utilize DTC's automated file or email all related documents to *redemptionnotification@dtcc.com,* and the notice shall include the following: • Security description and CUSIP number(s) • statement that the redemption/refunding is rescind/cancel; • amount of the redemption or refunding being rescinded; • Publication Date of any related notices; • Redemption date of event being rescinded; • Redemption Agent's name and address; and • Administrator's contact information. Recission notice requests to DTC 30 days or more after the Redemption Date will only be accepted and processed when the Agent has provided a DTC debit request letter from each DTC Participant paid in the redemption. The letter is to include the DTC indemnification statement and medallion stamp. (Note: The authorized signer of the medallion stamp must be a different party than the signer of the letter.) To request a letter template, please contact *redemptionnotification@dtcc.com.*''
V.A.2. (Notice of Revision)	From time to time, an issuer may seek to revise a pending redemption event. DTC requests information and documentation to process the revision. To enhance clarity relating to this process, DTC would add a new subsection V.A.2. (Notice of Revision) that sets forth the information and documentation that DTC needs to be able to process the revision. In this regard, the new subsection would state: ''To notify DTC of a revision to a redemption announcement, such as called amount, redemption date, or publication date, Issuer or Agent shall send a notice to DTC specifying: • Security description and CUSIP number(s); • the redemption notice is revised from the prior notice and clearly indicates the revised information (*e.g.,* called amount, redemption date, pub date); • Amount of the redemption or refunding being revised; • Publication date of the notice; • Redemption date of event being revised; • Redemption Agent's name and address; and • Administrator's contact information. Revision notices requests to DTC 30 days or more after the Redemption Date which increase the called amount will not be accepted. A new notice with a current Redemption Date will be required. Interest must be paid up to the new Redemption Date. Revision notice requests to DTC 30 days or more after the Redemption Date which decrease the called amount will only be accepted and processed when the Agent has provided a DTC debit request letter from each DTC Participant paid in the redemption. The letter is to include the DTC indemnification statement and medallion stamp. Note: The authorized signer of the medallion stamp must be a different party than the signer of the letter.) To request a letter template, please contact *redemptionnotification@dtcc.com.*''
V.A.3. (Notice of a Security Declared ''Null, Void and Worthless'').	DTC's Null/Void Worthless Letter template provides agents with the required verbiage to initiate a mandatory corporate action that authorizes DTCC to delete/cancel a participant position on its books and records.[19] The letter[20] is available for download on DTCC's website and contains the required indemnification language to confirm that the securities are deemed null, void, and worthless, and that there will be no future payments. Pursuant to the proposed rule change, DTC would add a new subsection V.A.3. to clarify that the template letter should be used if a Security will not make a final paydown/redemption and the agent or issuer/agent intends to have the Security removed from the books and records. The new subsection would state the following: ''In the event a security will not make a final paydown/redemption, as may be the case with a structured security, or in the event that a security is being or has been cancelled pursuant to a bankruptcy, court order, or other similar circumstance and is therefore worthless, the Issuer, Trustee or Agent must instruct DTC to remove the position from DTC's books and records on the basis that the security is null, void, and worthless, that all interests in the security have been cancelled, and that there will be no further payments. The Issuer, Trustee or Agent instruction to DTC must be in the form of the ''Null, Void, and Worthless'' (''NVW'') letter template available on the DTCC's website at *https://www.dtcc.com/settlement-and-asset-services/agent-services/corporate-action-information-for-agents* and must be emailed to the applicable email address as set forth in the following paragraph. The letter, including an indemnification of DTC, must not be altered or edited.

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	Issuer, Trustee or Agent shall email the completed and signed NVW letter for a security not making a final paydown/redemption to *redemptionnotification@dtcc.com*. Issuer, Trustee or Agent shall send the completed and signed NVW letter to DTC for convertible securities, warrant or rights deemed null, void, and worthless to *conversionsandwarrantsannouncements@dtcc.com*. Issuer, Trustee or Agent shall send the completed and signed NVW letter to DTC for other event types to *mandatoryreorgannouncements@dtcc.com*.
	DTC reserves the right to request revised or additional documentation from the Agent, Issuer or Trustee as DTC deems necessary or appropriate.''
V.A.4. (to be renumbered from V.A.1.) (Pro Rata Pass-Through Distributions of Principal).	Considering the proposal to add the new subsections under Section V.A., as described above, current Section V.A.1. will be renumbered as V.A.4. This subsection provides requirements for notification to DTC and processing for pro rata pass-through distributions of principal. The subsection will be updated to clarify that such a pass-through is referred to as a ''final pay-down'' as opposed to a ''pay-down'' and adjust a related reference accordingly. The text of the subsection would also be revised for clarity and readability and to add that in addition to email, notification of a final pay-down can be provided to DTC via BMA5.
V.A.5. (to be renumbered from V.A.2.) (Partial Redemptions for Auction Rate Securities (''ARS'') and Requests for ARS Lottery Results.	Considering the proposal to add the new subsections under Section V.A., as described above, current Section V.A.2. will be renumbered as V.A.5. Also, a reference to the DTCC Customer Service Hotline, which can be called for further information regarding instructions on processing requirements, would be updated to reflect the current name of this customer support line, which is referred to as the ''Client Support Line.''
V.A.6. (to be renumbered from V.A.3.) (Redemption Notification Exceptions).	Considering the proposal to add the new subsections under Section V.A., as described above, current Section V.A.3. will be renumbered as V.A.6.
V.B.1. (Standards for Put Notifications)	Text would be removed that states ''DTC requires Agents to meet standards for put notifications as they apply to notifications to depositories and to the extent that this OA or related LOR does not supersede them.'' This text is redundant as the specific provisions relating to such put notifications are described in detail directly below the text to be deleted.
V.B.1.a. (Initial Notices of Puts)	The text would be clarified to indicate that email addresses must be provided to DTC for the delivery of put exercise instructions.
V.B.1.b. (Timing)	This subsection on the timing of notices to DTC would be modified to add that DTC should be notified no fewer than 10 days prior to payment date for mandatory puts. This is in addition to a stated requirement that the notice should be sent to DTC no fewer than 10 days prior to the expiration of the applicable tender period for puts with instruction windows. Mandatory puts would not necessarily involve an instruction window and therefore the existing text would not apply to mandatory puts.
V.B.1.c. (Additional Notices)	This subsection states a notice requirement relating to partial redemptions and information that should be included in a notice. The proposed rule change deletes a provision that such notices should be sent by the Issuer or Agent to one or more nationally recognized information services that disseminate put notices. This is a provision relating to a notification that would occur outside DTC and is not required for DTC to process the partial redemption.
V.B.1.d. (Warning on Envelope for Physical Notice Delivery).	This subsection contains a provision relating to notice relating to the circumstance where a bond indenture requires a physical notice to be sent in connection with a redemption. The subsection contains a requirement that a warning should be printed on envelopes provided to DTC in this regard and provides an example of such a warning and instructions for delivery of the notice. This subsection will be deleted as this relates to an obligation between an agent/issuer and the indenture trustee for the issue, and such notice is not necessary to be provided to DTC for DTC to process the event.
V.B.2.b. (Collateralized Mortgage Obligations (''CMOs'') and Asset-Backed Securities (''ABSs'').	This subsection contains a provision that is currently misplaced relating to death redemptions, which is an estate feature of some bonds that provides that the bond may be put back to the issuer as a type of early redemption in the event of the death of a bondholder. The provision is misplaced and has been moved to the section relating to early Certificate of Deposit (''CD'') redemption/Survivor Options.
	The proposed rule change also makes a grammatical change to enhance readability.
V.B.2.c. (Put ''Extendible'' Issues'')	This subsection sets forth notice requirements for issues that may be subject to a ''put'' provision that allows the security to be exchanged into a new security in accordance with the terms of the issuance. The proposed rule change will make technical and clarifying changes relating to an example of such a put (i) to modify terminology in a parenthetical used to refer to an extendible bond, from being referred to as ''Extendible'' to instead refer to it as ''the extendible bond'' and (ii) modify text in the example to refer to the new bond as having a ''shortened'' maturity rather than a ''new'' maturity. The word ''as'' would also be added to the text for the example before modified text ''with a shortened maturity date.''
	In this regard, the existing text subject to these modifications currently states:
	''A security subject to a ''put'' provision may be exchanged for a new security, in accordance with the terms and conditions of such put, with a new maturity date (*i.e.,* ''Extendible'') if a holder does not elect to retain the position.''
	The modified text would state:
	''A security subject to a ''put'' provision may be exchanged for a new security, in accordance with the terms and conditions of such put, as with a shortened maturity date if a holder does not elect to retain the position (*i.e.,* the extendible bond).''
	The subsection would also be modified to add an additional email to which related confirmations must be sent to. In addition to *putbonds@dtcc.com,* the text will provide that *putsprocessing@dtcc.com* could also be used for this purpose.

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V.B.2.d. (Put Bonds (Repayment Options))	The proposed rule change would shift the location of text within the subsection, relating to certain notice requirements and related late fees for put bonds, to enhance clarity and readability. The proposed rule change also amends the notice requirements to remove the option to deliver notices to DTC using physical delivery methods in the event email transmission is unavailable. The proposed change would also modify text for accuracy of terminology.
V.B.2.e. (Early CD Redemptions/Survivor Options).	This subsection contains provisions contained in the terms of certain Securities relating to survivor options which permit early redemption of a security in the event of the death of a bondholder or if the bondholder is adjudicated as incompetent. This section is focused on the early redemption of certificates of deposit and MMI Survivor Options. In this regard, the heading of this subsection would be clarified to reflect this focus by adding a reference to early CD redemptions in addition to survivor options, as well as adding ''MMI'' before ''Survivor Options''. In this regard, the heading reads as ''Survivor Options'' and the modified title would read ''Early CD Redemptions/MMI Survivor Options''. The text would be revised to clarify the system functions and procedures used for the early redemptions of certificates of deposit that are issued in DTC's MMI Program and those that are not issued in the program. In this regard, the text would state that Participants should use the CD Early Redemption Request (''CERR'') function on PTS/PBS for non-MMI CDs to notify DTC in this regard, and Participants should use the ''PUTS'' function on PTS for CDs issued in the MMI program to notify the Issuing and Paying Agent (''IPA''). (In the MMI program, redemptions are initiated directly between a Participant and an IPA on DTC's MMI platform, whereas the Participant provides instructions directly to DTC for other redemption types and DTC communicates those instructions to the agent. Text be updated and clarified relating to information actions required for Participants and Agents to instruct and process early redemptions. As such the following deletions and additions would be made. The following text would be deleted: ''When submitting instruction via CERR functions, hard copy supporting documentation is not required to be delivered to DTC *concurrently* with instructions from Participants for certain put exercise instructions, for example, a bond issue with a ''death put'' provision does not require the submission of a death certificate concurrently with an exercise instruction, however, hard copy *documentation* must follow promptly. The presentment of the supporting documentation to the Agent is not monitored by DTC. Agent shall receive the specified Securities in accordance with DTC's CERR procedures. Upon receipt of payment, DTC will credit Participant, and the Participant shall forward the payment to the legal representative of the named beneficial owner. If such Securities are structured so that the redemption option (*i.e.,* ''death put'') pays holders accrued interest, Agent must include such accrued interest with the principal payment which shall be calculated from the day prior to the regular interest payment date to and including the day the funds are wired to DTC. Such funds shall be sent to the account in the manner set forth in Section III(C)(2), Redemption and Maturity Payment Standards.'' The deleted text would be replaced with the following: ''(1) Early CD Redemptions (Non-MMI) • Instruction Processing (with supporting documentation): For early CD redemption instructions submitted through CERR, DTC will provide the Agent the instructions from Participants, and if in addition to the instruction the Agent requires the Participant to present the beneficial-owner supporting documentation, (*e.g.,* death certificate), DTC will electronically provide to the Agent (unless otherwise notified by DTC) the supporting documentation received from Participants on the condition the Agent meets the following requirements: ○ Agent agrees to accept the beneficial owner documentation via email from DTC and further agrees it fulfills the documentation requirement of the submission to make the payment; ○ Agent can accept the DTC email delivery in the form of a password-protected/encrypted email; and ○ Agent provides DTC a group/business unit email address (as opposed to an individual employee's email address) for the delivery of the documentation. If any of the above conditions cannot be met, DTC will not provide the Agent the supporting documentation and Agent will be responsible to obtain the documentation directly from Participants as may be needed. • Instruction Processing (without supporting documentation): For early CD redemption instructions submitted through CERR where the event indicates supporting documentation is not required to complete the submission for payment, DTC will provide the Agent the instructions from Participants including contact information at the Participant should the Agent want to obtain the documentation at a later time. When the event indicates that documentation is not required, Participants submitting instructions will certify that they will retain the documentation for 30 months from the submission should the Agent want to obtain such documentation.

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	• Early CD Redemption Instruction Confirmation: Agent is required to notify DTC of any issues with instructions submitted to Agent, (*e.g.,* invalid documentation, annual or quarterly cap reached, lifetime cap reached) within 5 business days of receipt by emailing *survivoroptions@dtcc.com*. For requests in good order, Agent will promptly inform DTC of the anticipated payment date for each instruction submitted to the Agent by emailing *CDdeathputs@dtcc.com*. • Early CD Redemption Payments: The Agent shall remit wire payment of early CD Redemption to DTC and include the CUSIP number, (*e.g.,* CUSIP 123654AA0), and the CERR transaction ID, (*e.g.,* Transaction ID E@PF0101171216), on the wire. For all payments, Agent must email wire payment details in an Excel file listing the CUSIPs, CERR transaction ID's, and amount to be paid. The email should be sent to *CDdeathputs@dtcc.com* with the subject of the email containing the same transaction ID (*e.g.,* Transaction ID E@PF0101171216) contained in the wire. The amount to be paid in the email attached Excel file must match the wire amount sent to DTC. If such Securities are structured so that the redemption option (*i.e.,* ''death put'') pays holders accrued interest, (as payment is not occurring on a scheduled interest payment date), Agent must include such accrued interest with the principal payment which shall be calculated from the day prior to the regular interest payment date to and including the day the funds are wired to DTC. Such funds shall be sent to the account in the manner set forth in Section III(C)(3), Reorganization Payment Standards. (2) MMI Survivor Options: IPA is to refer to the ''Survivor Options Puts User Guide for Agents'' for instructions on viewing instructions, accepting/rejecting instructions, and responding to withdrawal requests, and selecting instructions for payments.''
VI.A. (Standards for Voluntary and Mandatory Reorganizations Notices).	This section provides notice standards, including timeframes and other requirements, for the processing of voluntary and mandatory reorganization events. The proposed rule change will revise the text of this section as follows: 1. The text of this section currently provides in its introductory paragraphs that notices for mandatory reorganization events must be sent to DTC no fewer than five business days prior to the transaction (event). Voluntary events require more time for processing than mandatory events, because under a voluntary event Participants need to submit instructions to DTC on how the event should be processed on their or their customers' behalf. For a mandatory event, such instructions are not applicable. This subsection currently provides for a 10-day notice period for voluntary events by stating that final source documentation must be provided to DTC at least 10 business days prior to the expiration of the voluntary event, but it resides further down in the section. The proposed rule change would move the text for the 10-day notice for voluntary events to be closer to the description of the five-day notice period (for mandatory events) to make it clearer to the reader as to which notice period applies to a mandatory or voluntary event. In the regard, revision would also add text to clarify that the five-business day requirement set forth in this section for notice applies with respect to mandatory events. Text referencing provision of preliminary source documentation and late notification fees that are charged for late notifications for voluntary events would be moved further up in the section for improved flow of the text. 2. The proposed rule change would delete the word ''distribution'' from text relating to processing of cash in lieu of fractional shares because this paragraph is referring to reorganization events, which currently states: ''the rate of distribution (*e.g.,* stock rate and exchange rate), including the rate for CIL fractions or roundup entitlements . . .'' This is because reorganization events do not result in distributions, but instead provide for entitlements to cash or securities. In addition, the referenced text above would be revised to clarify that the ''rate'' is a ''payment rate'' and clarify how the rates are expressed for debt and equity. 3. The proposed rule change would add text noting that DTC does not support the distribution of fractional shares of securities.[21] 4. The following note would be added to the text: ''Important Note: If there is a change in terms, a revised notice must be provided to DTC immediately upon publication. Agent is to confirm that DTC took the appropriate action with the information provided, (*e.g.,* extended/revised the DTC expiration date when given a new expiration date).'' 5. The proposed rule change would add that a notice should include information on whether shares issued as the result of exercise of dissenter rights would be issued as a certificate or in Direct Registration Statement format. 6. The subsection provides an email address for submission of notices of voluntary events. The proposed rule change would clarify that notices for three of the event types listed, namely conversions, right exercises, and warrant exercises should be sent to a different email box than the email box currently listed for all voluntary reorganization events. The email address currently listed for all such events is *voluntaryreorgannouncesments@dtcc.com*. This will continue to be a valid address for all events listed therein except for the three mentioned above, for which notices should be sent to *conversionsandwarrantsannouncements@dtcc.com*. In addition, text would be added stating that notifications pertaining to Put events should be sent to *putbonds@dtcc.com*. Also, a reference to ''dutch auctions'' will be changed to ''Dutch auctions'' to capitalize ''Dutch'' to reflect that it is referring to a specific type of auction.

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	7. The proposed rule change would revise text that describes requirements relating to events that DTC is unable to process and that must be paid outside of DTC. For these events, the OA states that details of the related entitlement must be provided. The revision would modify a clause that currently states ''Agents will accept responsibility to make payment directly to DTC Participants and agree to provide DTC details of the entitlement being allocated to DTC Participants, including calculations at the instruction level at the time of the allocation to DTC Participants and to notify DTC that instructed positions can be drawn down from the DTC balance as DTC has no ability to confirm whether such payments were made to or received by DTC Participants'' to add ''if applicable between ''including'' and ''calculations.'' 8. The proposed rule change would add wording in a sentence relating to issues listed on an exchange, to make a reference to the plural ''securities'' to also refer to the singular ''security'' so that the applicable text would reflect ''the security or securities.'' In addition, ''cash and/or stock merger'' would be added to examples of transactions that are corporate actions. 9. Pursuant to the DTC Fee Schedule, DTC may assess fees for the processing of a corporate action whose structure does not conform to DTC's processing standards.[22] Pursuant to the proposed rule change, DTC would move text describing these fees from subsection VI.D.4. to this section, with clarifying modifications to clarify DTC's discretion to establish an appropriate fee for a given event once notice is received by DTC. The proposed text would read: ''Upon receipt of a notice and evaluation of the event/offer details DTC may assess non-standard corporate action processing fees as DTC deems appropriate to announce and process the corporate action event through DTC. Approval of the fee will be required prior to DTC committing to handling the offer/event as well as agreement to provide DTC with allocation information in a specified format (*e.g.,* spreadsheet). Payment of fees is due upon receipt of an invoice from DTC.'' 10. Revisions to this section would also include technical changes to clarify the text.
VI.B. (Fractional Entitlements in Cash or Additional Roundup Shares).	Section IV.D.2., described above, sets forth requirements relating to the handling of distributions that may result in fractional entitlements. Reorganizations can also result in the distribution of fractional entitlements. The proposed rule change would add a new section VI.B. (Fractional Entitlements in Cash or Additional Roundup Shares). Such distributions are processed similarly as distributions that are not associated with reorganizations. To provide clarity in this regard, the proposed rule change will add the following text to this new subsection that is like that stated in Section IV.D.2. Specifically, the new text would state: ''In the event the corporate action rate of distribution results in fractional entitlements, Issuer shall provide DTC one of the following: *(a)* cash in lieu (''CIL'') of fractions or; *(b)* additional roundup shares, or; *(c)* written notification to DTC that fractional shares will be dropped. Important Note: *DTC does not support the distribution of fractional shares of securities. Fractional entitlements should not be calculated at the Cede & Co. level only.* For mandatory corporate action events, Issuer and their Agent when paying CIL of fractions or additional roundup shares are to calculate and pay such entitlement down to the beneficial owner level when the event notification specifically refers to fractional entitlements being calculated at the shareholder/beneficial owners level, however, if the timing of the event precludes providing the opportunity for participants to identify and receive payment calculated at the beneficial owner level, or it is not specified in the event, then calculations can be done at the DTC participant level. For voluntary corporate action events, the treatment of fractional entitlements (CIL, roundup, or dropped) must be calculated at the Voluntary Offering Instruction (''VOI'') level. For CIL or additional round-up shares, Issuer or Agent must: (1) accept instructions from DTC to liquidate a designated quantity of full shares or issue additional roundup shares to satisfy Participant CIL/roundup entitlements *down to the beneficial owner level.* Such instructions will be presented to Issuer or Agent on the date agreed upon by DTC and Issuer or Agent. Issuer or Agent must provide DTC ample time (preferably 5 business days after the distribution) to collect Participant instructions; (2) include additional roundup shares to DTC's overall share entitlement; (3) provide the CIL price to DTC on the date the price is established. Such price shall be provided to DTC by email in accordance with the type of corporate action to *mandatoryreorg@dtcc.com, reorgtenders@dtcc.com,* or *reorgconv@dtcc.com*. (4) wire funds for the payment of CIL of fractional entitlements to DTC's Reorg Deposit Account via Fedwire using the Originator Beneficiary Instruction ''Vol. CIL,'' or ''Mand CIL'', as applicable, (absent any other arrangement between paying agent and DTC); and (5) upon issuance of additional roundup shares, for securities held in the DTC FAST program, reconcile and confirm to DTC the FAST balance or for Non-FAST issues deliver physical Securities to DTC. Such Securities shall be delivered to DTC at: Registered Corporate Vault, The Depository Trust Company, 570 Washington Blvd., 5th Floor, Jersey City, NJ 07310''.
VI.C. (Processing of Specific Mandatory Reorganizations).	This subsection will be renumbered from IV. B. to IV. C. The subsection describes processing requirements for specific types of mandatory corporate actions, including an Item 1 for ''Reduction of Payment on Treasury Shares or Repurchased Debt Securities'' and Item 2 for ''Mandatory Separation of a Unit After the Closing Date.''

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	The proposed rule change would renumber the above two items as 3 and 4, respectively and add three additional items, including a new Item 1 for ''Standards for Restricted to Unrestricted Exchanges,'' a new Item 2 for ''Standards for Maturity-for-Stock Events,'' and Item 5 for ''MMI to Non-MMI Exchanges.'' *Item 1* The new Item 1 (Standards for Restricted to Unrestricted Exchanges) would provide a cross-reference for notice and documentation requirements relating to exchanges of restricted shares for unrestricted shares, including securities that are eligible for resale pursuant to Rule 144(b)1, in the case of former 144A securities, or pursuant to Section 4(1) of the Securities Act, in the case of former Regulation S restricted securities. In this regard this subsection would refer the reader to Section I(B)(5), Instruction Letters Regarding the Expiration of a Restrictive Period, for the notice and documentation requirements. *Item 2* It is DTC's practice to require certain notices and information relating to mandatory events where a security is being exchanged for stock (as opposed to cash) in order that it may be able to make the entitlement security eligible and timely facilitate the exchange. In order to enhance clarity relating to the notices and information required by DTC in this regard, the new Item 2 (Standards for Maturity-for-Stock Events) would delineate these standards and read as follows: ''Issuer or Agent shall provide to DTC notice as soon as possible but no later than three business days prior to the maturity date for a Security which will make payment of a Security or Securities upon maturity in lieu of all or part of the cash payment. Notice shall be on Issuer or Agent's letterhead and sent to DTC's Reorganization Announcements Department by email at *mandatoryreorgannouncements@dtcc.com*. The email subject line shall state the maturing CUSIP number, the maturity date, and that the maturity is for stock (*e.g.,* CUSIP 123456AB, due xx/xx/xx, maturity for stock). The notice shall include the following: • Issuer/Security description and CUSIP number of the maturing security, the maturity date, and that it is a maturity-for-stock event; • Issuer name and CUSIP number of the entitlement stock, total number of shares to be paid to DTC, and the rate of payment. (Note: When the maturing security is denominated in shares, the rate of payment is to be calculated per share, and when the maturing security is denominated in principal amount, the rate of payment is to be calculated per $1,000 principal amount.); • Participant account name and number holding the entitlement shares at DTC; • If a cash component is applicable, provide the total cash payment amount to be paid to DTC and the cash rate; and • If an accrued interest payment is applicable, provide the total interest payment amount to be paid to DTC, the interest rate, and the number of days of accrued interest. In addition to the notice, (when the entitlement Security will be provided to DTC by a debit to a DTC Participant's account), DTC must receive the holding Participant's letter authorizing DTC to reduce their DTC position in the entitlement security by the total quantity of shares to which DTC's nominee name, Cede & Co., is entitled. In the event the Participant's letter is sent separately from the notice, it must be emailed to DTC no later than 3:00 p.m. ET on the business day prior to the maturity date to the following email addresses: *mandatoryreorgannouncements@dtcc.com,* and *mandatoryreorg@dtcc.com*. Such letter must be on the DTC participant's letterhead, and include the following: • Issuer/Security description and CUSIP number of the maturing security; • Participant account name and number; • Issuer/Security description and CUSIP number of the entitlement shares to be reduced (*i.e.,* debited) from the Participant's account; • total number of entitlement shares to be debited; • Participant contact name and telephone number; • Participant officer-level signature authorizing the number of shares to be reduced from the Participant's account; • DTC indemnification statement; and • medallion signature guarantee stamp affixed to such letter. (Note: The authorized signer of the medallion stamp must be a different party than the signer of the letter) *Important:* The holding DTC Participant must ensure that the total quantity of shares to which DTC's nominee name, Cede & Co., is entitled and needed to fund the distribution is on deposit in the holding DTC Participant's General Free Account no later than 10:00 a.m. ET on the maturity date. The template of the DTC Participant (debit) letter can be obtained contacting DTC's Reorganization Announcement Department at *mandatoryreorgannouncements@dtcc.com*. Further note, in the event DTC will not be funded the total quantity of entitlement shares due DTC, Agent shall provide to DTC a notice of the reduction in the shares (and if applicable the cash component) due to DTC by no later than 3:00 p.m. ET on the business day prior to the maturity date to the following email addresses: *mandatoryreorgannouncements@dtcc.com,* and *mandatoryreorg@dtcc.com*. The notice shall include the information from the Agent and the Participant(s) as described in Section VI(C)(3), Reduction of Payment on Treasury or Repurchased Securities. Delivery of the notices to an email address other than the email addresses set forth above does not constitute a valid notification. *Failure to comply with any of the notification requirements could result in DTC being unable to support the processing of the event.*''

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	Item 3 Renumbered Item 3 (formerly Item 1) relates to the reduction of payment on Treasury Shares or Repurchased Debt Securities. This item would be revised for to clarify and consolidate text relating to requirements for a confirmation letter that the Agent must ensure that each Participant provides to DTC in order for DTC to timely process the event using the appropriate payment amount. *Item 4* Renumbered Item 4 (formerly Item 2) relates to the mandatory separation of a unit from an eligible security after the closing date. The section would be clarified by adding a note that the unit must be DTC eligible at the time the Unit Security was made DTC eligible, or the unit must become eligible in accordance with the provisions of the OA. *Item 5* From time to time, an issuer and/or agent may request that a security be made eligible for DTC's Money Market Instrument (''MMI'') Program but later determine that it should have been placed in DTC's non-MMI services. DTC requires certain documentation and information from the Issuer and Issuing and Paying Agent for the MMI issue in order for it to be exchanged for a non-MMI CUSIP. In order to enhance clarity relating to notices, documentation and information required by DTC in this regard, a new Item 5 (MMI to Non-MMI Exchanges) would be added to this subsection and read as follows: ''For DTC to agree to announce and process an MMI (CUSIP) to Non-MMI (CUSIP) exchange the following conditions must be met. DTC will not make a Non-MMI CUSIP eligible which will mature 30 days or less from the eligibility date nor perform an exchange from a CUSIP that will mature 30 days or less from the exchange date. (*See* I (C) 6 Short-Term Maturities) The Issuing Paying Agent (''IPA'') must provide notice to DTC on IPA letterhead by email to *mandatoryreorgannouncements@dtcc.com* by no later than 5 business days prior to the exchange date acknowledging the reason for the exchange, (*i.e.,* security was incorrectly issued as an MMI CUSIP), the MMI CUSIP and the Non-MMI CUSIP, security description, and the rate of exchange. In addition to the exchange notice, the following must be provided: ○ notice from the Issuer which includes the DTC indemnification language acknowledging the listed CUSIP(s) were issued incorrectly as MMI securities. ○ written acknowledgment from the IPA to be billed all eligibility and exception processing fees for each exchange per CUSIP ○ the Non-MMI CUSIP obtained from the CUSIP Service Bureau for each exchange and a copy of the prospectus, offering document, or offering statement describing terms of the Non-MMI security to make the new CUSIP DTC eligible. ○ other documentation that may be required by DTC's Underwriting Dept. to determine the eligibility of the NON–MMI security (*e.g.,* new Letter of Representations for BEO issues; and, ○ Dependent upon the review of the information provided, DTC reserves the right to request revised or additional documentation from the Agent and/or Issuer as DTC deems necessary to process the requested exchanges.''
VI.D. (Processing for Specific Voluntary Reorganizations).	This section will be renumbered from IV. C. to become IV. D. In addition, the proposed rule change would clarify the timing by which a Participant's submission of an instruction relating to a voluntary reorganization is effective. In this regard, the following note would be added to the text of this section. ''Note to Agents and Issuers regarding Participant instructions for events processed through a DTC instruction processor (*i.e.,* ATOP, ASOP, or APUT): By processing an event through a DTC instruction processor (''Instruction Processor''), including, but not limited to, ATOP, ASOP, or APUT, the Agent and Issuer acknowledge and agree that the date and time of a Participant's submission of its instruction to DTC (as reflected in the Transaction ID of the completed transaction) is deemed to be the date and time of the Agent's receipt of the instruction and, if applicable, the tendered securities. By way of example, but without limitation, for purposes of determining the timeliness of a Participant's instruction and tender in connection with an event, the Participant's instruction is deemed to have been timely received by, and, if applicable, the securities timely tendered to, the Agent when the date and time of the submission of a Participant's instruction to DTC (as reflected in the Transaction ID of the completed transaction) is prior to the applicable cutoff/expiration date and time, even if the transaction does not complete until after the applicable cutoff/expiration date and time for the event.''
VI.D.2. (Mortgage-Backed Securities with Monthly Early Redemption Features).	This subsection would be removed from the OA as it is redundant to language already included relating to Puts.
VI.D.2. (Rights Offers (Use of DTC's Automated Subscription Offer Program (''ASOP'')).	This subsection would be renumbered from IV.D.3 to IV.D.2. This subsection would also be modified to modify the sentence that states: ''In the case of rights offers, DTC's ASOP procedures and systems must be utilized to process subscription exercise activities, including the submission of instructions for basic subscriptions, the exercise of step-up and oversubscriptions, sales of rights, and notices of guaranteed deliveries, and all related activities.'' The change would remove the words ''step-up and'' from this sentence.
VI.D.3.a. (Convertible Issues/Warrants/Rights Notifications).	This subsection would be renumbered from IV.D.4.a to IV.D.3.a. The text of this subsection would be revised as follows:

OA section	Revision
	1. A reference to ''company/agent'' would be revised to ''Issuer/Agent'' for consistency with the term as used in the OA; 2. Text relating to notice provisions relating to the alteration of terms for conversions and warrants would be revised to move text up from further down in the section that reflects timeframes by which notice to DTC is required. This text states that DTC must be notified in accordance with the terms of the offering document, to instead state that DTC must be notified no fewer than 10 business days prior to the effective date of such change, or to the extent an event ''triggers'' the change (*i.e.,* on short notice) then notice must be provided to DTC immediately, but, in any event, no later than 24 hours after the triggering event, and that the Agent is to confirm receipt of such notice to DTC. This proposed rule change would facilitate the provision of information to DTC in sufficient time for DTC to process any such alteration in terms. 3. The email address to which such notices should be sent would be revised to *voluntaryreorganizations@dtcc.com* to *conversionsandwarrantsannouncemetns@dtcc.com*. The provision would also be revised to require such notices to be delivered by email as opposed to email or to a physical mailbox. 4. Text would also be revised for clarity relating requirements for information that must be included in a notice provided to DTC under this subsection and certain notification requirements for variable rate entitlements would be moved to further down in the text of the OA to a renumbered Section IV.D.4.c, as described below. 5. Text would be added to clarify the requirements for an Agent to notify DTC relating to a change in terms affecting an expiration date. 6. The proposed rule change would make other technical and clarifying changes to this subsection with respect to updating cross-references as well as grammatical changes.
VI.D.3.b. (Convertible Issues/Warrants/Rights Processing).	This subsection would be renumbered from IV.D.4.b to IV.D.3.b. The subsection would be modified: 1. To add text moved from IV.D.4.a. relating to conversions with variable rate entitlements, as described above, and move and condense text from further below in the subsection that such notification include information as to whether a CIL entitlement is to be paid per the instruction with the method of calculation and provide an example stating ''market price or the Volume Weighted Average Price.'' 2. To separate text in a bullet relating to processing of a conversion through a DTC voluntary program so that text relating to an agreement of an issuer and agent relating to a delivery instruction to debit the balance of a security certificate in connection with a conversion, is separated from text setting forth the agreement of the issuer and agent agreeing that any new securities resulting from a conversion, warrant or right exercise shall (i) be issued as of the date on which the conversion, warrant, or right instruction is entered into the DTC system and (ii) follow with issuance occurring no more than two business days from the date of receipt by DTC of the instructions and the Agent is required to notify DTC by 12:00 noon ET the following day of any instructions that have been rejected. 3. To delete text relating to CIL entitlements, as described above and which are replaced by the applicable bullet described in 1 above and 4. Modify a sentence that states ''For rights offering with oversubscriptions, proration and rounding, Agent must agree to utilize DTC's template for providing payment details for oversubscription, proration and rounding, to add the reference ''as well as guaranteed delivery (protect) submissions and cover of protects'' between ''rounding,'' and ''Agent''.
VI.D.4.a. (Tender/Exchange Processing)	This subsection would be renumbered from IV.D.5.a to IV.D.4.a. This section describes tender and exchange processing and processing of mergers with elections. It requires the use of DTC's ATOP system for such processing. The subsection would be modified to clarify that DTC will not process the event if the agent is not an ''ATOP agent'' by adding the following text: ''For DTC to support the processing of the offer/event, Issuer's (or Offeror's) Agent must be an established ATOP agent with DTC (*i.e.,* has an on-line connection to DTC's ATOP-automated tender offer platform) at the time of the announcement submission to DTC.'' Examples provided with respect to other transaction types that ATOP may be utilized for (at DTC's discretion) would be modified to expand the text from referring only to consent solicitations (with a fee), collection of tax withholding rate or exemption, conversion events where the entitlement can be cash and collection of CIL entitlements to also include (a) conversion events where the entitlement can be securities and are subject to an extended settlement period (which could be in addition to or in the alternative to conversion events where the entitlement can be cash), and (b) cashless warrants. The qualification that a consent limitation be ''with a fee'' would also be removed, to indicate that any collection of a consent solicitation could be processed by ATOP (with or without a fee (but processing of such an event would still subject to DTC's discretion as previously mentioned)). A provision stating that a Letter of agreement (LOA) approval by an Agent is required within 24 hours of DTC posting to ATOP, and a reference to applicability of ''late notification fees'' relating to processing delays stemming from a late approval of a LOA, would be moved from the end of this subsection to text higher up where the LOA is first referenced in this section, so that it appears in the context of other stated requirements relating to the LOA. Also, the reference to ''within 24 hours'' would be modified to instead reference ''1 business day'' to take into consideration instances where a deadline for an agent's approval might otherwise fall on a non-business day.

OA section	Revision
	Text would also be added to clarify the timing by which DTC must receive certain information and documentation relating to an entitlement to facilitate timely processing. In this regard, the added text will state that the entitlement must have a CUSIP number and the Agent must notify DTC of such CUSIP number assigned to the new Securities no less than 3 business days prior to allocation of the entitlement if security is already DTC eligible. The added text would also state that if the security is not DTC eligible, the Agent must provide all required documentation no later than 5 business days prior to allocation of the entitlement security for DTC to complete the eligibility process prior to allocation. The text would also state that additional eligibility processing time could be required dependent upon the determination of the eligibility review and the requirement for additional documentation, (*e.g.,* legal opinion for a Non-US security) and Issuer and Agent shall plan accordingly.
VI.D.4.c. (Altering the Terms of an Offer)	The subsection would also be modified to make technical and clarifying changes to the text. This subsection would be renumbered from IV.D.5.c. to IV.D.4.c. This subsection provides requirements for communication to DTC of a change in the terms of an offer. The text includes that all extensions to an offer must be provided to DTC via email ''by noon on the day following the expiration date of the event and if applicable, shall include any and all changes to terms of the offer.'' This provision would be revised to add emphasis to the timing of this deadline to add ''no later than'' in front of ''noon.'' It is important that the Agent confirm that its extension of an expiration date of an offer is accurately reflected on DTC's records. The subsection includes text indicating the need for an Agent to confirm DTC's receipt of the applicable notice via email or by phone. Pursuant to the proposed rule change, this text would be clarified to state that the agent may make this confirmation by viewing the ''Transaction Entry End Date'' field in ATOP. If the information is not shown as updated, then the Agent should notify DTC via email or phone.
VI.D.4.f. (Consents)	This subsection would also be revised for technical and grammatical changes. This subsection would be revised for technical and grammatical changes.
VI.E. (Chargeback of Reorganization Payments)	This subsection would be revised to add examples of the type of refunds of payments covered by this section.
VI.F.1. (Consents and Legal Notices)	This subsection would be revised to make technical changes, including updating to reflect the elimination of hard copy delivery of notices.
VI.F.2. (Security Position Reports (''SPRs'')	This section describes how issuers, trustees and authorized third parties may access security position reports (''SPRs''). This subsection would be revised to clarify and consolidate text and make technical changes relating to the requirements relating SPRs, including with respect to how SPRs are accessed and how third parties may be authorized to obtain and maintain access reports. The proposed rule change would also add contact information for support resources relating to SPRs.
VI.F.3. (Shareholder Meetings)	This subsection describes processes relating to the announcement of shareholder meetings and issuance of omnibus proxies. The following text would be added to this subsection: ''Issuers and Agents are advised that in the event a voluntary offer (*e.g.,* tender) at DTC is active on the record date of the meeting announcement and a Participant's instructed position is in the contra-CUSIP on record date, it will be added to that Participant's record date position in the target CUSIP (*i.e.,* issuer's security) for purposes of the omnibus proxy and the accompanying SPR. If the active voluntary offer is being made by the Issuer (as opposed to a third-party) and the Issuer, in accordance with the terms of its voluntary offer, wants DTC to exclude the instructed positions of Participants in the contra-CUSIP from the omnibus proxy and accompanying SPR, the Issuer or their Agent must contact DTC, at least 5 business days before the record date for the meeting by emailing DTC at *proxyannouncements@dtcc.com*. DTC can require indemnification from the Issuer to take such action.'' The text would be updated to include that a shareholder meeting announcement should include the ''CUSIP number of the issuer's security'' in addition to other information fields already listed. Text saying that the ''company name'' field would also be updated to read ''issuer/company name''. This subsection would also be revised to make technical changes, including, but not limited to, relating to language hardcopy delivery and move text within the subsection for enhanced readability.
VII. Additional Operational Requirements for Variable-Rate Demand Obligations (''VRDOs'').	This section would be revised to reflect that delivery of instructions and notices should be sent to DTC electronically rather than via physical delivery.

[9] *See* Rule 5, *supra* note 6.

[10] Pursuant to the Rules, the term MMI Program means the Program for transactions in MMI Securities, as provided in Rule 9(C) and as specified in the Procedures. *See* Rule 1, Section 1, *supra* note 6.

[11] Pursuant to the Rules, the term (i) ''MMI Issuing Agent'' means a Participant, acting as an issuing agent for an issuer with respect to a particular issue for MMI Securities of that issuer, that has executed such agreements as the Corporation shall require in connection with the participation of such Participant in the MMI Program in that capacity, and (ii) ''MMI Paying Agent'' means a Participant, acting as a paying agent for an issuer with respect to a particular issue of MMI Securities of that issuer, that has executed such agreements as the Corporation shall require in connection with the participation of such Participant in the MMI Program in that capacity. *See* Rule 1, *supra* note 6.

[12] Eligibility for inclusion in the MMI Program covers Securities that are money market instruments, which are short-term debt Securities that generally mature 1 to 270 days from their original issuance date. MMI Securities include, but are not limited to, commercial paper, banker's

Continued

2. Statutory Basis

Section 17A(b)(3)(F) of the Act [23] requires that the rules of the clearing agency be designed, *inter alia,* to promote the prompt and accurate clearance and settlement of securities transactions. DTC believes that the proposed rule change is consistent with this provision because it would update the OA to clarify text, provide additional detail on existing processes, update DTC's contact information and therefore provide Participants, Issuers and Agents with transparency with respect to DTC's eligibility and asset servicing processes. By providing such transparency, the proposed rule change would allow each of these parties' greater transparency on processing of transactions in their Securities and, therefore, would promote the prompt and accurate clearance and settlement of securities transactions.

The proposed rule changes are also designed to be consistent with Rule 17Ad–22(e)(23) of the Act,[24] which was recently adopted by the Commission.[25] Rule 17Ad–22(e)(23) requires DTC, *inter alia,* to establish, implement, maintain and enforce written policies and procedures reasonably designed to (i) publicly disclose all relevant rules and material procedures, including key aspects of its default rules and procedures, and (ii) provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. The proposed rule changes, as described above, would update DTC's OA with respect to rules, material procedures and certain fee-related provisions relating to DTC's securities eligibility and asset servicing processes. As such, DTC believes that the proposed changes would promote disclosure of relevant rules and material procedures and provide sufficient information to enable participants and other users of DTC's services to evaluate fees and other material costs of utilizing DTC's services, in accordance with the requirements of Rule 17Ad–22(e)(23), promulgated under the Act, cited above.

(B) Clearing Agency's Statement on Burden on Competition

DTC does not believe that the proposed rule change would have any impact on competition because the proposed changes merely relate to updates and clarifications of the OA which would not significantly affect the rights and obligations of users of DTC's services and would not disproportionally impact any users.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. If any written comments are received, they would be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at https://www.sec.gov/regulatory-actions/how-to-submit-comments.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

DTC reserves the right to not respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) [26] of the Act and paragraph (f) [27] of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–DTC–2023–010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–DTC–2023–010. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the

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acceptances and short-term bank notes and are issued by financial institutions, large corporations, or state and local governments. Most MMI Securities trade in large denominations (typically, $250,000 to $50 million) and are purchased by institutional investors. Eligibility for inclusion in the MMI Program also covers medium term notes that mature over a longer term.

[13] *See* Rule 5, *supra* note 6.

[14] *See* Rule 1, *supra* note 6.

[15] DTC's FAST program allows an Agent which is an approved FAST Agent to act as custodian for DTC and increase or decrease the amounts of a balance certificate representing Securities eligible for DTC book-entry services. *See* OA Section II.B.a. (FAST), *supra* note 5.

[16] A SCL, or Shipment Control List, is a form generated by DTC that lists identifying information about a shipped security certificate, including the number of shares or other interests, CUSIP number, and dollar value. An SCL serves as a manifest for a transfer agent receiving security certificates from DTC. *See* OA Section II.B.a. (FAST), *supra* note 5.

[17] The BMA5 and REDCAL are automated system to system files provided by agents that contain rate and announcement information for distributions and redemptions.

[18] The BMA, DCN and REDCAL are automated system to system files provided by agents that contain rate and announcement information for distributions and redemptions.

[19] *See* DTCC's website at *https://www.dtcc.com/settlement-and-asset-services/agent-services/corporate-action-information-for-agents.*

[20] *See* Null/Void/Worthless Letter temple, *available at https://www.dtcc.com/-/media/Files/Downloads/Settlement-Asset-Services/agent-services/Null-Void-Worthless-Letter-Temp.docx.*

[21] *See* Securities Exchange Act Release No. 75094 (June 2, 2015), 80 FR 32425 (June 8, 2015) (SR–DTC–2015–007).

[22] *See* Guide to the DTC Fee Schedule, *available at https://www.dtcc.com/-/media/Files/Downloads/legal/fee-guides/DTC-Fee-Schedule.pdf* at 7.

[23] 15 U.S.C. 78q–1(b)(3)(F).

[24] 17 CFR 240.17Ad–22(e)(23).

[25] The Commission adopted amendments to Rule 17ad–22, including the addition of new subsection 17ad–22(e), on September 28, 2016. *See* Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14). DTC is a ''covered clearing agency'' as defined by new Rule 17ad–22(a)(5) and must comply with subsection (e) of Rule 17Ad–22. *Id.*

[26] 15 U.S.C. 78s(b)(3)(A).

[27] 17 CFR 240.19b–4(f).

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of DTC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–DTC–2023–010 and should be submitted on or before November 2, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–21945 Filed 10–11–23; 8:45 am]

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[28] 17 CFR 200.30–3(a)(12).

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Part III

Department of Transportation

Federal Railroad Administration

49 CFR Parts 217, 218, 229, et al.
Locomotive Image and Audio Recording Devices for Passenger Trains; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 217, 218, 229, and 299

[Docket No. FRA–2016–0036, Notice No. 2]

RIN 2130–AC51

Locomotive Image and Audio Recording Devices for Passenger Trains

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FRA is requiring the installation of inward- and outward-facing locomotive image recording devices on all lead locomotives in passenger trains, as required by the Fixing America's Surface Transportation Act (FAST Act). In general, the final rule requires that these devices record while a lead locomotive is in motion and retain the data in a crashworthy memory module. The rule also treats locomotive-mounted recording devices on passenger locomotives as ''safety devices'' under existing Federal railroad safety regulations to prohibit tampering with or disabling them. Further, this rule governs the use of passenger locomotive recordings to conduct operational tests to determine passenger railroad operating employees' compliance with applicable railroad rules and Federal regulations. Finally, this rule requires Texas Central Railroad (TCRR) to install and maintain trainset image recording systems appropriate to TCRR's operation.

DATES: This final rule is effective November 13, 2023.

ADDRESSES: *Docket:* For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* at any time.

FOR FURTHER INFORMATION CONTACT: Brian Roberts, Attorney Adviser, Office of the Chief Counsel, at email: *Brian.Roberts@dot.gov* or telephone: (202) 306–4333; or John Mayser, Specialist, Office of Railroad Safety, at email: *John.Mayser@dot.gov* or telephone: (202) 493–8008.

SUPPLEMENTARY INFORMATION:

Table of Contents

Table of Abbreviations

The following abbreviations are used in this document's preamble:

AAR—Association of American Railroads
Amtrak—National Railroad Passenger Corporation
APTA—American Public Transportation Association
BLET—Brotherhood of Locomotive Engineers and Trainmen
C3RS—Confidential Close Call Reporting System
CFR—Code of Federal Regulations
DOT—Department of Transportation
FAST Act—Fixing America's Surface Transportation Act
FRA—Federal Railroad Administration
Metra—Commuter Rail Division of the Illinois Regional Transportation Authority
Metrolink—Southern California Regional Rail Authority
NCTD—North Country Transit District
NPRM—Notice of Proposed Rulemaking
NTSB—National Transportation Safety Board
OEM—Original equipment manufacturer
PTC—Positive Train Control
RIA—Regulatory Impact Analysis
SMART—International Association of Sheet Metal, Air, Rail and Transportation Workers
TCRR—Texas Central Railroad
TTD—Transportation Trades Department, American Federation of Labor and Congress of Industrial Organizations (AFL–CIO)

I. Executive Summary

FRA is publishing this final rule as mandated by section 11411 of the FAST Act, codified at 49 U.S.C. 20168 (the Statute), and under the agency's general railroad safety rulemaking authority at 49 U.S.C. 20103.[1] The Statute requires FRA (as the Secretary of Transportation's delegate)[2] to promulgate regulations requiring each railroad carrier that provides regularly scheduled intercity rail passenger or commuter rail passenger transportation to the public to install inward- and outward-facing image recording devices in all controlling locomotives of passenger trains.[3] This final rule implements the Statute's requirements regarding such recording devices on ''controlling'' locomotives, which will normally be ''lead'' locomotives consistent with FRA's existing regulations on locomotive event recorders. Before the Statute was enacted, the Railroad Safety Advisory Committee (RSAC) accepted a task from FRA in 2014 to address National Transportation Safety Board (NTSB) Safety Recommendations R–10–01 & –02[4] concerning locomotive-mounted recording devices (RSAC Task No. 14–01). The RSAC established the Recording Devices Working Group (Working Group) to recommend specific actions regarding the installation and use of locomotive-mounted recording devices, such as inward- and outward-facing video and audio recorders.[5] The RSAC did not vote, or reach consensus, on any recommendations to FRA regarding the adoption of regulatory text addressing locomotive-mounted video or audio recording devices.

In light of the Statute's mandate, relevant NTSB recommendations, the RSAC Working Group's discussions, accident history, and railroad safety violations that FRA had investigated,[6] FRA issued a notice of proposed rulemaking (NPRM) on July 24, 2019, proposing inward- and outward-facing image recording devices be required on all lead passenger train locomotives.[7] FRA received comments from fifteen different individuals or organizations in response to the NPRM.

Having carefully considered the public comments in response to the NPRM, FRA issues this final rule amending the regulatory requirements of Railroad Operating Rules (49 CFR part 217), Railroad Operating Practices (49 CFR part 218), Railroad Locomotive Safety Standards (49 CFR part 229), and Texas Central High-Speed Rail Safety Standards (49 CFR part 299). This final rule requires intercity passenger and commuter railroads[8] to install compliant image recording systems on the lead locomotives of all their passenger trains by October 12, 2027, except for TCRR, which is required to have compliant image recording systems installed on its trainsets prior to commencing revenue service, as specified under part 299. Further, beginning October 12, 2024, any locomotive image recording system installed on new, remanufactured,[9] or existing passenger train lead locomotives must meet the specified requirements of this final rule, including the requirement that the last twelve hours of data recorded be stored in a memory module that meets the existing crashworthiness requirements in part 229. In addition, this final rule requires that all locomotive-mounted recording devices in passenger locomotives be treated as ''safety devices'' under part 218, subpart D, thereby making it a violation of applicable Federal regulations to tamper with or disable any locomotive-mounted recording system or device.

FRA notes that the image recording device requirements for passenger train locomotives in this final rule supplement FRA's existing locomotive event recorder regulation in part 229. Locomotive event recorders are required on the lead locomotives of trains traveling over 30 mph and already record numerous operational parameters that assist in accident/incident investigation and prevention (*see* 49 CFR 229.135).

FRA used a cost-benefit analysis to evaluate the impact of the final rule on passenger railroads required to install and maintain locomotive image recording devices. FRA estimated the low and high costs of this final rule over a 10-year period, using discount rates of 3 and 7 percent, with the results shown in the tables below.

[1] The former Federal Railroad Safety Act of 1970, as codified at 49 U.S.C. 20103, provides that ''[t]he Secretary of Transportation, as necessary, shall prescribe regulations and issue orders for every area of railroad safety supplementing laws and regulations in effect on October 16, 1970.''

[2] The Secretary's responsibility under 49 U.S.C. 20103, 20168, and the balance of the railroad safety laws, is delegated to the Federal Railroad Administrator. 49 CFR 1.89.

[3] A detailed discussion of the Statute's requirements is provided in the NPRM (84 FR 35712, 35714–35715).

[4] A detailed analysis of the NTSB Recommendations is provided in the NPRM (84 FR 35712, 35715–35723).

[5] *https://rsac.fra.dot.gov/radcms.rsac/task/GetDocument/10*. A detailed discussion of the RSAC proceedings is provided in the NPRM (84 FR 35712, 35723).

[6] A detailed discussion of accidents investigated by FRA is provided in the NPRM (84 FR 35715–35723).

[7] 84 FR 35712.

[8] As proposed in the NPRM, railroad carriers providing ''intercity rail passenger transportation'' and ''commuter rail passenger transportation'' are subject to this final rule and are the same as those covered by 49 U.S.C. 24102 (passenger railroads required to install positive train control (PTC) systems under 49 U.S.C. 20157(a)).

[9] *See* 49 CFR 229.5.

TABLE E.1—TOTAL 10-YEAR COSTS AND BENEFITS OF LOCOMOTIVE IMAGE RECORDING DEVICES, LOW RANGE

[Costs are in 2018 dollars, $ in millions]

	Discounted at 7%	Discounted at 3%	Annualized at 7%	Annualized at 3%
Costs	$42.2	$46.2	$6.0	$5.4
Cost Savings	2.0	2.4	0.3	0.3
Net Costs	40.2	43.9	5.7	5.1

Qualitative Benefit: Potential reduction in safety risk resulting from deterrence of unsafe behaviors, increase to safety culture, and information for accident investigation and future accident prevention.

TABLE E.2—TOTAL 10-YEAR COSTS AND BENEFITS OF LOCOMOTIVE IMAGE RECORDING DEVICES, HIGH RANGE

[$ In millions]

	Discounted at 7%	Discounted at 3%	Annualized at 7%	Annualized at 3%
Costs	$87.3	$94.0	$12.4	$11.0
Cost Savings	2.0	2.4	0.3	0.3
Net Costs	85.3	91.6	12.1	10.7

Qualitative Benefit: Potential reduction in safety risk resulting from deterrence of unsafe behaviors, increase to safety culture, and information for accident investigation and future accident prevention.

The primary source of expected benefits is the potential reduction in safety risk. FRA conducted a literature review to determine the effectiveness rate of inward- and outward-facing recording devices, but was unable to determine an appropriate rate. The benefits for the final rule are qualitatively discussed. The reduction in safety risk is expected to come primarily from the change in crew behavior. Railroads can deter unsafe behavior if crewmembers realize their actions may be observed on a frequent, but random, basis by railroad supervisors. Locomotive image recorders cannot directly prevent an accident from occurring, but rather can provide investigators with information after an accident occurs that can help to prevent future accidents of that type from occurring.

II. Discussion of Specific Comments and Conclusions

In the NPRM, FRA specifically requested information from the public as well as comments on its proposals. Commenters provided valuable information and comments on issues where FRA asked for comments as well as on various other issues. In total, FRA received comments from fifteen different individuals or organizations in response to the NPRM.

An FRA employee also received an email from New York's Metropolitan Transportation Authority providing information about the economic cost of the requirements proposed in the NPRM. FRA is treating that email as a comment and it is addressed in the Regulatory Impact Analysis (RIA) of this final rule. The full email has also been placed into the rulemaking docket along with a memorandum from FRA explaining the context for the email. Further, in its submitted comments, the International Association of Sheet Metal, Air, Rail and Transportation Workers (SMART) disagreed with FRA's characterization in the NPRM that a public hearing would be provided only if a party was unable to adequately present his or her position by written statement; however, neither SMART, nor any other party, requested a public hearing on this rulemaking. Accordingly, a public hearing was not provided.

Most of the comments in response to the NPRM are discussed below or in the Regulatory Impact and Notices portion of this final rule. The order in which the comments are discussed in this final rule, whether by issue or by commenter, is not intended to reflect the significance of the comment raised or the standing of the commenter.

A. Inward- and Outward-Facing Recording Devices on Freight Locomotives

In the NPRM, FRA did not propose to require the installation and use of inward- and outward-facing recording devices in freight locomotives, nor did FRA propose that any of the NPRM's requirements apply to inward- and outward-facing locomotive recording devices that have been voluntarily installed by freight railroads. While FRA discussed the issue of inward- and outward-facing recording devices on freight locomotives at various points in the NPRM, FRA specifically addressed the issue under the heading ''Mandatory Installment of Inward- and Outward-Facing Recording Devices on Freight Locomotives.'' In that section, FRA discussed its decision not to propose such a requirement because: (1) the Statute did not require recording devices be installed on freight locomotives; (2) the cost of installing such devices could outweigh the safety benefits; and (3) many freight railroads, including all Class I railroads, had already installed or were in the process of installing such recording devices.

In addition, FRA specifically asked for public comment on whether some or all freight railroads should be required to equip their locomotives with recording devices and, if FRA did not require freight railroads to install these devices on their locomotives, the extent to which the requirements proposed in the NPRM should apply to inward- and outward-facing locomotive recording devices on freight railroads that have already installed such devices or install such devices in the future.

As proposed in the NPRM, FRA is declining to adopt any requirements that freight locomotives install or use inward- or outward-facing recording devices in freight locomotives, nor will any requirements of this rule apply to inward- or outward-facing locomotive recording devices that have been voluntarily installed by freight railroads. The Statute requires inward- and outward-facing image recording devices in controlling passenger locomotives as well as gives the Secretary discretion to require in-cab audio recording devices. 49 U.S.C. 20168(a), (e)(1)(A). There is no statutory requirement to create standards for, or apply any of the requirements of this final rule to, freight locomotive image or audio recordings.

Furthermore, FRA is not creating a requirement that audio devices be installed on freight locomotives.

FRA did not receive comments showing that benefits would outweigh costs for freight railroads. Accordingly, FRA declines to require freight railroads to install recording devices at this time. However, freight locomotives that are used in commuter or intercity passenger service, other than for rescue purposes, are passenger locomotives and are subject to all the final rule's requirements. In other words, freight locomotives that do not perform any passenger railroad related service, or are used only for rescue purposes, are not subject to the requirements of this final rule. Additional discussion on this topic is provided below.

1. Requiring Inward- and Outward-Facing Locomotive Recording Devices on Freight Locomotives

The Association of American Railroads (AAR) commented that requiring freight railroads to install locomotive recording devices was not necessary, as many freight railroads had already installed, or were in the process of installing, recording devices voluntarily. AAR stated that a survey of AAR's Class I member railroads showed that these railroads ''will have installed approximately 20,500 inward-facing cameras and 22,000 outward-facing cameras in the near future.''

The Brotherhood of Locomotive Engineers and Trainmen (BLET), the Transportation Trades Department, AFL–CIO (TTD), and SMART also expressed opposition to FRA requiring freight railroads to install inward- and outward-facing locomotive recording devices. SMART agreed with FRA's statement in the NPRM that the cost for freight railroads to implement similar procedures as those proposed in the NPRM for passenger trains may outweigh the potential safety benefits.

The NTSB and Wi-Tronix, LLC (Wi-Tronix), a company that provides connected solutions for locomotive fleets, commented that FRA should require inward- and outward-facing locomotive recording devices in freight locomotives. The NTSB contended that inward- and outward-facing audio and image recorders are needed in freight railroad operations, referencing NTSB Safety Recommendations R–10–01 and R–10–02, which were issued following four separate NTSB accident investigations involving freight rail operations. The NTSB asserted that the need for recording devices in freight railroad investigations is exactly the same as in passenger railroad investigations given that: (1) freight and passenger trains operate on the same tracks and both pose risks of accidents that have the potential to significantly affect the public; and (2) recorded information about safety issues identified in freight railroad accidents and incidents could inform, mitigate, or prevent similar safety issues in passenger railroad operations. Therefore, the NTSB believed it would be ''shortsighted'' for FRA to limit the rule to apply only to lead passenger locomotives.

Like the NTSB, Wi-Tronix also commented that the rail network is integrated and that commuter and intercity passenger trains often share the same track and dispatch system, among other things, with freight trains. Acknowledging the increase in video system use for safety and operating rule compliance, Wi-Tronix stated that there ''are roughly 20 times the number of freight locomotives compared with passenger locomotives,'' and the full safety benefits of the technology would not be realized without the requirement covering all locomotive types.

FRA recognizes the potential safety benefits of locomotive recording devices in freight locomotives as noted in the NTSB's and Wi-Tronix's comments. However, FRA disagrees that the full safety benefits of this technology can only be achieved with a specific regulatory requirement that freight railroads install inward- and outward-facing image and/or audio recorders.

As stated in the NPRM, many freight railroads, including all Class I railroads, have either already installed or are in the process of installing recording devices in their locomotives. As noted by AAR in its comment, ''approximately 20,500 inward-facing cameras and 22,000 outward-facing cameras'' will be installed on AAR Class I member railroads ''in the near future.'' In addition, AAR points out in its comments that recordings from these voluntarily installed systems are already subject to the accident data preservation requirements in 49 CFR 229.135(e).[10] Therefore, the data from these voluntarily installed devices in freight locomotives will be available for FRA's and the NTSB's accident investigation purposes, if necessary.

Furthermore, requiring freight railroads to comply with the final rule's requirements would be expensive with questionable benefit. FRA has investigated few, if any, freight railroad accidents where freight locomotive image data should have been present but was not because it was destroyed in the accident. Furthermore, while the vast majority of Class I railroads have or are installing inward- and outward-facing cameras, very few short line railroads (Class II or Class III railroad) have either inward- or outward-facing cameras installed on their locomotives. In fact, for these much smaller railroads, FRA estimates that only 1% have inward-facing locomotive cameras and 25% have outward-facing cameras installed on their locomotives. This is not necessarily surprising as Class II and Class III railroads are less likely to need locomotive cameras given the lower speeds, shorter distances, and the less regular nature of the services that these railroads operate. These definitionally smaller operations would be significantly affected economically if FRA imposed the requirements of this final rule to freight railroads and would have difficulty absorbing the cost without much safety benefit.

Therefore, for the reasons explained above, FRA is declining to require freight railroads to install recording devices at this time. FRA will continue to monitor the freight industry's voluntary installation of the devices and the effectiveness of those devices in freight rail operations. Based on this continued monitoring, FRA may take additional action in a separate proceeding to address the use of locomotive recording devices on freight railroads.

In addition to its opposition to FRA requiring inward- and outward-facing recording devices on freight locomotives, AAR also suggested that FRA add language to part 229 mirroring the preemptive effect language in §§ 217.2 (preemptive effect of railroad operating rules) and 218.4 (preemptive effect of railroad operating practices). AAR asserted that both these provisions clarify FRA's intent to create a national standard and this final rule should include this preemption language for national uniformity. AAR added that, to preclude the creation of a patchwork of conflicting state and local requirements applying to freight railroads, FRA should state that its decision to not propose a locomotive recording device requirement for freight railroads reflects the agency's position that it is unnecessary to issue such a regulation.

In issuing this final rule, FRA has sought to stay within the Statute's mandate, 49 U.S.C. 20168, and not undertake a broader revision of part 229. Accordingly, FRA declines to add

[10] If a locomotive is equipped with an event recorder or ''any other locomotive mounted recording device or devices designed to record information concerning the functioning of a locomotive'' and is involved in a 49 CFR part 225 reportable accident, § 229.135(e) requires the railroad to preserve the data recorded for one year.

specific preemption language to part 229.[11]

2. Application of Requirements to Freight Railroads That Voluntarily Install Inward- or Outward-Facing Locomotive Recording Devices

In addition to FRA inviting comments on whether the agency should require the installation of inward- and outward-facing recording devices on freight locomotives, FRA also sought comment on whether the proposed requirements should apply to recording devices that have already been installed on freight locomotives. Except for AAR, which supported FRA's proposal to exclude freight trains from this proposed rule, all the commenters generally favored applying the requirements of this final rule to freight locomotives that have voluntarily installed inward- or outward-facing recording devices.

Based on the same reasoning provided above, the NTSB commented that FRA should ensure the same level of safety for both passenger and freight railroads and that any recording device that either a passenger or freight railroad has voluntarily installed should be required to meet the minimum standards in this final rule. While BLET, SMART, and TTD all opposed requiring freight railroads to equip their locomotives with recording devices, they all agreed that freight railroads that voluntarily install such devices should nonetheless have to comply with the final rule's railroad employee protections and adhere to a uniform national standard created by FRA and applicable to both freight and passenger locomotive recording devices, regardless of whether they were installed before or after the rule's issuance. TTD specifically urged FRA to apply the final rule's requirements to protect against employee retaliation under part 217 operational testing, regardless of whether FRA requires the installation of the locomotive recording device(s).

After considering the comments, FRA is declining to impose any of the requirements in this final rule on freight railroads that have voluntarily installed recording devices on their locomotives. However, it is FRA's expectation that all railroads that voluntarily install recording devices on their locomotives, including freight railroads, will adhere to practices that are consistent with those in this final rule, such as those provided under new part 217 requirements that serve to protect employees from targeted testing as a form of retaliation when railroads conduct operational testing using recording devices or their recordings.

FRA has independent authority to disapprove a freight railroad's operating rules testing program, required under Part 217.[12] Therefore, if FRA finds that a freight railroad is not using its locomotive recording devices in good faith to fulfill the railroad's operational testing requirements, but is instead using locomotive cameras and/or audio recording devices to pursue retaliation against its employees, FRA could disapprove the railroad's operational testing program. FRA therefore expects freight railroads will adhere to the same, or similar, principles as being codified for passenger railroads, based on FRA's authority under the existing provision. Application of the new part 217 operational testing requirements in this final rule are discussed in Section II.L and the Section-by-Section Analysis below.

3. Application of Requirement to Freight Locomotives Performing Rescue Operations

Finally, the American Public Transportation Association (APTA) submitted a comment asking FRA whether freight locomotives that do not have inward-facing locomotive cameras compliant with this final rule would be allowed to ''rescue'' passenger trains that fail en route. In such situations, a freight locomotive ''rescues'' the failed passenger train by operating as the lead locomotive of the passenger train and hauling the train to its destination or repair point. Having considered APTA's comment, this final rule includes a new provision, § 229.139(l), that excludes freight locomotives from compliance with the requirements of new § 229.136 when they are performing rescue operations for intercity or commuter passenger trains. However, this exception applies only for the limited purposes of rescuing an intercity or commuter passenger train; a freight locomotive used in regular passenger service will not be covered by the exception. The exclusion is based on identical language in the definition of ''locomotive'' for purposes of FRA's Passenger Equipment Safety Standards in § 238.5 of this chapter.[13] As FRA originally stated in establishing the Passenger Equipment Safety Standards, FRA ''believes that a limited exception is warranted for a freight locomotive used to haul a passenger train due to the failure of the passenger train's own motive power; FRA does not wish for the passenger train to be stranded.'' [14]

B. Audio Recording Devices

1. Requiring Audio Recorders on Passenger or Freight Locomotives

While the Statute gives FRA discretion to require the installation of audio-recording devices on passenger train lead locomotives and to establish corresponding technical details for such devices, FRA did not propose specific rule text in the NPRM that would require audio recording devices. Rather, FRA requested comment on numerous specific issues related to audio recorders, to evaluate whether to require audio recorders in passenger or freight locomotives in this final rule. Specifically, FRA asked about: (1) the usefulness of audio recordings in certain accident investigations; (2) what benefits they provide in addition to the benefits of image recordings; and (3) whether any benefits outweigh the installation cost for these devices, the cost of crashworthy memory for these devices, the loss of personal privacy for occupants inside the locomotive cab, or the potential that recordings from these devices could be abused by railroad supervisors.

FRA also asked for comments on whether FRA should require audio recorders to stop recording after the locomotive has stopped, if FRA were to adopt a requirement for the installation of locomotive audio recorders in the final rule. In addition, FRA asked whether FRA should require exterior recording devices that would be capable of recording sounds such as the locomotive horn/bell, audible grade crossing warning devices, engine noises, and other sounds relevant during post-accident investigations, and what the utility of these recordings would be when weighed against the potential cost. In responding to these questions, FRA asked commenters to provide specific information on the costs of installing audio recorders.

In response to these requests for comments, most parties agreed with FRA's proposal not to require the installation of locomotive audio recording devices in either passenger or freight locomotives. Commenters who advocated for the installation of such devices pointed to their usefulness in post-accident investigations. Although FRA did not receive responses to all its requests for comments related to audio recording devices, commenters did

[11] Under longstanding U.S. Supreme Court precedent, parts and appurtenances of locomotives have been held subject to field preemption. *See Napier* v. *Atlantic Coastline RR. Co.,* 272 U.S. 605 (1926).

[12] *See* 49 CFR 217.9(h).

[13] Under § 238.5, neither the term ''locomotive'' nor ''passenger equipment'' ''include[s] a freight locomotive when used to haul a passenger train due to failure of a passenger locomotive.''

[14] 64 FR 25540, 25578 (May 12, 1999).

respond to the question of when to stop audio recordings in the same manner as they responded to the question of when passenger railroads should stop their locomotive image recordings. FRA is addressing those comments together in the next section.

As for the question whether FRA should require locomotive audio recordings at all, BLET, TTD, and SMART asserted that audio recorders should not be required. Moreover, BLET and SMART specifically asked FRA to prohibit audio recordings within the locomotive cab. BLET stated that, although audio and image recordings could be used to aid in accident investigations, the recording devices would also add another level of distraction and discomfort for train crews (*e.g.,* audio headsets) and, for the safety purposes of the system to be achieved, the devices would at a minimum have to be operative on each lead locomotive while the train is in motion, require crashworthy data storage modules, and require the availability of an extra headset in the case of an en route failure.

In response to FRA's request for comments on whether to require exterior recording devices, BLET stated that all key locomotive operations, including throttle, braking, locomotive horn/bell, are already captured on the locomotive's event recorder. Further, BLET noted that because grade crossing warning devices are intended to warn motorists, not the train crew, it would be more helpful instead to mount audio recorders at highway-grade crossing signal control boxes. Accordingly, BLET saw no value in requiring exterior locomotive recording devices; however, if FRA were to consider requiring such devices anyway, BLET commented that FRA should consider exterior audio devices that could be engaged or disengaged by selecting from the locomotive's software preferences for the camera. BLET stated the cost to do so would be nominal as it is already an included feature on some locomotives. BLET further indicated that this feature was discussed at RSAC Working Group meetings.

TTD asserted that audio recording devices would have a negative impact on train crews' morale and the labor-management relationship, and could possibly record and lead to the release of private conversations unrelated to safety-sensitive tasks. TTD noted that a substantial amount of information is already recorded or transmitted, or both, via on-board equipment and radio communications, and eventually will be through image recorders. Thus, TTD did not see how audio recording devices would improve safety and asserted that FRA should not mandate audio recorders in the final rule.

SMART commented that during RSAC Working Group meetings, both railroads and labor organizations expressed unanimous opposition to a locomotive audio recorder requirement. SMART believed employees deserve some privacy protections and concurred with FRA's reasoning in the NPRM that audio recorders should not be required.

In addition to labor organizations, APTA commented that it also opposed requiring locomotive audio recorders. APTA stated that the railroad industry supports most of FRA's NPRM analysis regarding audio recordings, and that the industry believes that locomotive audio recordings are redundant and secondary to both locomotive image recorders and pre-existing communication systems, such as radio. APTA also stated that audio recordings, like video recordings, are not monitored by the railroads in real time, and therefore, have minimal value in preventing accidents.

Notwithstanding APTA's assertion that the industry opposed a locomotive audio recorder requirement, the National Railroad Passenger Corporation (Amtrak) commented that FRA should create an exterior recording device requirement to aid in post-accident investigations because these devices are extremely beneficial in private litigation. Amtrak provided figures on the cost of installing image recording devices for their fleet to be $10,080 as well as the cost per locomotive of new audio equipment to be $23,349, as FRA requested. Additionally, in the RIA, FRA estimates a range that starts at $6,000 for each audio recording device up to a cost of $23,349. This lower estimate was based on discussions with FRA's subject matter experts and online research.

Amtrak also commented that the benefits provided by locomotive audio recordings would outweigh concerns about the potential loss of personal privacy for locomotive cab occupants, because while operating a locomotive, the use of audio-visual recordings would be a condition of employment applicable under the railroad's enforcement of rules. In addition, Amtrak asserted that the benefits of locomotive audio devices would outweigh the potential for abuse by railroad management because Amtrak has an established company program and process in place providing that the use of audio and visual recordings is for compliance means only.

The NTSB also urged FRA to require both internal and external locomotive audio recorders as part of this final rule. As noted in the NPRM, the NTSB has conveyed to FRA that to satisfy NTSB Recommendations R–10–01 & –02, FRA would need to include both audio and image recording provisions in this rulemaking.[15] Further, in its submitted comments, the NTSB stated that for more than 10 years, voluntarily-installed image and audio recorders have assisted the NTSB with its investigations. According to the NTSB, the technology is fully developed and mature, and the devices are readily available and are already being manufactured, installed, and used. The NTSB also commented on what it believed to be sufficient technical specifications for locomotive audio recording devices and cited the recording capabilities of locomotive audio recording devices used by Amtrak as a model. The NTSB also stated that because memory storage requirements for audio recordings are significantly less than those for image recordings, additional memory for audio recordings should not be needed. Finally, while recognizing the high levels of background noise inside locomotive cabs from its experience investigating railroad accidents, the NTSB stated it did not believe that headsets or other specialized audio recording equipment, beyond what is currently being used by railroads that have voluntarily installed such devices, will be necessary.

The NTSB cited how important both inward-facing locomotive image and audio recordings were in its investigation of the December 18. 2017, derailment of Amtrak passenger train 501 in DuPont, Washington. According to the NTSB, these internal locomotive audio and visual recordings helped the agency determine that neither personal electronic device use nor brief conversations between the engineer and conductor were causes of the derailment.

While internal locomotive audio recordings were useful in the NTSB's investigation of the Amtrak passenger train 501 accident, NTSB's comment states that it was audio recording devices inside the locomotive along with inward-facing locomotive video recording devices that helped the NTSB make determinations as to what could be excluded as the cause of the 2017 Amtrak accident in Dupont, Washington. Furthermore, the NTSB investigation into this accident is just one specific investigation into one specific railroad accident. FRA did not

[15] National Transportation Safety Board, *Safety Recommendations R–10–01 and R–10–02* (Feb. 23, 2010); available online at: *https://www.ntsb.gov/safety/safety-recs/recletters/R-10-001-002.pdf.*

find any specific evidence that would lead the agency to believe that internal audio recorders would be useful in all accident investigations.

Wi-Tronix also commented on FRA's decision to not include an audio recorder proposal in the NPRM and agreed with the NTSB that, based upon its incident investigation experience over the years, the availability of audio locomotive recordings has played a critical role in determining the chain of events during an accident investigation and the implementation of the technology is essential in getting the ''step-change improvement'' in human factor safety that FRA desires. Wi-Tronix also commented on the potential for privacy concerns with audio recordings that were raised by TTD and SMART. Wi-Tronix believes that with current technology, recorded audio information could be sequestered and be made available only to regulators and other officials on a limited basis after an emergency incident. Further, Wi-Tronix stated that artificial intelligence and machine learning could use the audio information for analytics anonymously without personal information included. Wi-Tronix said that the implementation of audio recordings, in conjunction with video recordings, is not a major cost driver for system implementation.

Finally, an anonymous commenter stated that installing inward and outward-facing recording devices could be beneficial when investigating railroad accidents. The commenter expressed hope that these recording devices will decrease the number of railroad related accidents.

After considering all the comments received on whether audio recording devices should be required on lead passenger locomotives, FRA has determined that a requirement for such devices on lead passenger locomotives is not justified. Accordingly, in this final rule, FRA is not adopting a requirement for the installation of audio recording devices on passenger or freight locomotives. FRA does not believe that the potential added utility of audio recordings, in addition to image recordings as well as the data provided by a locomotive's event recorder, outweighs the cost that would result. Indeed, while audio recording devices may provide some additional useful information in certain accident investigation scenarios, the overall usefulness of locomotive audio recordings is diminished by the statutorily mandated requirement of inward- and outward-facing locomotive cameras as well as existing requirements for event recorders on all lead passenger locomotives. Further, as previously stated, there is no requirement in the FAST Act that passenger or freight locomotives be equipped with either internal or external audio recording devices. Therefore, FRA is allowing railroads to decide whether to equip their locomotives with external and/or internal audio devices.

Passenger locomotive cabs, unlike freight locomotive cabs or even commercial airliner cockpits, are typically occupied by only one crewmember, while additional crewmembers are located in the passenger train consist assisting passengers. As there is usually only one crewmember in the locomotive cab while a passenger train is in motion, it is unclear what information internal locomotive audio recorders would provide that inward-facing locomotive cameras could not. For example, as cited in the NPRM, in both the 2008 Chatsworth Southern California Regional Rail Authority (Metrolink) accident,[16] and the 2015 Philadelphia Amtrak accident,[17] the locomotive engineers operating the trains were the sole occupants of the locomotive cab while the other crewmembers were in the passenger consist. Also, as TTD commented, a substantial amount of information is already recorded via onboard equipment and radio communications. Therefore, other than radio communications with other train crewmembers or the train dispatcher, which are often already recorded, there may not be any other voice communications inside the cab to record.

External locomotive audio recorders are unlikely to provide much additional information in post-accident investigations. As stated by BLET, all key locomotive operations, including throttle, braking, and locomotive horn/bell, are already required to be captured on the locomotive's event recorder. If an accident occurs, this data can be retrieved from the event recorder. Combining the event recorder data with information gained from external locomotive cameras diminishes the need for external audio recording devices. Accordingly, given the information already available to FRA and other investigators from event recorders and locomotive cameras, FRA cannot justify mandating the installation of an external audio recording device at this time.

Moreover, locomotive audio recorders will not greatly increase a passenger railroad's ability to deter railroad safety violations, such as the use of prohibited personal electronic devices, beyond the deterrence already provided by inward-facing image recorders. Because the locomotive engineer is typically alone in the locomotive cab, it is unlikely that audio recordings will pick up audio information useful to prove that a rail safety violation occurred that could not be determined from video footage. In fact, audio recordings might not pick up anything at all.

Further, FRA shares SMART's and TTD's concern that because train crews might be more likely to congregate in the locomotive cab when not performing their safety-related duties (*e.g.,* sitting in a siding), locomotive audio recorders might be more likely to pick up private conversations between crewmembers than the audio proof of a railroad safety violation. As stated in the NPRM, FRA has concerns that these time periods would likely include personal conversations between employees and might have much more potential for abuse than do inward-facing image recordings. While a commenter suggested that audio recordings might be sequestered in a way that they would only be accessible by regulators and other government officials, like FRA and the NTSB, audio recordings would share the same memory module as image recordings, and FRA anticipates that passenger railroads would want to review them as part of their part 217 operational testing plans.

Finally, based on information provided by the railroad industry, FRA subject matter experts, and online research, FRA estimates that the inclusion of audio recording devices would cost passenger railroads between $25.2 and $98.1 million dollars within the first four years of implementation to install on over 4,200 passenger locomotives. Although FRA recognizes that Wi-Tronix commented that the cost of locomotive audio recorders in conjunction with image recording device would be nominal, there may be only a small number of accidents where audio recordings might be beneficial and Wi-Tronix did not provide any data to support its cost assertion.

FRA understands from RSAC Working Group discussions and its own research that the audio recording devices and microphones contained within a locomotive's image recorders have some costs, but railroads indicate a crash-hardened memory module for audio recordings might increase costs of compliance. FRA is also concerned about the background noise levels inside the cabs of certain locomotives and has previously conveyed that concern to the NTSB. Because of the noise, additional equipment may be

[16] *See* 84 FR 35712, 35716–35717.

[17] *Id.* at 35717.

needed to record crew voice communications so the recordings can accurately be deciphered by railroad managers and accident investigators. This would also be expected to add to the cost of installing such equipment.

However, FRA also disagrees with BLET and SMART, and nothing in this final rule precludes passenger or freight railroads from voluntarily installing and using either internal or external locomotive audio recording devices as part of their operation, if they so choose. The FAST Act provided FRA with discretion whether to include a regulatory requirement for inside-locomotive audio recording devices,[18] and while this rule will not require the installation of inside- or outside-audio recording devices, it will also not preclude the devices. However, if a passenger railroad chooses to install locomotive audio recording devices in their locomotives, then certain requirements from this rule do apply to those devices.

2. Referencing Audio in the Definition of ''Recording Device'' in Part 229

FRA also received a comment from APTA suggesting that FRA remove any reference to audible sounds from the definition of ''recording device'' as proposed in the NPRM. For the reasons discussed in Section II.T below, FRA disagrees and intends that audio recordings be subject to the preservation requirements and other relevant requirements of § 229.136.

C. Recording Device Run-Time/Shutoff When Trains Stop Moving

In the NPRM, FRA requested comments on a number of questions regarding whether FRA should set a specific run-time or shutoff requirement for locomotive recording devices. Specifically, FRA requested comment on its proposal to provide passenger railroads the discretion to decide whether locomotive recording devices would continue to record when a locomotive is not in motion, if the railroad retains a recording of the last 12 hours of operation of the locomotive on a memory module compliant with the requirements proposed in § 229.136. FRA also asked for comments on: what safety benefits would result from recordings made when a locomotive is occupied, but not moving; whether a specific run-time or shutoff requirement would present any technical hurdles for the railroads, and if so, the cost of those hurdles (in dollars); the privacy implications of recordings being made during down times when the crew is not performing safety-related duties; the potential risk of data being overwritten if an accident occurs in a remote location and the device continues to record; and finally, whether passenger railroads should be exempt from any requirement to stop locomotive recording devices from recording when the locomotive is stopped.

FRA received numerous responses to these requests for comments. Most of the comments focused on what the run-time/shutoff standard should be, if any. Both Amtrak and APTA expressed views consistent with FRA's proposed standard that passenger railroads have the discretion to determine their own run-time/shutoff standard for locomotive recording devices. APTA noted that locomotive cabs are workplaces, whether occupied or not, and therefore they should be able to run their locomotive cameras continually. APTA asserted that allowing cameras to run continually would serve as a deterrent against locomotive safety device tampering, assist with potential criminal investigations (such as vandalism), and provide a valuable tool for railroad security. However, APTA stated while its members support the position that railroads should be able to record using their locomotive image recorders when the locomotive is stopped, the decision whether to record while the locomotive is stopped should be left to the individual railroad.

Amtrak's comments were similar to APTA's. Amtrak opposed FRA adopting a stricter standard than that proposed in the NPRM. Amtrak also contended that railroads should be allowed to record after the train has stopped moving (*e.g.,* for security purposes when a locomotive cab is unoccupied, to record mechanical tests such as brake tests and calendar day inspections).

The NTSB commented that FRA should require inward-facing cameras to record whenever a locomotive is powered on, regardless if the locomotive is moving or stationary, and that railroads should not have the discretion to decide to stop recording when a locomotive is not moving. The NTSB stated that safety-sensitive duties frequently occur when locomotives are stationary, and there is no way to limit recordings to only capture safety-related activities. According to the NTSB, by recording anytime the locomotive is powered on, key pre-accident events would be recorded, such as pre-job briefings, and critical post-accident events, such as calling emergency services, would be recorded and available in post-accident analysis. The NTSB also asserted that requiring continuous recording while a locomotive is powered on would help identify those occasions when an employee tampers with or disables a safety device.

In contrast, BLET, SMART, and TTD disagreed with the aforementioned comments as well as FRA's proposal in the NPRM to provide passenger railroads maximum flexibility in determining the run-time/shutoff time for their recording devices. BLET commented that, regardless of whether the recorders are image or audio recorders, they should be shut off and no longer recording when the train's motion has stopped and the brakes are applied. According to BLET, it would be unacceptable if the cameras can still run when a locomotive is stopped and everything over the course of a crew's duty tour would be under analysis by the railroad.

Further, BLET stated that the time when a train has stopped moving is the only time that a crew has available to eat, use the bathroom facilities, or just relax, noting some railroads permit and even encourage napping to mitigate employee fatigue. BLET claimed there are numerous studies that prove if an individual is recorded on camera continually it will increase the individual's stress level, which thereby increases the individual's fatigue. BLET also pointed out that on many occasions, a train crew may have expired under the hours of service laws and simply be waiting to be relieved. BLET asserted that no safety benefits would result from filming and recording these types of non-operational activities.

BLET also expressed concern for train crewmembers' privacy if inward-facing cameras record when no safety-related duties are being performed. BLET commented that cameras could record employees changing their clothing or needing to express breast milk, which BLET believed cannot be safely and perhaps lawfully done in the sanitary compartment.

Finally, BLET asserted that FRA should not only consider a regulatory restriction on the run-time/shutoff for locomotive recording devices but should also address use of the cameras for monitoring employees. Specifically, BLET commented that some railroads have claimed the technological capacity to view the inside of a locomotive cab regardless of whether the camera's output is being recorded. Therefore, according to BLET, not only should railroads be prohibited from recording when a locomotive is stopped, but railroads should also be prohibited from surveilling their employees when a locomotive is stopped and the cameras

[18] *See* 49 U.S.C. 20168(e)(1)(A).

should be deactivated when a locomotive is stopped.

SMART and TTD suggested a slightly different standard than that proposed by BLET in that FRA should require railroads to shut off their inward-facing cameras five minutes after a train has stopped. TTD asserted that a five-minute window of additional recording after the train has stopped moving would allow FRA the necessary time to gather post-accident or -incident investigation information, without infringing on the crew's privacy. TTD stated that, in contrast, the standard proposed in the NPRM would allow the railroads to record at all times, even when the train is stopped and the crew is not performing any safety-sensitive duties. TTD asserted that there is no value to recording when trains are stopped, such as at sidings, which occurs with some frequency. Further, TTD agreed with BLET that operating a train is a fatiguing job and that constant filming of train crews will increase tension, and according to SMART, likely also result in ''unsafe practices.''

SMART echoed TTD's position that inward-facing cameras should not record when trains are stopped and crews are not performing safety-sensitive activities. Like TTD, SMART pointed out that crews often sit in a siding or at a signal for hours with no safety-related duties being performed. SMART also stated that requiring inward-facing locomotive cameras to stop recording five minutes after a train stops would protect against any personal harassment from the unnecessary recording of personal, but not safety-sensitive information.

However, while both TTD and SMART believed a strict five-minute shutoff standard after a train has stopped moving is necessary for inward-facing image recorders, both organizations specifically stated they did not object to a less prescriptive run-off/shutdown requirement for outward-facing cameras. In fact, they stated that the outward-facing cameras would provide the security benefits cited by APTA and Amtrak, and protect the railroad by helping deter vandalism, theft, and other criminal activities.

After consideration of all comments received on this issue, in this final rule, FRA is adopting the standard it proposed in the NPRM. FRA will not prescribe a mandated run-time/shutoff requirement for passenger locomotive recording devices. As will be discussed in greater detail below in Section II.C, as long as the locomotive's required inward- and outward-facing cameras are recording anytime the locomotive is in motion and the passenger railroad is complying with all other requirements of the final rule described below (*e.g.,* no video recording in the locomotive's sanitation compartment), the railroad has the discretion to continue recording images, and audio if installed. FRA concluded that, as APTA and Amtrak pointed out in their comments, allowing railroads to record both inside and outside of the locomotive cab when the locomotive is not in motion can serve legitimate safety functions, such as preventing tampering, assisting with criminal investigations (such as vandalism and trespassing), and be an overall useful tool for railroad security. In addition, FRA agrees with NTSB's point that recording when a locomotive is powered on may have potential informational value in post-accident investigations.

As discussed in the NPRM, the railroad industry is highly regulated, and there are already a large number of Federal statutes and regulations governing railroad employees' performance of safety-related duties when they occupy the cab of a lead locomotive.[19] In fact, the Supreme Court has recognized that ''the expectations of privacy of covered employees [here, train crewmembers] are diminished by reason of their participation in an industry that is regulated pervasively to ensure safety. . . .'' [20] A locomotive is a shared work space between various railroad employees. During one railroad employee's tour of duty, railroad supervisors, FRA inspectors, and other authorized individuals may access the cab of the locomotive and observe the employee's actions and communications in the cab, at any time, without providing any notice. In fact, the general public is often able to view train crewmembers occupying the locomotive cab and certain of their actions through the passenger locomotive's windows when the locomotive is located near a railroad right-of-way or a highway-rail grade crossing and also in certain cab control car configurations or at certain station platforms. Therefore, as passenger train crews can be monitored or frequently observed in locomotive cabs even without recording devices, they have no expectation of privacy in the locomotive cab, whether or not the locomotive is moving.

FRA also requested and received comments on the potential risk of overwriting valuable recorded data if an accident occurs in a remote location and a locomotive's recording device(s) continue to record after the accident has occurred and the recordings before and during the accident are recorded over. Both the NTSB and APTA submitted comments on this issue.

The NTSB indicated it has found that, in most major accidents, the locomotive loses power, which stops all recording devices and negates the risk of overwriting accident data. However, the NTSB commented that railroads should put procedures in place to preserve recordings in the event of a less severe accident in a remote location where the locomotive does not lose power and the footage could be overwritten.

APTA commented that concerns about passenger trains might be misplaced and pointed out that instead of passenger trains, freight trains are more likely to pass through or stop in remote areas or areas that are potentially harder to access, and have longer one-direction trip-duty times than commuter and, in some cases, intercity passenger trains. APTA stated that commuter trains trip lengths are shorter, and it is not uncommon for a train to travel in one direction leading with a conventional locomotive and then do a reverse trip in the other direction leading with the train's cab car. APTA also maintained that crew on-duty times for commuter and intercity passenger routes are generally shorter and scheduled to minimize any jobs approaching 12 hours on duty so that crews have additional rest before their next trip, and that crews may even change train consists. APTA believed these elements contribute towards reducing the potential for critical video being overwritten in an accident.

In addition, the NTSB commented that FRA should address the issue of buffering in this final rule to ensure that all critical events occurring before an accident occurs are recorded. The NTSB stated that frequently saving data to permanent storage from temporary memory—that is, buffering—will help prevent the loss of audio and images due to accidents and power disruptions, as it has experienced varied success with recording devices capturing the time period before an accident. The NTSB noted that, in the February 8, 2018, CSX Transportation accident in Cayce, South Carolina, the outward-facing image and audio recorder did not record critical events before the accident; instead, the audio stopped

[19] For example, railroad employees who operate trains within the United States are subject to drug and alcohol testing (both random and for cause) (49 CFR part 219), operational testing (*e.g.,* 49 CFR parts 217, 218, 220, 240, 242), hours of service laws (*see* 49 U.S.C. ch. 211, 49 CFR part 228), and regulations governing the use of personal electronic devices (49 CFR part 220), among many other requirements.

[20] *Skinner* v. *Railway Labor Executives Association,* 489 U.S. 602, 627 (Mar. 21, 1989).

recording a few minutes before the accident, and the image recording stopped about a minute before the accident, without recording the misaligned switch that derailed the train. Conversely, the NTSB cited the December 18, 2017, Amtrak accident near DuPont, Washington, where the inward- and outward-facing image and audio recordings did capture critical events up to the time of derailment.

After carefully considering both NTSB's and APTA's comments, FRA has determined it would be premature to create a regulatory requirement for passenger railroads addressing the potential for data being overwritten if an accident occurs in a remote location where there is no loss of power to the recording device, but the memory module is not immediately available. Although FRA agrees that passenger railroads should consider the possibility that commuter or intercity passenger trains could have an accident in a location where the locomotive does not lose power, the footage in the memory module may not be readily retrieved, and the footage could be overwritten, FRA has found no evidence of such a passenger train accident occurring. FRA also agrees with APTA's comment that, overall, passenger trains are far less likely to pass through or stop in remote areas when compared to freight trains. Therefore, lacking evidence of such a passenger train accident or incident occurring, and considering the limited likelihood of such a situation occurring in the future, FRA declines to adopt a regulatory provision specific to the risk of data being overwritten in such a scenario.

D. Exclusion of Existing Installed or Ordered Equipment

FRA received numerous comments stating that locomotive image recording devices previously installed or ordered before the publication date of the final rule should be excluded from complying with the final rule's requirements. For reasons discussed below, FRA disagrees with the comments and will not allow previously installed or ordered locomotive image recording devices or voluntarily installed audio recording devices to be excluded from this final rule's coverage. Instead, as proposed in the NPRM, this final rule provides passenger railroads with a four-year implementation period within which all of their lead locomotives must be brought into compliance with the rule's requirements.

APTA commented that FRA should allow exclusions for recording devices that have been installed or are in the process of being installed prior to the issuance of the final rule. APTA asserted that if FRA does not exclude these devices, there is a strong possibility that railroads that were early adopters of locomotive recording device technology will be financially penalized because the proposed requirements for image recorders would be too prescriptive and older locomotive recording devices could not comply. APTA also maintained that the cost to retrofit existing lead locomotives would be significant and could delay the availability of data for use by the passenger railroads as well as FRA and the NTSB for post-accident investigations. APTA stated that 76 percent of passenger locomotives already have image recording devices installed and that 93 percent of passenger railroads have installed image recording devices in all of their vehicles, or are in the process of doing so, and that ''a few large railroads'' equipped, or partially equipped, their fleets with recording devices within the last year. Given APTA's assumption that locomotive image recording systems have a life span of eight years, APTA believed that these railroads will lose most of the full life-cycle of the recording devices if FRA does not include an exclusion clause in this final rule.

AAR also agreed that FRA should include an exclusion provision to protect early adopters of this technology. According to AAR, during the 2014 RSAC Working Group meetings FRA proposed that recording systems installed on locomotives prior to the rule's effective date would be considered compliant for ten years from the final rule's publication date, with the exception that memory modules would be required to meet the crashworthiness requirements within three years of publication. AAR therefore suggested that recording systems installed prior to the final rule's publication date be considered compliant until ten years from that date, whether or not all of the functional requirements of the rule were met by the already-installed system.

The North Country Transit District (NCTD), which operates the COASTER commuter rail service in Northern San Diego County, California, suggested that the final rule should exclude locomotive recording devices that were installed prior to the effective date of the final rule and do not meet the crashworthy memory module requirements. NCTD stated it began installing inward- and outward-facing cameras with audio recorders in 2012 and had just completed a global replacement of cameras and recording devices on its entire locomotive and cab car fleet.

Finally, the Commuter Rail Division of the Illinois Regional Transportation Authority (Metra) also agreed with many of the same comments that passenger railroads have already begun to utilize recording equipment and, therefore, FRA should allow existing equipment to continue to be used to avoid punishing early adopters of the technology.

Although FRA appreciates the concerns raised by the commenters, FRA does not believe it in the public's interest or the interest of rail safety to provide an exception from the final rule's requirements for locomotive image recorders installed prior to the rule's publication date. Older cameras that do not meet the final rule's requirements would likely not provide the benefits (deterrence and accident investigation) that the rule seeks to provide. As discussed above, the Cayce accident is a prime example of how accident investigations could be adversely affected by use of older camera systems, because external locomotive image (and audio) data was lost in the accident. Under the requirements of this final rule, locomotive recordings must now be stored on a certified crashworthy memory module as required by the FAST Act, or an alternative remote storage system approved by FRA. If FRA were to exempt older image recording systems from the requirements of this final rule, it would increase the likelihood of more vital accident data being lost by use of non-compliant systems. Four years is an adequate time for passenger railroads with installed or currently ordered locomotive recording systems to get remaining value out of the recording systems without unduly putting value maximization of current locomotive recording systems above passenger rail safety. In addition, the NTSB has supported FRA's four-year implementation period as encouraging prompt implementation of the final rule's requirements. As stated above and in the NTSB's comment, the NTSB's report from the DuPont accident showed there is a clear investigative benefit to the information obtained from locomotive recording devices. According to the NTSB, ''any further delays beyond the proposed 4-year deadline would be unacceptable,'' given NTSB issued Safety Recommendation R–10–01 in 2010.

Passenger locomotive image recorders that do not meet the final rule's requirements might not be sufficient to identify railroad safety violations as well as provide adequate data for post-

accident/incident analysis. Moreover, even if FRA were to allow previously installed or ordered equipment to be excluded from this final rule's requirements, retrofitting the vast majority of, if not all, passenger locomotives would still be necessary as the Statute requires locomotive recorder data to be stored on crashworthy memory modules and very few, if any, passenger railroads currently store their image recordings on such modules. As discussed in the Section II.K below, a four-year implementation period is an adequate timeframe for passenger railroads to comply with the final rule. Passenger railroads will have four years to stagger any modifications or retrofits that are necessary to bring their locomotives' recording systems into compliance with the final rule.

E. Certified Crashworthy Event Recorder Memory Modules

1. Necessity of Crashworthy Memory Modules

FRA received numerous comments about the proposed requirement to store locomotive recorder data on a certified crashworthy event recorder memory module and potential alternatives to meet an appropriate crashworthiness level to protect stored locomotive image recording system data. APTA stated that a crashworthy memory module is unnecessary due to the installation of positive train control (PTC) on passenger railroads, which will eliminate most of the accidents that FRA cited in the NPRM, and that passenger railroads believe crashworthy memory retention could be achieved by simply positioning the recording devices in an area to minimize impact forces. However, APTA supported FRA's suggestion to provide waivers for the memory module's crashworthiness when the recording is transmitted to a remote location, stating the technology surrounding image recordings is advancing more quickly than the rulemaking process, and encouraged FRA to consider waivers for remote storage options in lieu of crashworthiness standards.

Wi-Tronix raised concerns that some of the proposed requirements for inward- and outward-facing cameras, such as the 12 hours of required storage together with the crashworthy memory module requirement, added unnecessary costs to railroads without a justification. Understanding the final rule's need for data preservation, Wi-Tronix asserted there are other technical approaches that could accomplish the same goals on a more cost-effective basis, stating that cloud solutions accomplish the same data retention and have the potential to be more economical while creating other value in the process.

Conversely, both the NTSB and SMART supported the proposed crashworthy memory module requirement. In addition, BLET commented that the paramount consideration and goal of the final rule should be a uniformity of standards throughout the whole railroad industry, whether locomotive recording devices be required by the Statute or voluntarily installed. Therefore, BLET believed it makes logical and economic sense to store all forms of recorder operational data (*e.g.,* event recorder data, safety-critical PTC data, and audio/visual recording data) in a single storage unit that meets the appropriate crashworthiness standards in appendix D to part 229. BLET also stated that FRA should be focused on the performance and survivability of crashworthiness options, and not necessarily the cost.

2. Potential Exemptions From the Crashworthy Memory Module Requirements

FRA also received comments about exempting from the crashworthy memory module requirement those systems that can store locomotive recorder data safely and remotely. As previously stated, APTA commented that FRA should avoid mandating onboard locomotive storage of data in favor of more flexible storage options for passenger railroads, including cloud or remote storage. Hitachi, Ltd. (Hitachi) agreed with APTA that remote storage should be allowed and recommended that the rule avoid mandating onboard crashworthy memory storage for locomotive recording data. Hitachi stated that image processing and data communications technology has matured in transmitting real-time images to be stored and analyzed remotely at centralized locations, and thus the final rule should avoid mandating onboard locomotive storage in favor of remote storage options that make more economic sense for the railroad.

The NTSB, however, disagreed with exempting locomotive recorders from crashworthiness requirements even when the recording system is designed to immediately transmit and store data at a remote location. The NTSB asserted the exemption would risk the loss of data when an accident occurs in an area where data cannot be reliably transmitted, such as in tunnels or remote regions. BLET also commented that wireless transmission and storage of locomotive audio or image data should be prohibited to prevent private, personal data from being hacked.

In response to these comments, FRA emphasizes that the requirements for crash and fire protection of in-cab recordings—*i.e.,* that each inward- and outward-facing image recording device have crash and fire protections for any in-cab image recordings that are stored only within a lead locomotive—are mandated by the Statute.[21] To implement this statutory requirement, in § 229.136(a)(5), FRA is requiring that any locomotive recording device data (including any audio recorder data) stored only within the lead locomotive be recorded on a memory module that meets the established requirements for a certified crashworthy event recorder memory module described in appendix D to part 229, which includes protection against fire. If a passenger railroad chooses to install a locomotive image recording device that does not store the recorded data only within the lead locomotive, but instead stores the data remotely using cloud storage or other remote storage alternative, the railroad must state so in its written description of the technical aspects of the locomotive image recording system submitted to FRA as part of the system's approval process required by § 229.136(g) of this final rule. FRA makes clear that use of a recording device system relying exclusively on cloud storage or other remote storage alternative would not require a waiver under 49 CFR part 211, as indicated in the NPRM, but instead may be authorized through the approval process under § 229.136(g).

For FRA to approve use of a locomotive recording device system that only uses remote storage for its recorded data, the passenger railroad must show conclusively how the remote storage system provides at least equivalent data protections to those provided by use of a certified crashworthy memory module under appendix D to part 229. Specifically, the railroad must describe how all of the data will be reliably and securely transferred to the cloud or other remote storage location and how that data will be reliably and securely stored and retrievable. The railroad must also show how the reliable and secure transfer of all locomotive image recording device data to a remote storage location will occur under a variety of situations, including situations involving accidents and/or incidents (especially in outlying or remote areas), system failures, or other similar contingencies. FRA will not approve the use of any locomotive

[21] 49 U.S.C. 20168(b)(2).

image recording system if the railroad does not clearly demonstrate both that the data cannot be lost due to its transfer from the locomotive image recording device to the remote storage location and cannot be lost or corrupted during storage and therefore irretrievable. This allows passenger railroads to enjoy the benefits of remote storage of data for these recording devices while preventing the potential for lost data, which could prove critical in a post-accident investigation, and ensuring that the transfer of data to the remote storage location is secure.

Freight railroads that have voluntarily installed or are planning to voluntarily install inward- or outward-facing recording devices on their locomotives are not required to store the data on a certified crashworthy event recorder memory module. However, FRA recommends that if a freight railroad chooses to use a memory module, it should mount and position the module in such a way as to provide the module with maximum protection.

3. Need for Stronger Memory Module Requirements

FRA understands the NTSB's preference for stricter recorder survivability standards. The NTSB has recommended FRA require event recorder data to be also recorded in another location remote from the lead locomotive(s) to minimize the likelihood of data destruction in an accident, as has occurred in certain accidents (NTSB Safety Recommendation R–13–22).[22] However, the standards in appendix D to part 229 require a crashworthy memory module, which is designated to withstand the conditions an event recorder may encounter, including accident conditions. A new, more stringent standard that would prevent the destruction of data in every passenger railroad accident scenario is likely not cost-beneficial, and is also likely unnecessary given the implementation of PTC systems.

As discussed in the NPRM, the railroad accidents that led NTSB to issue recommendations related to locomotive image and audio recording devices were caused by human factors—and nearly all were PTC-preventable. Thus, given the full implementation of PTC systems on intercity passenger and commuter railroad main lines, the likelihood of similar accidents occurring should be greatly reduced, if not eliminated. In turn, the need should diminish for more stringent crashworthy memory module requirements to preserve image and audio recordings for use to investigate accidents resulting from human factor causes on main track.

Memory modules are acceptable that meet the specified performance criteria in either Table 1 or Table 2 of section C, appendix D to part 229. As FRA discussed in the rulemaking promulgating the crashworthy memory module standards, each set of criteria in Tables 1 and 2 is a performance standard, and FRA has not included any specific test procedures to achieve the required level of performance. FRA did not believe it necessary to include specific testing criteria in the regulation, as the rail industry and equipment manufacturers are in the best position to determine the exact way they will test for the specified performance parameters.[23] FRA's position remains the same today and notes that not requiring specific test procedures also accommodates adoption of any future testing methods that are developed.

4. Storing Audio Recordings on the Crashworthy Memory Module

APTA commented that it was opposed to requiring recordings from voluntarily installed recording devices to be stored on a certified crashworthy memory module under part 229, appendix D. FRA does not agree. Although this final rule does not require passenger railroads to install locomotive audio recorders, because installing such devices is not required by the FAST Act, if passenger railroads voluntarily install audio recording devices, the data recorded must be maintained on a crashworthy memory module to ensure the data is available for use by FRA as well as other Federal agencies (and railroads themselves) to conduct effective post-accident/incident investigations and more accurately determine the causes of accidents/incidents. Accordingly, § 229.136(a)(5) requires any passenger locomotive recording device data, whether image or audio data, to be recorded on a certified crashworthy memory module as described in part 229, appendix D, or on an alternative, remote storage system, as approved by FRA. For further discussion on this final rule's accident/incident preservation requirements for locomotive recording devices, please see the discussion under § 229.136(f) in this rule's Section-by-Section Analysis.

F. Outward-Facing Locomotive Image Recording Systems and Devices

1. Placement of Outward-Facing Locomotive Image Recording Devices

APTA expressed concern about the proposal to require aligning an outward-facing locomotive image recording device to point parallel to the centerline of tangent track on which the lead locomotive is traveling. APTA believed the proposal would require mounting the camera within the gauge of the track and stated that, because many locomotive designs have center collision posts or center doors, the cameras may need to be mounted on the side of the locomotive and be aimed towards the center of the track. APTA therefore requested the rule be clarified accordingly to permit such camera placement.

However, the rule text needs no such clarification because this rule does not require outward-facing image recording devices to be mounted on the centerline of a passenger locomotive. FRA recognizes that cab car and multiple-unit (MU) passenger locomotives have features that may inhibit the placement of cameras on the centerline, and FRA never intended to require cameras to be mounted on the centerline. The rule requires cameras to be aimed ''parallel'' to the centerline of tangent track, wherever the cameras may be placed on the leading end of the locomotive, and FRA is adopting the proposed rule text without change.

2. Requirements for Outward-Facing Locomotive Image Recorders Are Too Prescriptive

APTA commented that requiring outward-facing locomotive image recorders to be able to distinguish the signal aspects displayed by wayside signals, as proposed in the NPRM, would be too prescriptive and overcomplicate the outward-facing camera system. APTA preferred a more performance-based standard, and added there are multiple environmental factors that affect the image quality of outward-facing camera footage that are not within the railroad's control. APTA also stated that the proposed standard to record at 15 frames per second (fps) and the proposed resolution requirement are vague and would make design compliance subject to many factors that would increase costs. APTA therefore offered alternative language allowing the railroads to determine the frame rate and resolution for their locomotives' outward-facing cameras. Similarly, Wi-Tronix asserted that basing the resolution requirement for outward-facing cameras upon whether a system

[22] National Transportation Safety Board, *Safety Recommendation R–13–22* (Aug. 14, 2013); available online at: *https://www.ntsb.gov/safety/safety-recs/recletters/R-13-018-023.pdf.*

[23] 69 FR 39785 (June 30, 2004).

could determine switch points from a 50-foot distance is too subjective, and instead suggested that an objective, technical resolution specification should be used and implemented. AAR also stated that FRA should remove prescriptive provisions, such as the NPRM's proposed requirements for outward-facing recording devices.

TTD commented that it did not object to less prescriptive requirements on outward-facing cameras for the purposes of preventing vandalism, theft, or other criminal activity. However, BLET supported more prescriptive requirements for outward-facing locomotive image recording devices, commenting that it favored requiring locomotive recordings to have an accurate date/time stamp calibrated to coincide with the date/time stamp on the lead locomotive's event recorder. BLET stated that investigative efforts would be hampered, instead of facilitated, if such a requirement were not adopted.

Finally, Metra commented that FRA should permit flexibility in the selection and implementing of railroads' locomotive image and audio recording systems. Specifically, Metra stated that if the systems meet the technical requirements, railroads should have leeway to determine the type and model of recording system used and what sound audio recording systems will capture (*e.g.,* cab versus exterior bell and horn).

After consideration of all comments received, FRA is adopting the requirements for outward-facing locomotive image recording devices in § 229.136(b)(1) as proposed in the NPRM. FRA understands concerns that certain requirements for outward-facing cameras are prescriptive; however, this was FRA's intention. As compared to the defined space inside a locomotive cab, the area outside and ahead of a locomotive is vast and unbounded. Consequently, establishing certain, more prescriptive, uniform performance parameters helps ensure that image recordings conform to minimum standards necessary for reliable, post-accident/incident investigation. A more performance-based approach risks potential variances and omission of necessary data. However, FRA makes clear that these standards are minimum standards, and passenger railroads do have considerable discretion as to how they want their outward-facing locomotive cameras to operate and record data.

G. Inward-Facing Locomotive Image Recording Systems and Devices

1. Inward-Facing Recording Devices as a Tool To Detect Fatigue

In the NPRM, FRA discussed the possibility of inward-facing image recorders being a tool to identify fatigue, prevent fatigue-related accidents/incidents, and identify when fatigue has been a relevant factor in an accident/incident. However, APTA commented that relying on image data as a fatigue-mitigation tool has limited application, stating it is unclear what criteria the industry would use to determine when an employee is fatigued and that such analysis on the part of the railroad could be subjective.

This final rule requires the inward-facing image recording systems to have sufficient resolution only ''to record crewmember actions''; FRA has not adopted the proposed text specifically addressing crewmember incapacitation. FRA is still hopeful that inward-facing locomotive cameras can be helpful devices to determine whether fatigue may have caused or contributed to an accident or incident. However, FRA agrees that requiring passenger railroad to make a determination that their inward-facing locomotive image recording systems have sufficient resolution to identify whether a crewmember is physically incapacitated is too subjective a standard.

2. Locomotive Recording Devices and Real-Time Monitoring

APTA sought clarification whether the proposal implied that passenger railroads must conduct real-time monitoring of their locomotive cabs. According to APTA, the passenger railroad industry does not support real-time monitoring and, if remote monitoring is added as a requirement, FRA would need to significantly adjust its cost burden estimates to account for staffing and other increased costs of such monitoring. As discussed in the Section-by-Section analysis below, FRA has not adopted the proposed language that APTA believed may imply a requirement to engage in real-time monitoring of the train crew. FRA intended no such requirement.

3. Inward-Facing Recording Device Coverage of the Locomotive Cab

APTA suggested changes to the proposal in § 229.136(c)(1) that the inward-facing recording system be positioned to provide ''complete coverage of all areas of the controlling locomotive cab where a crewmember typically may be positioned.'' APTA commented that the proposal was too prescriptive, stating that multiple designs of locomotives would require various solutions and therefore the devices should be positioned to provide coverage of areas of the controlling locomotive cab as defined by the operating railroad.

Similarly, SMART disagreed with requiring the inward-facing image recorders to provide ''complete'' coverage of the locomotive cab, and instead suggested that the standard should provide for ''overall'' coverage. SMART acknowledged that an inward-facing locomotive image recording device must be positioned to provide coverage of the controlling locomotive, but believed requiring ''complete'' coverage might be overly broad and imply coverage to include every minute area of the locomotive.

In general, the requirement to provide ''complete'' coverage is intended to ensure that the recording system not omit footage of crewmember actions in any part of the locomotive cab that might be vital in post-accident/incident investigations.[24] Allowing the operating railroad to define the areas of the lead locomotive to be covered by the inward-facing recording system or allowing only ''overall'' coverage may lead to a lack of a uniform minimum amount of coverage that risks omitting critical data. Therefore, FRA is still requiring that inward-facing image recording systems provide ''complete'' coverage of all areas of the controlling locomotive cab but puts some limits on the requirement. ''Complete'' coverage only needs to be ''of all areas of the lead locomotive cab where a crewmember typically may be positioned, including complete coverage of the instruments and controls required to operate the controlling locomotive in normal use.'' This clause ensures that passenger railroads will not be found in violation of the standard if their inward-facing image recording system does not cover mostly inaccessible corners of the locomotives where activities necessary to operate the locomotive would not occur.

4. Recording in Low-Light Conditions

APTA opposed including the language in proposed paragraph § 229.136(c)(1)(ii) (now in (c)(1)(iii)) requiring recording systems to automatically switch to infrared or another operating mode that enables the recording to have sufficient clarity when ambient light levels drop too low for

[24] FRA has exempted the locomotive's sanitation compartment in paragraph (c)(3), because the privacy needs of the train crew outweigh, among other things, the potential that actions occurring in the sanitation compartment will cause or contribute to an accident/incident.

normal operation. Instead of what it termed a too prescriptive and one-size-fits-all approach, APTA believed the requirement should provide that the camera system be capable of using ambient light in the cab during all times in passenger service. Conversely, the NTSB agreed with FRA's proposal.

FRA disagrees that the proposed requirement for a recording system to switch to another operating mode to enable effective recording when ambient light levels are too low for normal operation is overly prescriptive. As proposed, the camera system may use any operating mode that enables the passenger railroad to record with sufficient clarity all areas of the lead locomotive cab where a crewmember typically may be positioned. Infrared technology is one way of meeting this requirement, but the use of infrared technology is not required. This is a key requirement, however, to ensure that regardless of the technology used to record inside the locomotive cab at nighttime or in other periods of low ambient light (*e.g.,* in tunnels), the inward-facing cameras must still be capable of recording crewmember actions with sufficient clarity. Accordingly, FRA is adopting this requirement as proposed in the NPRM.

In addition, BLET commented that locomotive technologies are already excessively distracting to crewmembers, there is no need for additional distractions, and cameras or independent light sources should never emit any light that distracts the crew from safely performing their duties or interferes with the crew's vision outside the locomotive window. APTA also stated that a crew should always be able to use the locomotive's sun visor to block direct sunlight that could affect the crew's sight and the identification of signals or other objects outside of the locomotive cab windows.

Existing FRA regulations provide that any illumination in low-light conditions cannot interfere with a crew's vision (49 CFR 229.127(a)), and the placement of image recording devices cannot obstruct a crew's view of the right-of-way from its normal positions in the cab (49 CFR 229.119(b)). The use of infrared technology itself is not a distraction to crewmembers and should be installed on a locomotive so it does not interfere with the ability of crewmembers to safely perform their duties. In addition, although FRA does agree that train crews should be able to use the locomotive's sun visor to block direct sunlight that could affect the crews' vision, FRA cautions railroads to not place the inward-facing cameras in such a way that they can be blocked by the train crew's use of the locomotive visor.

5. Frame Rate for Inward-Facing Recording Devices

APTA commented that it supported the proposed standard to require inward-facing recording devices to record at a frame rate of at least 5 fps. In contrast, BLET commented that 5 fps could be too low a frame rate for use during accident reconstruction if the pictures are not fluid enough to capture action as it happens at the speed it happens. Although BLET understood that allowing inward-facing image recorders to record at a lower frame rate enabled passenger railroads to store more image data at a lower expense, BLET was concerned that the frame rate could create synchronization inaccuracies when the video and audio are captured or played back at different rates. Therefore, BLET stressed that the final rule should specify a frame rate that will prevent these types of inaccuracies.

The NTSB agreed with BLET that a recording rate of 5 fps was not sufficient for inward-facing image recorders. According to the NTSB, because locomotive operating compartments contain numerous indicator lights and displays, cameras recording at 5 fps may not adequately capture possible intermittent warnings or indicator lights. The NTSB stated that it was not aware of any memory limitations that would necessitate such a low frame rate and, instead, recommended at least a 10-fps recording rate for inward-facing image recorders.

FRA understands the concerns raised by BLET and the NTSB. However, FRA is adopting 5 fps as the minimum standard to provide passenger railroads maximum flexibility to comply with the requirements of this final rule. As previously discussed in the NPRM as well as below, a rate of 5 fps is APTA's recommended practice for the selection of recording systems for use in transit-related closed circuit television recording systems and in low-traffic areas or areas where only walking-pace motion is likely (such as passenger areas). Moreover, this frame rate is only a minimum standard. For instance, FRA expects that some passenger railroads may install inward-facing recording systems with a higher frame rate to enhance the use of the devices for operational testing. In addition, under paragraph § 229.136(g), discussed below in the Section-by-Section Analysis, passenger railroads must provide a written description of the technical aspects of any locomotive image recording system installed to comply with this section. Under § 229.136(c)(1)(i), FRA will not approve an image recording system that does not have ''sufficient resolution to record crewmember actions,'' even if the system records at a minimum frame rate of 5 fps. As a result, recording systems that cannot accurately provide information or sufficiently record what is occurring within the locomotive cab will not be approved prior to installation.

6. Prohibition on Recording Activities Within a Locomotive's Sanitation Compartment

BLET and SMART both supported the proposed requirement that inward-facing locomotive cameras may not record any activity within a locomotive's sanitation compartment as defined in § 229.5, and that no image recording device be installed in a location where the device could record activities within the locomotive's sanitation compartment. Although the Supreme Court has ruled that a locomotive is a workplace and therefore employees have no expectation of privacy,[25] train crewmembers have an expectation that their actions will not be recorded on the locomotive's inward-facing recording device(s) within the passenger train's sanitation compartment. FRA is adopting the proposed prohibition on recording the sanitation compartment in the final rule without substantive change.[26]

H. Notice Provided When Locomotive Recording Devices Are Present

FRA received several comments in response to what, if any, notice passenger railroad crewmembers should receive that locomotive recording devices are present in the locomotive cab. APTA commented that its member passenger railroads have already addressed this issue by providing information using operational notices to affected employees. APTA also added, as discussed above, that courts, including the Supreme Court, have ruled that a locomotive is a workplace and employees have no expectation of privacy within it. In contrast to APTA's comment, Amtrak stated that providing notice by Form FRA F 6180–49A alone, as proposed in the NPRM, was inadequate because it could in practice limit who sees the information. Instead, Amtrak recommended that FRA require signage alerting the crew that audio-visual recording devices are present. SMART agreed with Amtrak's comment

[25] *Skinner* v. *Railway Labor Executives Association,* 489 U.S. at 627.

[26] *See* 49 CFR 229.136(c)(2) of this final rule.

that signage should be required and that there should also be a visible light on the recording device that indicates to crewmembers when the device is in operation.

Because as noted above, crewmembers have no expectation of privacy in a locomotive cab, excluding the sanitation compartment, FRA has concluded that although it proposed to provide notice of recording devices to crewmembers via a notation on Form F 6180–49A (Locomotive Inspection and Repair Record), such notice is not required as a matter of privacy concerns. Therefore, FRA will not require railroads to post signage alerting crewmembers that audio-visual recording devices are present.

However, the value of requiring the presence of a locomotive recording device to be noted on a locomotive inspection and repair record, similar to § 229.135(a)'s requirement for locomotive event recorders, is to ensure that the device is inspected and in proper operating condition as this rule requires. In this regard, as discussed below in Section II.I.3, when a railroad removes a locomotive image recording device from service, a qualified person must record the date the device was removed from service on Form FRA F 6180–49AP (Passenger Locomotive Inspection and Repair Record). This requirement varies slightly from the requirement proposed in the NPRM, where FRA proposed that the notation indicating a locomotive image recording device has been removed from service be made under the REMARKS section of Form F 6180–49A. This is no longer the case. Instead, FRA has created a new form, Form F 6180–49AP, specifically for passenger locomotives.[27] It is in the REMARKS section of new Form F 6180–49AP that a qualified person will note the date when a locomotive image recording device is removed from service.

As discussed below in the section-by-section analysis for new § 229.22, Passenger locomotive inspection and repair record, Form F 6180–49AP will serve as the new counterpart to Form F 6180–49A, and will include a designated row for entering information about annual testing of locomotive image recording devices required under § 229.136, consistent with the designated row on Form F 6180–49A (as well as new Form F 6180–49AP) for entering information about required locomotive event recorder testing. FRA makes clear that this new form will in no way affect use of the F 6180–49A form by locomotives in freight or switching service, which are not subject to the requirements of this rule, nor will it affect use of the F 6180–49A form by passenger locomotives that are not used as the lead locomotives in commuter or intercity passenger train service.

Further, FRA understands and does not dispute the legal precedent raised by APTA that locomotives are highly regulated workplaces, and employees have no expectation of privacy while performing, or ready to perform, operating duties within a locomotive. The only area where train crews do have an expectation of privacy is within a locomotive's sanitation compartment, treatment of which is discussed above in Section II.G.

I. Repairing, Replacing, or Removing Locomotive Image Recording Devices From Service

1. Practicableness of the Standard

FRA received several comments on the appropriateness of the standard in proposed § 229.136(i) that would require inward- and outward-facing locomotive image recording devices to be repaired or replaced at the next calendar day inspection or be removed from service. Many commenters claimed the standard was too burdensome and should be revised. APTA asserted that requiring these systems to be repaired or replaced by the next calendar day inspection is impractical, stating that locomotive image recording systems can fail for many different reasons, and repairs can sometimes take several days. According to APTA, the passenger railroad industry has limited fleet availability and restricting locomotives or trainsets due to locomotive image recording system failures alone could have a substantial impact on dispatching trains, potentially taking an entire trainset out of service when the cars are semi-permanently coupled. APTA contended that the proposed standard was financially unrealistic and, if adopted, would require the industry to obtain additional locomotives or trainsets, driving up the cost of the final rule and significantly affecting the rule's cost-benefit analysis. APTA stated that the Statute prevents FRA from adopting a standard that ''requir[es] a railroad carrier to cease or restrict operations upon a technical failure of an inward- or outward-facing image recording device or in-cab audio device,'' [28] and asserted that the operating railroad should be free to repair or replace the device ''as soon as practicable'' under the Statute. APTA added that, given passenger railroads' voluntary installation of these devices, railroads find it in their best interest to repair or replace these devices for many reasons independent of Federal requirements.

Metra agreed with APTA's assertion that FRA's proposed standard conflicted with the Statute. Metra suggested that FRA should interpret ''as soon as practicable'' under the Statute to mean 48 hours at a minimum. Metra stated that, because the locomotive recording systems it uses require substantial investment in both money and workforce any requirement to repair or replace non-functioning equipment that provides for less than 48 hours is not practicable. In its comments, AAR agreed with Metra that ''as soon as practicable'' should be at least 48 hours from the discovery that the device has failed, citing the cost of image recording devices, the multitude of components that could cause the device to fail, and the inevitability of tampering.

Amtrak also commented on the appropriateness of FRA's proposal and suggested basing the standard on the ''next capable facility'' rather than on a specific unit of time. According to Amtrak, long-distance passenger trains may operate for multiple days until a suitable repair facility is available to replace equipment and often calendar day inspections are performed at outlying locations where minimal workforces do not have the suitable means to replace equipment. Amtrak believed a requirement to repair the equipment at the next capable facility would address this concern, and that this standard should apply to both inward- and outward-facing locomotive cameras.

A private citizen also commented that, in some situations, passenger trains are parked overnight far from comprehensive repair facilities. The commenter therefore believed there should be an allowance for locomotive recording devices to make it back to an appropriate repair facility without cancellation or delays to passenger trains. The commenter stated that ultimately the use and repair of the devices should not force passengers into less safe situations by requiring them to drive instead of taking the train, given that rail is a safer mode of travel.

However, not all commenters objected to FRA's proposed standard. BLET stated that locomotive cameras should be treated the same as any device mounted on or in a locomotive cab, asserting that locomotive cameras are appurtenances under § 229.7 and should be treated in a similar fashion to event

[27] FRA published a 60-day **Federal Register** notice to solicit public comments on the new F 6180–49AP form. 87 FR 50914 (August 18, 2022).

[28] *See* 49 U.S.C. 20168(j).

recorders under § 229.135. BLET believed the calendar day inspection requirement mirrors long-established requirements for removing event recorders from service under § 229.135(c), is no more burdensome than the event recorder requirement, and should be included in this final rule.

FRA agrees with BLET's reasoning and is largely adopting the standard proposed in the NPRM that all inward- and outward-facing image recording devices either need to be repaired or replaced within the next calendar day inspection or be removed from service. However, after consideration and review of the comments received, FRA reexamined how this requirement would affect long-distance intercity passenger trains and is creating a new exception to the requirement for these trains. Instead of taking a lead locomotive on a long-distance intercity passenger train out of service if it cannot be repaired or replaced by the next calendar-day inspection, the locomotive may continue in service until arrival at its destination terminal or its nearest forward point of repair, whichever occurs first. At that point, the locomotive must be taken out of service until the device is repaired or replaced.

FRA determined an exception for long-distance intercity passenger trains was necessary, taking into further account the implications of the difference between the application of this final rule and the locomotive event recorder rule in § 229.135. Section 229.135 requires locomotive event recorders to be installed on both freight and passenger locomotives, yet this final rule requires locomotive image recording devices to be installed only on passenger train lead locomotives. Because a much smaller number of locomotives will be required to have compliant image recording devices than event recorders, FRA expects there will be a correspondingly smaller number of locations throughout the nation where properly equipped replacement locomotives and image recording devices are available, as well as where appropriate parts and equipment for repair are available. Accordingly, long-distance intercity passenger trains may need to travel beyond the location of their next calendar day inspection until a suitable repair facility is available to repair or replace the equipment, especially because calendar day inspections for long-distance intercity passenger trains are sometimes performed at outlying locations, as Amtrak commented.

This exception is limited to long-distance intercity passenger trains. The majority of passenger locomotives in this Nation operate in commuter service or short-distance intercity passenger service [29]—service supported by centralized inspection and repair locations. Passenger railroads operating trains in commuter or short-distance intercity passenger service are therefore expected to have adequate parts, equipment, and facilities available at calendar day inspection locomotives to repair or replace defective image recording systems or devices.

2. Standard's Consistency With Locomotive Recording Devices' Designation as Safety Devices

Hitachi commented that allowing a passenger train to continue in operation without the proper image recording capabilities until the next calendar day inspection conflicts with FRA's defining locomotive recording devices as a safety device under part 218. FRA disagrees that there is a contradiction. Taking a locomotive out of service immediately because a safety device (*e.g.,* a locomotive image recorder) is not working could potentially lead to a more dangerous safety issue (*e.g.,* stranding passengers or overwhelming the safe capacity of station platforms).

3. Documenting When a Locomotive Image Recording Device Has Been Removed From Service

APTA commented that when a railroad removes a locomotive image recording device from service, the final rule should not require a qualified person to record the removal date on Form FRA F 6180–49A, under the REMARKS section. As discussed above in Section II.H, APTA repeated its objection to the NPRM's proposed requirement that the railroad note the presence of any image or audio recording system on Form FRA F 6180–49A. APTA stated that passenger railroads already address the issue by providing information to affected employees through operational notices. In addition, APTA believed adding this paperwork burden is not beneficial to safety, and claimed that FRA has not considered this cost in its cost-benefit analysis.

Although FRA agrees with established legal precedent that train crews have no expectation of privacy in a locomotive cab, excluding the sanitation compartment, FRA disagrees that this form notation requirement is a paperwork burden without a safety benefit. As discussed above in Section II.H, passenger railroads will be required to note in the REMARKS section of new Form FRA F 6180–49AP, specifically for passenger locomotives, when an image recording device has been removed from service. This notation will serve as a quick reference to inform crewmembers and other passenger railroad employees (*e.g.,* mechanical employees responsible for locomotive repairs, maintenance and inspection) of the status of the locomotive's recording devices and the image recording system on board any passenger locomotive. The final rule varies slightly from the requirement proposed in the NPRM in that such a notation will be made in the REMARKS section of Form FRA F 6180–49AP—not Form F FRA 6180–49A. Form F 6180–49A will be exclusively used by locomotives in freight or switching service and by passenger locomotives that are not operated as the lead locomotives in commuter or intercity passenger train service. In response to APTA's cost-benefit analysis comment, FRA has updated its cost-benefit analysis to discuss that the costs are incorporated in locomotives' routine scheduled maintenance. The removal from service requirements in § 229.136(i) do not apply to audio recording devices, which are not required to be installed under this final rule.

In its comments, Amtrak asserted that a notation on form FRA F 6180–49A is not sufficient notice that a locomotive's inward- or outward-facing camera is out-of-service. Instead, Amtrak recommended making a record in an electronic maintenance system and opening a work order for repair, along with applying a non-compliant tag on the equipment. Amtrak stated such a process would be similar to that for the failure of dynamic brakes under § 232.109 of this chapter.

FRA maintains that the requirement as proposed is adequate to provide notice that either the locomotive's inward- or outward-facing camera system is malfunctioning. Moreover, the reporting of any defect on a locomotive is subject to the calendar day inspection requirements in § 229.21. However, part 229 does not require a non-compliant tag to be placed on a locomotive with a defective event recorder under § 229.135, and no such tag is required under this final rule.

J. FRA Approval Process for Locomotive Image Recording Systems and Devices

1. Necessity of the Approval Process

In response to FRA's proposal, APTA questioned why an approval process

[29] Short-distance intercity passenger service means service provided exclusively on the Northeast Corridor or between cities not more than 125 miles apart. 49 CFR 238.5.

was needed, stating that the recording system is not safety-critical. Further, APTA commented that FRA had not accounted for the approval process in the cost-benefit analysis, asserting that an approval process for any element increases the cost of the rule and implementation time. According to APTA, given the widespread, voluntary implementation of these systems, FRA should not require their approval and should, instead, allow passenger railroads to create and maintain a written description that can be made available upon request to FRA at any time.

FRA has not adopted APTA's comment. The Statute requires FRA, as the Secretary's delegate, to establish a review and approval process for inward- and outward-facing locomotive image recorders.[30] This final rule therefore includes a review and approval process as the Statute requires. Nonetheless, FRA has adjusted the economic analysis to include the approval process cost; for more detailed information on the cost, please see the RIA accompanying this final rule. Further, for the reasons discussed below in Section II.M, FRA disagrees with APTA's assertion that image recording devices are not safety-critical. Notably, FRA is amending part 218's prohibitions against tampering with safety devices specifically to include passenger locomotive recording devices and is adopting § 229.136(j) to expressly prohibit disabling or interfering with passenger locomotive recording systems.

2. Clarifying the Approval Process

In commenting on proposed § 229.136(g), Wi-Tronix stated that the approval process for locomotive recording devices needed clarification. According to Wi-Tronix, the proposed requirements would lead to confusion and delays in the marketplace because railroads often look for a certified product or service and have little desire to go through an additional certification process. Wi-Tronix requested FRA clarify whether suppliers can self-submit a system for approval, and believed the timelines and process (including each railroad needing separate certification) to be commercially impractical and lead to increased costs and slow the rule's implementation.

Separately, Amtrak requested changing the approval process submission timeframes, citing constraints due to clerical limitations and the logistics of acquiring equipment. Amtrak stated that a more realistic and achievable timeframe would be 90 days for existing systems and 180 days for proposed systems.

FRA disagrees that the approval process is unclear. Section 229.136(g)(1) explains what a passenger railroad must include in its description of the technical aspects of the locomotive image recording system. Although the paragraph does not provide extensive technical detail, FRA does not consider this to be a limitation but rather to provide the passenger railroads flexibility in preparing their submissions.

FRA also believes 60 days from the effective date of this final rule provides railroads sufficient time to prepare and submit descriptions of the technical aspects of their existing locomotive image recording systems. (Please note that the 60-day period after the final rule's effective date reflects an earlier effective date than indicated in the NPRM, so that the overall length of the submission period is the same.) This final rule takes effect on November 13, 2023, which is 30 days after publication of this final rule. Accordingly, railroads have a total of 90 days from this final rule's publication to prepare and submit descriptions of the technical aspects of their existing locomotive image recording systems. Such description of the technical aspects may be submitted to FRA in electronic form.

In this final rule, FRA is also correcting an error in proposed § 229.136(g)(2) in which FRA stated that the submissions for existing systems must be made ''not less than'' 30 (now 60) days after the effective date of the final rule. However, the explanation of this proposed paragraph in the NPRM's Section-by-Section Analysis did correctly state that the submissions must be made ''not more than'' 30 (now 60) days after the effective date of a final rule. FRA is correcting the erroneous language in the text of paragraph (g)(2) accordingly, as railroads are not required to wait until the end of the period to make their submissions. FRA is also revising the approval process in this final rule to make clear affirmative approval from FRA will be required before a passenger railroad's inward- or outward-facing locomotive image recording system can be installed or placed into service. This is a change from the proposal in the NPRM that, in the absence of written disapproval from FRA within 90 days of FRA's receipt of the submission, the railroad's locomotive image recording system would be considered approved. FRA has concluded that a transparent and conclusive approval process is required, and it would not be in the public's interest to allow for the possibility that a non-compliant system could be approved through unexpected events or inadvertence. At the same time, FRA plans to publish a list of any previously approved systems on its website for railroads' convenience, as FRA noted in the NPRM.[31]

Because this final rule requires FRA's affirmative approval before a locomotive image recording system can be installed or placed into service on a locomotive, if a railroad chooses to submit the required information 180 days before installation of these systems, consistent with Amtrak's comment, FRA would not object. In fact, as a practical matter, FRA encourages railroads to make their submissions well in advance of the submission deadline, so that if the submission were incomplete or requires clarification, or if FRA were to disapprove any or all of a railroad's submission, the railroad could timely respond to minimize, if not avoid altogether, any impact on the railroad's proposed installation schedule or the use of railroad resources.

Finally, in response to Wi-Tronix's comment, the submission must come from the applying passenger railroad, as opposed to a supplier or other party, though it may of course be prepared in consultation with a supplier or other party. This is necessary as each railroad may use potentially different types of locomotives with different internal and external characteristics. How each passenger railroad complies with the requirements of § 229.136, such as (but not limited to) how the inward- and outward-facing locomotive cameras are installed or placed, is for the passenger railroad to describe and demonstrate.

3. Application of the Approval Process to Freight Locomotives

Finally, similar to other comments BLET made on the NPRM, BLET stated that the requirements of § 229.136(g) should apply whether a system is installed on a voluntary basis or mandated by law. FRA disagrees. As discussed previously, the requirements of this rulemaking do not apply to freight locomotives that have or will have installed locomotive image recorders. However, FRA expects that all railroads that voluntarily install recording devices on their locomotives will adhere to practices that are consistent with those in this final rule, and FRA invites parties with questions about the voluntary installation of recording devices on locomotives to contact FRA for such technical assistance.

[30] 49 U.S.C. 20168(c).

[31] 84 35714.

K. Implementation Period of the Rule

1. Four-Year Implementation Period

FRA received several comments about the proposed four-year implementation period within which all lead passenger train locomotives in commuter or intercity passenger service would be required to be equipped with compliant inward- and outward-facing image recording devices. Commenters provided different suggestions on how FRA should set the implementation date for the final rule. APTA stated that if FRA would not exclude from the final rule existing locomotives already equipped with recording devices, the rule should take effect 10 years from its publication date. APTA believed the 10-year period would allow passenger railroads to obtain the full, life-cycle value of locomotive image recording systems installed or soon to be installed, *i.e.,* already under contract and designed. APTA contended that this would be a more effective use of funds, as most passenger railroads are public transportation agencies funded by taxpayer dollars, and also stated that these public agencies must adhere to strict, public procurement rules, and consequently need a considerable amount of time to get public agency procurements completed.

Metra suggested that FRA phase-in the requirements with an 8-year implementation period in which passenger railroads have 70 percent of their locomotive fleets compliant within the first 5 years. Metra stated that it was generally supportive of FRA's implementation requirement, but found the proposed 4-year timeframe to be insufficient for an entity the size of Metra, which has over 529 pieces of equipment requiring installation.

Other commenters supported the proposed 4-year implementation period. The NTSB stated that the deadline would encourage prompt implementation of the final rule's requirements. As the NTSB discussed in its report on the DuPont accident, and as discussed earlier in this final rule, there is a clear investigative benefit to the information provided by locomotive recording devices. The NTSB also noted that it had issued NTSB Safety Recommendation R–10–01 in 2010, on the need for locomotive recorder devices, and that any further delay beyond the proposed deadline in the NPRM would be unacceptable. SMART also commented that the final rule should allow 4 years for passenger railroads to install compliant recording devices, but sought to require that as compliant devices are installed on locomotives, railroads should comply with the other requirements of the final rule.

FRA maintains that 4 years is an adequate time-period for passenger railroads to comply with the final rule's requirements. Granting passenger railroads a full 10 years or a phased-in 8 years to comply with the minimum requirements would be both excessive and not in the best interests of the public or rail safety. As the NTSB commented, recent accidents involving passenger trains have proven how valuable locomotive image recordings can be as part of post-accident/incident analysis to identify rail safety hazards. The 4-year period allows passenger railroads sufficient time to get significant remaining value out of their equipment while taking into account the increased post-accident investigation benefit and other benefits that result from compliance with the final rule's requirements.

2. Application of the Final Rule to Image Recording Systems on New, Remanufactured, or Existing Locomotives

FRA invited comment on the appropriateness of the proposal that image recording systems installed after one year from the final rule's publication date on new, remanufactured, or existing locomotives used in commuter or intercity passenger service meet the requirements of this final rule. Based on concerns about the length of the public procurement process, number of locomotives already equipped with image recording devices, and the lifespan of these devices, APTA and Hitachi asked that FRA extend the time to comply until after two years from the final rule's publication date.

FRA has decided against extending the time from one to two years because the one-year period is intended to provide an appropriate margin of time for passenger railroads to obtain image recording systems compliant with the requirements of this final rule for installation on new, remanufactured, and existing locomotives. These requirements are minimum standards and are achievable. In this regard, AAR commented that FRA should compare the standards in this rulemaking with the May 29, 2019, standards proposed by Transport Canada to prevent conflicting requirements between Canada and the United States.[32] FRA compared the two standards and did not identify any concerns. FRA has also compared the final standards issued by Transport Canada and this final rule.[33] Transport Canada's standards for inward-facing cameras are more stringent than those in this final rule; however, Transport Canada's standards do not require outward-facing locomotive cameras, which are specifically required by the FAST Act and therefore this final rule.[34] Lead locomotives on Canadian passenger trains that enter the United States from Canada must comply with all of the requirements of this final rule.

L. Operational (Efficiency) Testing

In the NPRM, FRA discussed the potential benefits to railroads that use locomotive recording devices as part of their operational (efficiency) testing programs and proposed requirements for railroads choosing to use locomotive recording devices to conduct operational testing under part 217, to protect employees from targeted testing as a form of retaliation. FRA received various comments regarding FRA's proposed amendments to part 217, and the agency's existing operational testing requirements.

1. Application of the Rule's Part 217 Amendments to Freight Railroads

AAR commented that because existing part 217 applies to both passenger and freight railroads, FRA's proposed revisions to § 217.9 (proposed new paragraphs (b)(3) and (4) governing operational testing using locomotive recording devices) would apply to both types of railroads. AAR noted that FRA's stated intent in the NPRM's preamble was that these provisions would apply to passenger railroads only. Accordingly, AAR suggested that FRA modify proposed paragraphs (b)(3) and (4) to specify that the paragraphs apply to passenger railroads only.

AAR is correct. FRA did not intend proposed new paragraphs (b)(3) and (4) to apply to freight railroads. Therefore, in this final rule, FRA is clarifying its intent to exclude freight railroads from these requirements by using the word ''passenger railroad,'' instead of ''railroad,'' in new paragraphs (b)(3) and (4) of §§ 217.9. However, as discussed above in Section II.A.2, it is FRA's expectation that all railroads that voluntarily install recording devices on their locomotives will adhere to practices that are consistent with those in this final rule, notably the new part 217 requirements that serve to protect employees from targeted testing as a form of retaliation when railroads

[32] *https://www.gazette.gc.ca/rp-pr/p1/2019/2019-05-25/html/reg5-eng.html.*

[33] *https://gazette.gc.ca/rp-pr/p2/2020/2020-09-02/html/sor-dors178-eng.html.*

[34] 49 U.S.C. 20168(a).

conduct operational testing using recording devices or their recordings. Further, under existing § 217.9(h), FRA reviews railroads' operational testing and inspection programs and, if necessary, may disapprove any such program for cause stated.

2. Burden of the Rule's Part 217 Requirements

APTA commented that FRA should not adopt in this final rule any of the requirements FRA proposed to add to § 217.9 because the regular monitoring of image recordings does not need to be under or part of a railroad's operational testing program. Instead, APTA asserted that passenger railroads should be allowed to establish their own practices to monitor employees' compliance with rules and deter them from unsafe actions. APTA also contended that the additional burdens from the requirements FRA proposed may incentivize railroads not to use recording devices in operational testing and therefore reduce one of the benefits of this rulemaking.

In addition, APTA claimed that requiring test subjects for operational testing using locomotive recorders to be selected at random would create an unnecessary cost and burden for passenger railroads, because the ability to use cameras in the railroads' current operational testing plans already exists and this cost was not considered in the NPRM's cost estimate. Finally, APTA objected to FRA's proposed condition that operational testing be completed within 72 hours of the completion of the tested employee's tour of duty, calling it impractical and indicating that such is allowed when testing for radio rules compliance.

FRA disagrees with APTA's comment that the regular monitoring of locomotive recordings does not need to be under a railroad's operational testing program or that passenger railroads should be allowed to establish their own plans and practices to monitor employees using these recordings. Section 20168(i) of the Statute prevents in-cab audio or image recordings from being used to retaliate against an employee. New § 217.9(b)(3) requires passenger railroads to describe how they will randomly select testing subjects, better enabling FRA to oversee that passenger railroads are fulfilling the requirements and railroad supervisors are not unfairly selecting specific employees for operational testing as a form of retaliation. FRA is including in-cab audio recorders and their recordings under paragraph (b)(3), as previously discussed. It does not make sense to require passenger railroads to select their operational testing subjects randomly when using image recorders or their recordings without applying the same protections to the use of audio recorders and their recordings.

FRA disagrees that the limitations on operational testing will cause passenger railroads to abandon using these devices for operational testing purposes altogether. APTA's assertion that any costs associated with these limitations are unnecessary is flawed, in part because the Statute itself prohibits the use of locomotive recording devices as a medium to retaliate against employees. Further, the RIA accompanying this final rule addresses in more detail APTA's claim that FRA has not sufficiently accounted for the cost of implementing a random selection program for locomotive recordings. Finally, while APTA compares testing for radio rules compliance with using locomotive recording devices for operational testing, listening to radio recordings provides a far more limited window into the crew's activities and has far less potential for abuse than locomotive recording devices.

3. Appropriateness of Using Locomotive Recordings for Operational Testing

BLET also objected to FRA's proposed revisions to § 217.9 allowing railroads to utilize locomotive recordings for operational testing purposes. BLET asserted that railroads have historically used operational testing as an indirect way to discipline their employees. According to BLET, although locomotive engineers are accustomed to how operational testing is currently done (*e.g.,* sporadic skills tests in the field), use of recording devices would put engineers under ''constant surveillance.'' BLET believed crewmembers would feel continually watched and change how they act as a result, because crews would be worried about performing for the camera first and reacting to the circumstances that are actually occurring second, which would negatively impact safety.

In contrast to BLET's comment, FRA received comments from TTD, Metra, and SMART, in support of FRA's proposed additions to § 217.9. TTD called FRA's proposed requirement for operational testing subjects to be selected at random a ''meaningful step towards fair usage of recorded images.'' Metra agreed with TTD and specifically asked FRA to make clear in the final rule that passenger railroads could not use subjective factors in the utilization of locomotive recordings to conduct operational tests. SMART and BLET also ''applauded'' FRA on its proposed random testing requirement and SMART stated that the provision would prevent a vindictive supervisor from tracking an employee the supervisor personally dislikes for punishment, such as a union representative. While still opposed to locomotive recordings being used for operational testing purposes at all, BLET also commented that how the random testing requirement was actually practiced by rail carriers in the field would be the determining factor on carrying out the intent of the regulation.

TTD also expressed its support for the proposed requirement that any operational test or inspection must be performed within 72 hours after the employee's tour of duty. TTD called this a critical tenet to ensure that data received by the railroads is not misused and believed FRA should not weaken any of the proposed protections in a final rule.

FRA agrees with TTD, Metra, and SMART and is adopting the proposed requirements in paragraphs (b)(3) and (4). FRA notes that APTA and BLET objected to the proposed requirements for opposing reasons. As stated above, APTA commented that FRA should not adopt any of the proposed requirements, not because APTA is opposed to using locomotive recording devices in operational testing, but because APTA believed the regulations would place constraints on the use of the devices that many passenger railroads already use as part of operational testing and cause these railroads to change their existing testing programs. APTA preferred FRA instead let railroads make their own decisions on how to use their locomotive recording devices. Conversely, BLET objected to the proposed requirements on the basis that railroads should not be allowed to use locomotive recording devices for operational testing in any circumstance, because they could be used to unfairly target their employees. As explained below, the conditions FRA is adopting in this final rule address the targeting of employees when passenger railroads use locomotive recording devices for part 217 testing purposes.

Without addressing BLET's allegation that operational testing has historically been used to target and discipline employees, FRA acknowledges that the amendments to § 217.9 in this final rule are intended to ensure passenger railroad supervisors do not use inward-facing locomotive cameras or in-cab audio recording devices to target specific employees. Hence, FRA's insistence that subjects for operational testing be selected at random, that there must be a testing plan that FRA can

review and disapprove for cause, and that all operational testing must be completed within 72 hours of the employee being tested completing his or her shift. BLET also commented that employees are used to having their skills sporadically tested in the field as opposed to the ''constant surveillance'' of inward-facing cameras. However, the new regulations require employees to be selected at random. Constant surveillance of a certain employee will violate the randomness requirement.

Further, as stated previously, locomotive engineers and other railroad employees who work in a locomotive have no expectation of privacy, with the exception of the locomotive's sanitation compartment. Railroad employees can be observed in the locomotive at various times by railroad management, FRA inspectors, or even members of the public. Although BLET maintained that the constant surveillance of railroad employees would negatively impact the employees' behavior, passenger railroads have been using locomotive cameras long before this rulemaking without any such observable impact on passenger train safety.

4. FRA's Authority To Regulate the Use of Locomotive Audio Recordings in Operational Testing

APTA commented that FRA should not adopt in § 217.9 any reference to audio recordings or related language as it would provide FRA with regulatory authority for something not within the scope of the NPRM or under current FRA regulations. FRA disagrees. FRA widely discussed and asked numerous questions about audio recording devices in the NPRM, in addition to raising the requirement in the NPRM. FRA specifically proposed that inward-facing locomotive image and in-cab audio recordings, if used for operational testing, would be subject to the proposed requirements in § 217.9. Additionally, FRA has for some time regulated railroads' operational testing programs, and specifically what railroads can and cannot do as part of these programs.

5. Effect on FRA's Confidential Close Call Recording System (C3RS)

BLET commented that allowing locomotive recording devices as an operational testing tool would have a negative effect on FRA's C3RS program. C3RS is a confidential reporting system that allows railroad employees in the field to report incidents where a potential accident was averted, or a risk was mitigated. The report is generated by the railroad employee without fear of reprisal from railroad management. BLET stated that confidentiality is the key to the success of the C3RS program but, with the constant surveillance of locomotive cameras, railroads may not feel there is an advantage to C3RS if they can simply watch accumulated video to identify trends. According to BLET, when a railroad has observed sufficient footage it could modify its operational testing to increase the number of exceptions and consequent cases of employee discipline, and thereby ignore the underlying safety problem or rule violation because the person committing the violation would be removed.

FRA does not believe that inward-facing cameras used for operational testing will negatively affect FRA's C3RS program. Passenger and freight railroads began installing inward-facing cameras in locomotives many years ago and FRA is not aware of any evidence, nor has BLET provided any, that these cameras have negatively impacted the C3RS program.

6. Rules or Regulations Locomotive Recording Devices Should Address as Part of a Passenger Railroad's Operational Testing Program

BLET commented that in the event recorder regulation all actions required to be captured are enumerated in the regulation. However, BLET asserted that for image or audio data captured by a camera or other recording devices, the NPRM lacked specificity as to which rules or regulations the data could be used to determine compliance. FRA did not provide in the NPRM, and declines to do so in this final rule, specific guidance on how the locomotive cameras should be used for evaluating compliance with specific rules or regulations, other than such use must comport with the stated protections for employees. FRA expects that railroads will use the locomotive image recording devices as a tool for purposes of carrying out their operational testing program requirements, evaluating compliance with the rules and regulations they already take into consideration as part of their operational testing programs.

M. Locomotive Recording Devices as Safety Devices Under Part 218

FRA received comments from APTA, BLET, and the NTSB on FRA's proposal to include image and audio recording equipment installed on a passenger train locomotive as a ''safety device'' under § 218.53(c). APTA objected to the proposed changes and did not believe including an image recording device as a safety device under part 218 was necessary. APTA claimed that although tampering has not been a known issue for passenger railroads, the railroads already have internal rules and policies that prevent tampering with locomotive image recording devices. In addition, APTA stated that locomotive cameras do not need protection from the public, as they are not readily publicly accessible, and that the presence or operability of locomotive image recording devices does not affect the safe operation of a passenger locomotive or the train it is powering because these devices are strictly forensic in nature and cannot prevent any accident or incident.

In contrast to APTA's position, both BLET and the NTSB supported including locomotive recording devices as safety devices under part 218. The NTSB agreed with FRA that treating a locomotive-mounted image or audio recording device as a ''safety device'' will deter employees from tampering with or disabling one of these devices. BLET also agreed, but added that the technical requirements and standards for locomotive recording devices should be no less stringent that the requirements for event recorders.

FRA agrees with the NTSB that including locomotive recording devices under the definition of ''safety device'' in § 218.53(c) will deter railroad employees from tampering with such devices. However, because a locomotive recording device is not currently defined as a ''safety device,'' FRA is not aware of the extent to which there may be tampering with these devices. FRA expects locomotive recording devices to be at least as, if not more, susceptible to tampering as event recorders, which are safety devices under part 218. For example, as stated in the NPRM, in one incident of tampering with an inward-facing locomotive camera system, FRA viewed a recording in which an engineer covered the inward-facing cameras on his locomotive, apparently unaware of another camera mounted on the ceiling near the back wall of the cab. That camera recorded him appearing to play a game on a personal electronic device while operating a moving freight train. Accordingly, the changes to part 218 will serve not only to discourage passenger railroad employees from tampering with these important safety devices, but to hold individuals who do engage in such tampering accountable under FRA's rail safety regulations.

Even if train crew tampering with locomotive image recorders would continue to be handled under passenger railroads' rules and policies, as APTA suggested, this does not confer the same significance as a safety device subject to part 218. By including passenger

locomotive recorders as safety devices under part 218, engineers and conductors directly risk the revocation of their FRA certification for tampering with these devices. Further, this change ensures that all passenger railroads handle tampering with locomotive recording devices according to uniform FRA standards, instead of having individual railroads apply potentially different internal rules and policies.

FRA also disagrees with APTA that the presence or operability of image recording devices does not affect the safe operation of a passenger locomotive or the train it is powering. Although locomotive recording devices can provide information about the actions of train crewmembers following the occurrence of an accident or incident, properly function recording devices can serve additional safety purposes. In its comments to FRA, NCTD stated that its COASTER commuter rail service can currently observe through its inward-facing cameras in real time when the equipment is in range of the railroad's wireless mesh network along NCTD's right-of-way. FRA notes the ability to observe a train crew in real time could provide the railroad an opportunity to intervene if, for example, it observed unauthorized persons in or around the locomotive cab, including closely monitoring interactions with passengers, in addition to curbing violations of railroad rules that could lead to a potentially catastrophic incident or accident. In this regard, Wi-Tronix commented that the benefits of being able to livestream video and data during emergency situations would be a great benefit to the public, as well as when the train crew experiences a health issue or there is hostile activity in the locomotive cab.

Regardless of whether locomotive recording devices are monitored in real time, the train crews' awareness of the devices will deter behavior that can negatively affect railroad safety, such as crewmember cell phone use while performing safety-sensitive functions, and the presence of cameras may also deter unauthorized occupancy of the locomotive or curb actions of other persons who may interact with the crew. Although the information currently provided by locomotive recording devices is mostly forensic in nature, the information can be critical in post-accident analysis and cannot be obtained from other sources such as locomotive event recorders. For instance, while locomotive event recorders provide information on data elements including locomotive speed and the amount and time of the locomotive's brake application, information from recording devices may be particularly useful in accidents arising from human factor causes, as image data can show investigators what the train crew was doing in the locomotive from a perspective that event recorders cannot provide. The railroads can then use this information to change railroad rules or revise their training programs to help prevent these types of accidents from reoccurring. This post-accident/incident data will be a vital source of information for FRA, the NTSB, and railroads to determine the cause of accidents/incidents as well as whether any action is necessary to prevent similar incidents from occurring in the future.

FRA also received a comment from Metra about the addition of § 218.53(d), which clarifies that the requirements of §§ 218.59 and 218.61 do not apply to recording devices voluntarily installed on freight locomotives. Metra noted that because these devices are voluntarily installed by freight railroads, the railroads can operate lead freight locomotives without such functioning recording devices. Metra is correct that freight railroads can operate freight locomotives without recording devices in compliance with this rule. However, as previously discussed, unless used as a rescue locomotive, a freight locomotive used in commuter or intercity passenger service must comply with all the requirements of this final rule.

N. Twelve-Hour Recording Period for Locomotive Image Recording Devices

1. Appropriateness of the 12-Hour Recording Period

APTA commented that although it understood FRA arrived at the 12-hour retention period for locomotive image recording data by reference to NTSB recommendations and the Statute's requirements, the requirement was excessive and unnecessary compared to the requirements of other federal agencies. APTA stated that the Federal Aviation Administration requires only 30 minutes of recording, claimed that the NTSB cited limited data supporting its recommendation for the 12-hour timeframe, and asserted that, unlike some freight trains, commuter train trip lengths are much shorter and ''turn backs,'' where the locomotive is in the lead in one direction and a cab car is in the lead in the other direction, are common after completing a run or directional trip. According to APTA, crew on-duty time for commuter and intercity passenger routes are scheduled to minimize jobs close to 12 hours on duty, some crews have a respite before their next trip, and some crews may also change train consists during their duty tour. APTA believed these elements contribute towards reducing the overwrite potential of critical image recordings available to investigate an incident and therefore asked that passenger railroads be allowed to determine their own time for storing their locomotives' image recording data. APTA added that passenger railroads already have image recording devices in other vehicles in a train consist for security purposes and noted they are generally recorded onto the same storage system as locomotive recording systems; consequently, APTA asserted that a shorter storage duration for locomotive recorders is necessary from a capacity perspective.

Hitachi also asserted that 12 hours of required recording time is excessive, commenting that accidents happen due to actions or inactions that span just minutes. Hitachi suggested a two-hour recording window would be more appropriate instead.

However, the Statute specifically mandates that locomotive image recording devices be capable of a minimum of 12 hours of continuous recording.[35] Accordingly, to comply with the Statute, this final rule cannot require anything less. Further, FRA disagrees that only the crew's actions immediately before an accident or incident are relevant to determining the cause of an accident or incident. The visual evidence of what was occurring in the time leading up to an accident or incident, including evidence of possible interactions with passengers or other persons, as well as evidence of outside objects striking or even entering the cab, can prove useful in any subsequent investigation of the accident or incident.

2. Feasibility of 24 Hours of Continuous Recording Capability

Responding to FRA's questions in the NPRM as to whether requiring passenger railroads to maintain a total of 24 hours of continuous recording capability would be feasible, Amtrak stated that the potential cost to double the recording timeframe from 12 to 24 hours would be ''astronomical,'' with only minimal additional benefits. According to Amtrak, the current marketplace does not have solutions that can capture recording time beyond approximately 14 hours and, under the hours of service laws, crews are only permitted 12 hours of continuous time on duty.

FRA agrees with Amtrak that the cost of a 24-hour recording timeframe would

[35] 49 U.S.C. 20168(b)(1).

outweigh the benefits, and that such a lengthy amount of recording time is not practical or necessary.

O. Privacy Considerations

FRA received several comments highlighting privacy concerns with FRA potentially taking possession of locomotive recordings as part of an accident investigation. The NPRM contains a detailed discussion of these privacy issues, and FRA specifically stated that it would ''rarely take possession of recordings.'' In its comments, APTA asserted that FRA should state that it will ''never'' take possession of recordings. According to APTA, the NTSB has protections in place that would protect the release of such recordings (49 U.S.C. 1114(c) and (d)), while FRA does not. APTA stated that FRA inspectors should be able to view any video or listen to any audio recordings, but to prevent the release of sensitive data, FRA should not take possession of the recordings. APTA asserted that FRA should not be allowed to take possession of recordings unless FRA has the same statutory prohibition as the NTSB protecting against the release of information.

The NTSB stated that it has longstanding legal restrictions and procedures in place that protect crew privacy and prevent the public release of sensitive onboard audio and video recovered in the accidents it investigates. The NTSB noted that 49 U.S.C. 1114(c) and (d) prohibit the agency from publicly disclosing voice and video recording from inside locomotive cabs involved in accidents or incidents. The law also specifies the circumstances under which the NTSB may make public an audio transcript or written depiction of visual information relevant to an accident or incident. Thus, the NTSB believes that current Federal law protecting against the public release of locomotive image or audio recordings during NTSB investigations is sufficient.

AAR also commented that the Statute stipulates that DOT may not disclose to the public ''any part of an in-cab audio or image recording . . . related to an accident or incident investigated by the Secretary.'' [36] According to AAR, the statutory language is clear that Congress intended to include both inward- and outward-facing cameras, and FRA should clarify in the regulatory text that ''in-cab'' means both inward- and outward-facing cameras, ''as colloquially, 'in-cab' refers to inward-facing cameras only.''

Finally, SMART commented that it supports the nondisclosure of audio and image recordings or transcripts of oral communications related to an accident investigated by FRA.

As raised in the comments, valid privacy concerns exist on the appropriate protection and dissemination of locomotive recordings that are made, particularly where an accident has occurred and the recordings may be graphic and violent. It is not desirable for railroad employees or their families to have such images released publicly. Congress has previously provided statutory protections for a train's audio and image recordings that the NTSB takes possession of during the course of its accident investigations (49 U.S.C. 1114(d) and 1154(a)). Therefore, when the NTSB takes possession of such locomotive recordings, it is prohibited from releasing the contents of the recordings (except that transcripts may be released as part of its accident investigation proceedings).

Similarly, the Statute (49 U.S.C. 20168(h)) prohibits FRA from publicly disclosing recordings that FRA takes possession of after a railroad accident has occurred. Subsection (h) of the Statute, which is similar to the FOIA exemption for locomotive recordings applicable to the NTSB at 49 U.S.C. 1114(d), prohibits FRA from disclosing publicly locomotive audio and image recordings, or transcripts of communications by and among train employees or other operating employees, or between such operating employees and communication center employees, related to an accident investigated by FRA.[37] Moreover, the Statute does not limit these protections to such recordings and transcripts of communications involving locomotives used only in intercity or commuter passenger train service. Section 20168(h)'s protections apply regardless of whether the underlying recording devices are required to be implemented by this final rule. Consequently, this subsection protects recordings and transcripts of communications involving locomotives on which the devices are voluntarily installed—notably, such locomotives used in freight service. In addition, FRA will apply these subsection (h) protections not just to recordings from inward-facing locomotive recording devices, but to recordings from outward-facing recording devices as well.

The Statute's prohibition on FRA disclosing publicly locomotive audio and image recordings or transcripts of oral communications among certain railroad employees addresses the concerns expressed by commenters. Therefore, FRA declines to adopt APTA's suggestion to ''never'' take possession of a locomotive recording. As stated in the NPRM, for the most serious of rail accidents, FRA anticipates that the NTSB will take possession of locomotive recordings, as they currently do, and that FRA will have the opportunity to view or listen to the recordings as a party to the investigation and in conducting its own parallel investigation under its separate statutory authority (49 U.S.C. 20107(a)(1)). However, in the vast majority of rail related accidents, the NTSB does not launch an investigation, and FRA is the sole Federal accident investigator. In these accidents or incidents, FRA normally attempts to view the recordings while they are still within the railroad's possession. However, if necessary, FRA has the statutory authority and obligation, as the Secretary's delegate to investigate railroad accidents, to take possession of locomotive image and audio recordings as part of an FRA accident investigation or investigation of a violation of a railroad safety law, regulation or order.[38]

P. Abuse of Locomotive Recording Devices

FRA received several comments expressing concerns that locomotive recording systems would be used as a form of retaliation against railroad employees, even though using passenger locomotive recording devices to retaliate against employees is prohibited by the Statute.[39] BLET commented that how locomotive recording devices are ultimately used is a critical issue for its members, and that the proposed rule contained no real protection from abuse. BLET asserted that, although the requirement that recordings be prohibited from being used to retaliate against an employee was well-intentioned, how retaliation is defined will be the key to ensuring whether Congress' intent to prevent recordings from being used as devices for retaliation will be realized. BLET also stated that FRA misunderstood Congress' non-retaliatory intent and that part 240 has been serially revised to thwart repeated attempts by numerous

[36] 49 U.S.C. 20168(h).

[37] Interested parties should note that FRA may make public a transcript or a written depiction of visual information that FRA deems relevant to the accident at the time other factual reports on the accident are released to the public.

[38] *See* 49 U.S.C. 20107(c).

[39] 49 U.S.C. 20168(i).

carriers to misuse its provisions as a way to discipline their certified engineer workforce. BLET asserted this will also occur with locomotive recording devices in the absence of a uniform set of standards and requirements for all locomotive recording devices that limits their use to legitimate accident investigations.

Hitachi also expressed concerns with how locomotive recording devices would be used and commented that there is significant room for abuse if the proposed analytic tools are used for purposes outside of the narrow scope defined by the proposed rule. Hitachi therefore recommended that FRA bar railroad operators or owners from utilizing recordings for purposes other than training or accident investigations.

SMART commented that FRA misinterpreted Congress' intent to prevent the use of locomotive recording devices for retaliation by concluding that the anti-retaliation provision of the Statute did not apply to railroad rules violations discovered via locomotive image or audio devices.[40] SMART claimed that the Statute is clear that in-cab audio or image recordings obtained by a passenger railroad cannot be used to retaliate against an employee, 49 U.S.C. 20168(i), and therefore FRA was reading something into the section not stated in the statute.

FRA disagrees with SMART's contention that the investigation of a railroad safety violation violates the Statute's anti-retaliation requirements. One of the purposes of this rulemaking is to use locomotive recording devices as a tool to identify and address safety violations that endanger public safety, such as personal electronic device usage while performing safety-critical duties. This purpose is not inconsistent with the Statute, which addresses retaliation implicated by other existing statutes (*e.g.,* the railroad employee whistleblower law at 49 U.S.C. 20109).

Amtrak commented that it already has an established company program and process in place governing the use of audio and visual recordings for compliance means only.

FRA disagrees with Amtrak's suggestion that a railroad's company policy is sufficient to prevent retaliation incidents. FRA proposed in the NPRM, and is now adopting in this final rule, several requirements to prevent railroad retaliation against trains crews and other railroad employees. This final rule, in compliance with the Statute,[41] specifically limits the purposes for which a passenger railroad may use a locomotive image or audio recording. In addition, to use any inward-facing locomotive recording device for operational testing, a passenger railroad must develop and comply with a program under part 217 to ensure that testing subjects are selected randomly and any operational test must be completed within 72 hours of an employee's tour of duty. This will prevent the selection of specific candidates for operational testing or being subject to review on footage for an extended period of time to find a potential Federal railroad safety or railroad operating rule to penalize the employee in question. Moreover, as discussed above, it is FRA's expectation that all railroads that voluntarily install recording devices on their locomotives will adhere to practices that are consistent with those required under this final rule, such as the new part 217 requirements that serve to protect employees from targeted testing as a form of retaliation when railroads conduct operational testing using recording devices or their recordings. For further discussion about these requirements, relevant comments, and FRA's response to those comments, please see Section II.L above.

Q. Recording Devices' Effect on Railroad Employees

BLET commented that monitoring the day-to-day performance of workers can have damaging effects outside any of the claimed benefits of the final rule. According to BLET, visual or audio surveillance will build resentment and a climate of distrust between the railroad and its workers. BLET asserted that no matter the privacy protections and respect of use adopted in passenger railroad policies, railroad employees will resent the presence of the locomotive recording devices and find their presence offensive, and there will be a multitude of unforeseeable consequences that neither FRA, nor the passenger railroads have considered.

It is likely that Congress took these concerns into account when mandating the installation of inward- and outward-facing image recording devices in all regularly scheduled intercity or commuter rail passenger locomotives in the Statute. Locomotive recording devices are not a novel technology. Locomotive cameras and recording devices have become common within locomotives over the past two decades. FRA does not believe this final rule will introduce a major change to the working conditions of a large segment of passenger train crews, as suggested by BLET.

R. Download and Security Features of Locomotive Recording Systems

1. Federally Mandated or Industry-Adopted Standard

FRA received several comments about the download and security feature requirements for locomotive image recording systems proposed in the NPRM (paragraph (d) of proposed § 229.136). Amtrak commented that this final rule should not regulate the download and security features of these systems, believing an industry-adopted standard is better suited to fit the technological capabilities of locomotive image recording systems. APTA agreed with Amtrak, and commented that passenger railroads should be allowed to develop their own best practices for conducting inspections and downloading data without prescriptive standards, stating that passenger railroads have been handling these downloads for quite some time.

In contrast, BLET commented that there should be uniform standards and requirements in this final rule for all locomotive-mounted recording systems, electronic downloads, and security features, such as encryption functions, etc. BLET stated that if this type of data is not encrypted and a strict chain of custody is not maintained, any credibility or value of using the data for post-accident investigation could be called into question. According to BLET, wireless transmission of audio or image recording data should also be prohibited to prevent such private, personal data from being hacked.

The standard FRA adopts in this final rule balances the concerns of the commenters. The standard adopted is broader than that proposed in the NPRM, which addressed electronic security measures only to prevent unauthorized downloads of recordings. As adopted in this final rule, § 229.136(d) requires passenger railroads to develop a system that allows only authorized downloads and has electronic security measures to prevent unauthorized access to, and download, deletion, or alteration of, the recording system or its recordings. FRA therefore expects that passenger rail will safeguard the recordings using encryption technology or equivalent data protection measures. However, this paragraph does not prescribe how such a system must be specifically created or structured, and recognizes that recordings must be accessible for review during an accident or incident investigation, as provided in 49 U.S.C. 20168(b)(3), and may be put to other lawful purposes, *see* § 229.136(f)(3). As a result, these requirements further

[40] 84 FR 35712, 35715 (July 24, 2019).

[41] *See* 49 U.S.C. 20168(d).

FRA's objective to protect the recording systems and their recordings, while providing railroads the flexibility on how to best achieve that protection, which will allow for differences in the specific systems used. For similar reasons, FRA disagrees that wireless download and transmission of audio or image recording data should be prohibited, because it would unduly restrict the technology that may be used. Whether data is downloaded and transmitted via wired or wireless technology, passenger railroads are responsible for ensuring the integrity of the process under § 229.136(d), which includes preventing the unauthorized downloading, deletion, or alteration of the recording system or its recordings.

2. Standard or Crashworthy Memory Modules

Hitachi commented that, as proposed, the requirements for download and security features of locomotive recording systems would seem to require both a standard and a crashworthy memory module. Hitachi stated that, if a crashworthy module meets all the requirements, then standard memory modules are unnecessary and could potentially create confusion.

FRA has not adopted the reference to standard memory modules in this final rule, as its inclusion in the NPRM was in error. Locomotive recording device data, whether it be audio or image recording data, must be stored on a crashworthy memory module. Because locomotive image or audio recordings cannot be stored on standard memory modules, the download and security features required of locomotive recording systems in § 229.136(d) refer only to certified crashworthy memory modules in this final rule.

S. Self-Monitoring and Self-Reporting Systems or Devices on Locomotive Image Recording Systems

1. Whether Cost of These Systems or Devices Was Adequately Considered

Wi-Tronix commented that locomotive image recording systems should be required to be self-monitoring and self-reporting, stating that the technology exists for these systems to monitor their own operational health and report their status. FRA agrees that a self-monitoring system is necessary to alert train crews and railroad maintenance crews conducting inspections whether the recording system is even working. Without a self-monitoring system, a locomotive could operate for an extended period of time without a functioning locomotive camera system.

APTA commented that the self-monitoring capabilities in the proposal did not appear to be a part of FRA's cost estimate for installation or ongoing operation and maintenance costs, and requested that FRA justify the requirement using a cost-benefit analysis. Although FRA did include the cost for self-monitoring capabilities in the NPRM's RIA, as FRA assumed that any locomotive image recording device would have a self-monitoring capability built into the initial design, FRA has updated the cost based on the comments that were received and provided a range of costs to better account for any variance that might occur in the cost of such devices.

2. Taking a Sample Download During a Periodic Inspection

In addition, APTA questioned the requirement that railroads take a sample download during a periodic inspection to ensure that the image recording system is functioning properly. APTA stated that passenger railroads need to limit those with the ability to download and access audio/image recordings, asserting that many railroads do not allow their maintenance personnel to do this. According to APTA, there could be a need to verify proper functioning during the periodic inspection, but taking a download should not be required and there are other ways to ensure proper functionality.

In the NPRM, FRA asked for comment on the types of restrictions that should be placed on sample recording device downloads from passenger train lead locomotives under proposed § 229.136(e)(2), as FRA anticipated that sample downloads for inspection or maintenance purpose might often be taken by non-managerial or operating employees, such as mechanical department employees in a locomotive repair facility. BLET responded by stating it is reasonable to conclude that railroads will need to check images and recordings from time to time to ensure the proper functioning of the system. However, BLET added that the individual checking the system should not also be conducting operational testing, unless that individual is qualified to do so and is authorized to perform operational tests, and requested that FRA require all recordings used for inspection or testing purposes to be deleted once system functioning is confirmed.

Based on the comments received, FRA is modifying the proposed requirement. Passenger railroads must still conduct a sample download from the image recording system's crashworthy memory module; however, FRA is changing the frequency of the download test from a periodic to an annual requirement. This change will reduce the need for railroad employees to download and observe image recordings. Of course, passenger railroads may ensure the proper functioning of a recording system at any time. The authority under § 229.136(f)(3)(vii) to perform inspection, testing, maintenance, or repair activities to ensure the proper installation and functioning of an inward-facing image recorder is not limited to fulfilling the minimum requirements of § 229.136(e)(2) to take a sample download from the image recording system's crashworthy memory module to confirm proper operation of the system.

FRA makes clear that the final rule requires the sample download for the annual test be taken directly from the image recording system's crashworthy memory module, or its equivalent in the case of remote storage approved under § 229.136(g). Taking the download from this memory module is necessary to ensure not only that the locomotive cameras are unobstructed and pointing in the correct position to capture crew activity, but to ensure that the camera system is properly recording to the memory module. For example, an inward-facing camera could be technically recording, but the camera could be out of focus. Further, this clarification is also intended to prevent any misunderstanding that passenger railroads could comply with this paragraph's testing requirements by simply streaming a recording from an image recording system without downloading the recording from the system's memory module. An actual download from the system's crashworthy memory module is required to ensure the integrity and proper functioning of the image recording system.

Although this final rule creates a specific annual test for locomotive image recording systems, passenger railroads must inspect the locomotive's image recording devices as part of other locomotive inspections required under part 229 (*e.g.,* daily, 33-day mechanical, 92-day periodic, and 184-day periodic inspection). During these inspections, the passenger railroad must note and correct any non-complying conditions related to locomotive recording devices that can be determined from these inspections, especially if it can be determined that the locomotive recording device is no longer functioning properly or there has been any tampering with the locomotive

recording system or any locomotive recording device.

T. Preservation and Handling Requirements for Locomotive Recording Devices and Recordings

1. Chain-of-Custody Requirements

In commenting on the preservation and handling requirement for passenger locomotive recording devices as proposed in the NPRM, APTA asserted that FRA did not account for the cost of the proposed chain-of-custody requirements as part of FRA's cost estimate for ongoing operation and maintenance costs added. APTA therefore requested that FRA justify these costs versus the established benefits. FRA acknowledges it inadvertently omitted these costs from the NPRM's RIA. FRA has revised the RIA accompanying this final rule accordingly to include these costs.

2. Prohibitions on the Public Release of Locomotive Recordings

FRA also received comments on whether FRA should create a specific provision that prohibits the public release of an image or audio recording by any person or railroad. BLET commented that there should be a restriction on public release, stating that without legal limitations upon disclosure, a regulatory scheme for governing the use of in-cab cameras presents a significant problem of public and personal privacy. According to BLET, FRA has not yet stated an intention to curb usage by the railroad carrier or shield employees from improper disclosure of sensitive footage, asserting that information from locomotive recorders should be strictly controlled to prevent posting on social media websites under the guises of promoting education and safety. BLET also asserted that FRA should prohibit a railroad from disclosing locomotive recording data of its employees to another railroad that is not the employing railroad. BLET added that if audio is recorded, it should be recorded on its own separate channel so it can be isolated for sound quality.

APTA commented that many agencies providing passenger rail service have significant protections in place to prevent the release of image or audio recordings, but stated that a specific provision, even limited in scope, prohibiting public release would supplement these agencies' existing policies and offer protections where other agencies have no such restrictions in place. The NTSB also commented that it supports FRA ensuring railroads have appropriate limitations established for the public release of in-cab audio and image recordings.

Under 49 U.S.C. 20168, which governs the installation of audio and image recording devices in passenger train service, Congress has limited the uses to which passenger railroads (49 U.S.C. 20168(d)) and the Secretary of Transportation (49 U.S.C. 20168(h)) can put locomotive image or audio recording device data, including those uses the Secretary deems appropriate under 49 U.S.C. 20168(d)(4). This final rule delineates those allowable uses of both image and audio recording device data in § 229.136(f)(3), and mere public disclosure is not an authorized use.[42] Indeed, as noted by a commenter, posting on social media websites under the guise of promoting education and safety is not an authorized use, nor can an image or audio recording obtained by a passenger railroad be used to retaliate against an employee.

Further, as provided in § 229.136(f)(2), image or audio recording system data from a locomotive in commuter or intercity passenger service that has been involved in an accident/incident that must be reported to FRA under part 225 of this chapter, can only be extracted and analyzed by the railroad for the purposes described in § 229.136(f)(3). The data cannot be used for any other purpose except by direction of FRA or another Federal agency. Likewise, FRA may not disclose publicly any part of an in-cab audio or image recording or transcript of oral communications by or among train employees or other operating employees responsible for the movement and direction of the train, or between such operating employees and company communication centers, related to an accident or incident investigated by FRA. However, FRA may make public any part of a transcript or any written depiction of visual information that FRA determines is relevant to the accident at the time a majority of the other factual reports on the accident or incident are released to the public.[43]

3. Application to Audio Recording Devices and Their Recordings

APTA separately commented that the requirements of § 229.136(f) pertaining to handling of recordings should not apply to audio recording devices or their recordings, stating that audio requirements were not part of the NPRM, and therefore should not be a part of the final rule. FRA disagrees. Although FRA did not propose in the NPRM and does not require in this final rule the installation of devices to record audio either inside or outside the locomotive cab, passenger railroads that have installed these devices or install these devices in the future must preserve resulting recordings according to the preservation and handling requirements of § 229.136(f)(2), if the locomotive is involved in a reportable accident or incident under 49 CFR part 225. Such information will be relevant to an accident investigation conducted by FRA, the NTSB, or other investigator.

4. Preservation Requirements Between Different Public Agency Rail Owners and Operators

APTA asked how the rule would address a situation where an accident occurs and one public agency owns the rolling stock, but another agency operates the rolling stock. APTA sought clarification as to which entity would be required to preserve the locomotive recording data.

The rule provides that the operating railroad at the time of the accident is responsible for maintaining the data. However, like many issues where there is shared usage of equipment between entities involved in providing passenger rail service, as a practical matter, FRA expects the entities to work such issues out by agreement. Such coordination among the entities involved in providing passenger rail service is also consistent with that expected under the System Safety Program rulemaking, 49 CFR part 270. The entities may mutually agree on fulfilling responsibilities under this final rule on each other's behalf, as tailored to their individual circumstances.

5. Providing Image and Audio Data in a Usable Format

APTA next asked how railroads could provide FRA or the NTSB image or audio data in a usable format when the software required for playback of such data downloaded from a locomotive is contractually controlled by a usage agreement involving the system's original equipment manufacturer (OEM), and the OEM requires each user of the software to sign the user

[42] While this rule delineates the allowable uses of image and audio recording device data, FRA notes that a private party may be required to disclose such data in a legal proceeding, such as a civil lawsuit, where the recording may contain probative information.

[43] 49 U.S.C. 20168(h). The NTSB restricts the public release of recordings it takes possession of during an investigation until its final report on the accident or incident has been published. However, once the final report has been released, the NTSB does not restrict the owner of any investigative information from publicly releasing that information, including in-cab locomotive recordings.

agreement. APTA asked how this situation would be handled and whether FRA or the NTSB would work directly with the OEM to acquire the software when the railroad has no legal ability to provide the software.

This question is a good example of why FRA is requiring railroads to either provide the image and/or audio data in a readable format, or make available any platform, software, media device, *etc.,* that is required to play back the image and/or audio data. FRA believes that whatever software the railroad uses could be put into a free format. The time to make a format change would be considered to be *de minimis.* FRA has found its accident investigations hindered when the recording devices used by passenger railroads were not in a usable format or the platform, software, or media device required the purchase of a system to play the image and/or audio data. It is not in the public's interest to inhibit FRA's use of locomotive image or audio recordings because they are in a format not readily accessible without the purchase of a unique program or other software or equipment from a private manufacturer. Therefore, it is FRA's intention through this final rule that the locomotive recording device record image or audio data be in a readily accessible format, or the railroad provide the program or other software or equipment so the locomotive recording can be accessed.

As noted above, entities providing passenger rail service may contract with other parties to fulfill the requirements of this rule and may therefore enter into agreements with manufacturers to develop their locomotive recording systems. FRA will not provide specific guidance on how the procurement and bidding process for such technology should be managed other than to reiterate FRA's concern as to the accessibility of the locomotive recording device data. Unless the recordings are in a readily available format for investigators to use, the post-accident value of the recordings and the accident investigations themselves may be impaired.

6. Permissible Uses for Locomotive Recording Devices

i. FRA Should Only Set Minimum Safety Requirements

APTA opposed FRA specifying in the NPRM permissible uses for locomotive recording device technology, asserting that the final rule should only set minimum safety requirements. APTA stated FRA should either not adopt such a proposal or instead take a broader approach that allows passenger railroads to develop their own uses for safety and security purposes. APTA cited to the experience railroads have using such data for several purposes, including investigating accidents. APTA added that allowing passenger railroads to use their locomotive image and audio recording devices to monitor locomotive cabs for unauthorized occupancy should be deleted as it could be interpreted as a requirement to use remote monitoring, which is not practical for the passenger railroad industry which operates thousands of trains a day.

FRA is adopting the permissible uses for locomotive recording devices as proposed. The Statute enumerates certain purposes for which passenger railroads may use locomotive recording device data and authorizes FRA, as the Secretary's delegate, to provide for other appropriate purposes.[44] Therefore, it would be contrary to the Statute to let passenger railroads set such purposes. Further, the provision allowing railroads to use recorder data to monitor unauthorized occupancy of the lead locomotive cab or cab car operating compartment comes directly from the Statute.[45]

The final rule does not require passenger railroads to remotely monitor their locomotives for unauthorized occupancy, though it allows passenger railroads to use their recording device data to do so. For further discussion on remote monitoring, please see Section II.G.

ii. Application to Freight Locomotive Recording Devices

In its comments, BLET stated that the permissible uses for locomotive recording device technology should apply to both passenger and freight railroads that voluntarily install locomotive recording devices. BLET further suggested that such a uniform set of standards and requirements provide for the encryption of image and voice recordings and access only by authorized personnel, to safeguard the identities of the recorded individuals. Moreover, in the event that surveillance data is used in disciplinary and/or certification revocation proceedings, BLET asserted that the identities of those who decrypt the data should be made known to the labor organizations representing the charged employees, and that such persons be made to testify as a witness at any discipline or revocation hearing, if requested by the labor organizations.

In addition, BLET commented that, in the NPRM, FRA repeated a misperception of what cameras can do to promote safety by asking whether there are other safety-appropriate uses for locomotive recordings. According to BLET, cameras provide no protection against accidents that would happen within an operational envelope, and do not prevent electronic device usage. BLET questioned what safety goal is achieved when a personal electronic device is found through locomotive recording data, when the recording itself could not prevent it. BLET also questioned the extent to which locomotive recording data in post-accident analysis can actually help in day-to-day operations. Overall, BLET believed locomotive recorders will serve only to document a problem someone already knew existed and negligence over time, but that safety will not improve as a result if the underlying issue is not addressed.

As previously noted, FRA lacks the justification to apply the requirements for permissible uses of locomotive recording device technology in this final rule to freight railroads, in accordance with FRA's implementation of the Statute. However, it is FRA's expectation that all railroads that voluntarily install recording devices on their locomotive will adhere to practices that are consistent with those in this final rule. In addition, BLET's suggestion to encrypt all locomotive recording data would unnecessarily increase the cost of this rulemaking, although FRA expects that encryption technology or equivalent data protection measures will be used, given the requirements in this final rule that such data may only be accessed by authorized personnel and its integrity be safeguarded against unauthorized download, deletion, or alteration. Finally, although FRA agrees that most of the benefits of this rulemaking will come from enhancing post-accident analysis through the information contained in locomotive recordings, FRA strongly disagrees that locomotive recording devices will provide no deterrence against personal electronic device use or other safety violations occurring during railroad operations. FRA also notes that, as identified by Congress, the recordings may serve to document a criminal act or monitor unauthorized occupancy of a locomotive.[46]

U. Factual Determinations When There Are Discrepancies Between Locomotive Image and Event Recorder Data

APTA commented that the NPRM did not address a situation where data from

[44] 49 U.S.C. 20168(d).

[45] *Id.*

[46] 49 U.S.C. 20168(d)(3).

a locomotive image recorder and an event recorder do not match and asked FRA which of the two devices will be determinative for factual considerations. FRA expects that any such discrepancies will be addressed on a case-by-case basis as part of the investigation following an accident or incident, taking into account the totality of the circumstances. This final rule does not make the data from one device primary over the other.

V. Personal Electronic Device Use and Locomotive Recording Devices

FRA discussed extensively in the NPRM how concerns about preventing accidents caused by distraction involving the use of personal electronic devices was one of the bases for this rulemaking, as well as the focus of NTSB recommendations and RSAC Working Group discussion. As a result, FRA received several comments about locomotive recording devices and how they would deter crewmembers from using personal electronic devices while performing safety sensitive service.

BLET commented that locomotive cameras will not deter negative behavior involving crewmembers or personal cell phone usage. BLET asserted that evidence shows individuals continued to use their personal phones when locomotive cameras were present, and that locomotive cameras will just show the behavior, which is already known to exist.

BLET also commented that FRA did not include a discussion in the NPRM on technology that can disrupt cell phone connectivity. BLET stated it partnered with Amtrak on a project that demonstrated the utility of technology that would both intercept cell phone connectivity outside of the locomotive and alert designated supervisors in real time of any attempt to use a cell phone. BLET found this to be a significant safety enhancement at relatively low cost, one that operates far less intrusively than inward-facing locomotive cameras, and noted that this technology was not mentioned in the NPRM as a potential ''alternative technology.''

Wi-Tronix commented that major passenger train incidents over the past decade proved that distracted driver operation is a critical problem and that technology also exists to monitor such activity in locomotive cabs. Wi-Tronix stated that the integration of image and audio recording data and the detection of such data in cellular logs, when integrated and synchronized with event recorder data, make an extremely powerful tool for accident/incident investigation and to influence behavior.

While BLET is correct that the presence of inward-facing locomotive recording devices will not entirely prevent the usage of personal electronic devices when performing safety-sensitive service, the presence of these devices will nonetheless provide a deterrent effect. FRA found a study by the Virginia Tech Transportation Institute that examined the change in commercial truck driver behavior when an image recording device was within the cab of the vehicle.[47] The study found that the two carriers which participated experienced a 27 percent and 52 percent reduction in human factor events per miles traveled, respectively.[48] While these results cannot be applied directly to the railroad industry, the study provides additional evidence that locomotive image recording devices can alter operator behavior, and thus reduce human factor accidents. However, as noted within the Virginia Tech study, any altering of operational behavior is most likely to be more prominent at the beginning of the observation period, and behavior could revert as time passes. Further, the presence of locomotive recording devices will help FRA and railroads identify individuals who violate Federal regulations against personal electronic device usage in part 220, subpart C, and various other railroad operating rules prohibiting cell phone usage.

Moreover, aside from the deterrent effect locomotive recording devices have in preventing personal electronic device usage, the recording devices provide other important safety functions unrelated to personal electronic device usage. For example, one of the primary functions of locomotive recording devices is to provide information as to the causes(s) of a railroad accident or incident. Therefore, although FRA encourages the use and development of technology to promote safety, the technology described by the commenters to detect or prevent personal electronic device usage cannot be considered an ''alternative technology'' for purposes of the statutory requirement to install inward- and outward-facing locomotive image recorders.

W. Positive Train Control

Railroad carriers providing ''intercity rail passenger transportation'' and ''commuter rail passenger transportation'' subject to this final rule are covered by 49 U.S.C. 24102 (passenger railroads required to install PTC systems under 49 U.S.C. 20157(a)). Although FRA did not specifically request comments on PTC, FRA received several comments relating to PTC technology, the nature of the overlap between passenger railroads required to install PTC and locomotive image recording devices, and the interaction between locomotive recording devices and PTC systems. Specifically, commenters asserted that passenger railroads should not be required to divert resources from installing, maintaining, and operating PTC systems to address the recording device requirements in this rulemaking.

APTA cited the accidents and associated NTSB recommendations discussed in the NPRM and stated that almost every one of the accidents would have been prevented by a functioning PTC system. In addition, APTA stated that most were accidents involving freight trains, not passenger trains.

Hitachi agreed with APTA that all the accidents discussed in the NPRM were arguably PTC-preventable accidents. Hitachi believed that, although image recording devices could prove useful as accident investigation tools in the future, accident prevention should currently be the primary focus and, as a result, railroads should not divert valuable resources from operating and maintaining PTC equipment ''to meet well-intentioned, but misguided FRA mandates.''

BLET also took issue with the accidents FRA discussed in the NPRM. BLET pointed out that two of the accidents, the 2008 accident in Chatsworth, California, and the 1999 accident in Bryan, Ohio, led to the NTSB recommending both the installation of PTC and the installation of locomotive image recording devices. According to BLET, the NTSB stated that PTC could have prevented these accidents from occurring. Therefore, BLET questioned why locomotive image recording systems would be appropriate where PTC is installed and operating, except perhaps to use outward-facing cameras to document signal visibility due to dense fog, which was at issue in the Bryan, Ohio, accident.

Additionally, FRA received a comment from a private citizen who stated that outward-facing locomotive recording devices offer no preventative qualities. The commenter believed that resources dedicated to outward-facing recording systems detract from finite resources available for safety, installing a form of PTC technology would be a

[47] Hickman, Jeffrey S., Richard J. Hanowski, and Olu Ajayi. *Evaluation of An Onboard Safety Monitoring Device In Commercial Vehicle Operations.* Report. Federal Motor Carrier Safety Administration, Virginia Tech Transportation Institute (2009).

[48] *Id.*

much better use of those resources, and that this final rule should not be adopted until PTC technology is installed on all rail miles.

FRA understands the concerns raised by commenters and does not dispute the commenters' assertion that many, if not all, of the accidents cited in the NPRM could have been prevented by the implementation of PTC systems, nor does FRA dispute the safety benefits of PTC systems. However, PTC is not an adequate ''alternative technology'' under the Statute, as PTC and locomotive recording devices serve different safety functions. PTC is designed to prevent certain accidents, and, although locomotive recording devices do have the potential to help prevent accidents, one of the main purposes of locomotive recording devices is to record information to provide to investigators after an accident or incident has occurred.[49] The information recorded by the recording devices cannot normally be provided by the PTC system, or other similar technology.

All PTC systems must be designed to prevent train-to train collisions, over-speed derailments, incursions into established work zones, and movement of trains through switches left in the wrong position, in accordance with the requirements of 49 CFR part 236, subpart I. As touched on above, one of the primary uses of locomotive recording devices is for investigating railroad accidents or incidents caused by human factors where standard event recorders can provide little or incomplete information about what occurred in the locomotive cab prior to the accident or incident.[50] PTC may be able to provide some information, but not a full accounting of the train crew's actions immediately before an accident. Therefore, PTC is not an adequate technology to replace the locomotive recording device requirements in the Statute.

As previously stated, the Statute requires the promulgation of regulations requiring passenger railroads to install recording devices in all controlling (or ''lead'') locomotives. When the locomotive recording devices statutory mandate was enacted, the statutory mandate to implement PTC on passenger railroads had long been in place.[51] In fact, between Congress' initial PTC mandate in 2008 and the Statute in 2015, Congress continued to be actively engaged in PTC policymaking through legislation and other activities. Congress held multiple oversight hearings about the technology and passed another piece of PTC legislation approximately five weeks prior to the passage of the Statute. It is clear that Congress passed the locomotive recording devices mandate for passenger trains with the awareness that the same passenger railroads would also be required to install PTC systems. As a result, FRA does not believe Congress intended PTC systems to be considered an ''alternative technology'' under the Statute that would excuse passenger railroads from implementing locomotive recording devices.

X. Locomotive Image Recorder Analytics

Wi-Tronix commented that data created by locomotive image recorders will need to be accessed for artificial intelligence and image analytics purposes, stating that artificial intelligence and image analytics are key elements to improving industry safety, as seen in the automotive industry. As a result, Wi-Tronix asserted there needs to be a mechanism to allow for sharing anonymous data for use in improving safety and operations.

FRA declines to develop a mechanism in this rule for sharing anonymous data from locomotive image recording devices. The Statute did not mandate the establishment of such a mechanism, and FRA expects that passenger railroads would be reluctant to share the data due to the need to address proprietary, liability, privacy and other potential issues and concerns. Although FRA strongly supports the use of data to promote safety purposes, this final rule is not the appropriate forum for imposing such a requirement, consideration of which would require the involvement of all stakeholders. See also the discussion under Section II.L.5 above, noting that this final rule will not affect the adoption of C3RS programs, which allow railroad employees to raise safety incidents confidentially and generate reports based on such incidents without identifying data.

Y. Procurement of Locomotive Recording Devices

Hitachi commented that FRA should investigate and suggest updates for procurements, to favor transit agencies, considering the best technology or exploring the most advanced technological applications. FRA declines to adopt this suggestion, as it is beyond the scope of this rulemaking. FRA's purpose in this final rule is to implement the statutory mandate to establish minimum standards for inward- and outward-facing locomotive image recording systems for passenger railroads. Railroads may, of course, exceed these minimum standards and work together in procuring and applying the technology, including the development of industry specifications and best practices consistent with this rule.

Z. Application of the Rule to GP-Style Long-Hood Locomotives

APTA provided a comment specific to commuter railroads that utilize some general purpose (GP)-style locomotives with one cab only on the short-hood end, and a narrow car body on the long-hood end. These locomotives can operate in the lead with the long- or short-hood forward while in revenue service. APTA sought clarification whether the long-hood of these locomotives must comply with the final rule, even if operated only occasionally long-hood forward, and believed that such use should be excluded by the final rule.

FRA disagrees with APTA's comment that these locomotives should be excluded from the final rule's requirements. If a railroad operates such locomotives long-hood forward in regularly scheduled passenger service, however occasionally the locomotive configuration may be used, the long-hood must be equipped with an outward-facing image recording device in the direction that the locomotive is traveling. FRA disagrees with APTA, in part, because an exclusion could incentivize use of locomotives in this configuration. FRA addresses the costs associated with long-hood forward use of locomotives in this final rule's RIA by increasing the number of impacted locomotives affected by the final rule.

AA. Inclusion of Passenger Railroad Cab Cars in the Rule's Requirements

Wi-Tronix, believing that passenger railroad cab cars may not be locomotives, commented that it would be critical that cab cars be covered by this final rule's requirements applicable to locomotives. FRA makes clear that cab cars are indeed locomotives subject to this final rule. Cab cars are formally recognized by the existing definition of ''control cab locomotive'' in § 229.5 to mean a ''locomotive.''

[49] *See* 49 U.S.C. 20168(d)(2) (Railroad carriers subject to the Statute may use recordings from inward- or outward-facing image recording devices for ''[a]ssisting in an investigation into the causation of a reportable accident or incident'').

[50] *See* also 49 U.S.C. 20168(d)(1) (Railroad carriers subject to the Statute may use recordings from inward- or outward-facing image recording devices for ''[v]erifying that train crew actions are in accordance with applicable safety laws and the railroad carrier's operating rules and procedures, including a system-wide program for such verification'').

[51] *See* 49 U.S.C. 20157(a).

III. Civil Penalties

FRA did not request or receive any comments regarding the potential civil penalties FRA could issue for violations of new or amended requirements in this final rule. FRA will modify the schedule of civil penalties on its website [52] to reflect the requirements of the final rule. Because such penalty schedules are statements of agency policy, notice and comment are not required before their issuance, and FRA did not propose a penalty schedule in the NPRM.[53]

FRA is authorized to assess a civil penalty of at least $976 and not more than $31,928 per any violation of the requirements established in this final rule.[54] However, penalties up to $127,712 may be assessed for a grossly negligent violation or a pattern of repeated violations that created an imminent hazard of death or injury to individuals, or has caused death or injury.[55] In accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, these minimum and maximum penalty amounts will be adjusted for inflation in the future.

IV. Discussion of Amendments to Part 299 Pertaining to Texas Central Railroad Trainset Image Recording Systems

Texas Central Railroad (TCRR) intends to implement a high-speed passenger rail system by using the Tokaido Shinkansen system's service-proven technology and by replicating Central Japan Railway Company's (JRC) operational and maintenance practices and procedures. The contemplated system will run between Dallas and Houston, Texas, with an intermediate stop in Grimes County, Texas, approximately 240 miles, at a speed not to exceed 205 mph. TCRR plans to implement the latest, service-proven derivative of the N700 trainset and other core systems currently in use on the Tokaido Shinkansen line, which have been refined for high-speed operations over the last 50-plus years.

On November 3, 2020, FRA published a final rule establishing regulatory requirements applicable only to TCRR—a rule of particular applicability (RPA).[56] Such a regulation, in addition to providing for regulatory approval, institutes a comprehensive regulatory framework that provides TCRR clarity on the minimum Federal safety standards that it must comply with through technology-specific, performance-based requirements. Through the RPA, FRA is able to protect the integrity of the Tokaido Shinkansen system as implemented in Texas, by establishing regulatory requirements codifying the service-proven technological, operational, and maintenance aspects of the Tokaido Shinkansen high-speed rail system operated by JRC.

On March 10, 2020, FRA published an NPRM proposing a set of safety requirements for TCRR (the TCRR NPRM). FRA proposed to make FRA's regulation implementing section 11411 of the FAST Act applicable to TCRR's high-speed trainsets used in revenue service.[57] However, the TCRR final rule was published before this final rule implementing section 11411 of the FAST Act. Accordingly, FRA noted in the TCRR final rule that it would make revisions to the TCRR final rule as part of this final rule.[58] The amendments to § 299.5 adopted in this final rule and new § 299.449 reflect these revisions.

During the 77-day comment period on the TCRR NPRM, FRA received comments from TCRR on the topic of locomotive image recorders. TCRR requested that FRA exercise its statutorily granted discretion under 49 U.S.C. 20168(e)(2) and exempt TCRR from the requirement to install inward- and outward-facing image recording devices, asserting that TCRR will implement an alternative technology or practice that provides an equivalent or greater level of safety or is better suited to the risks of the operation. In support of its request, TCRR stated that such alternative technologies or practices to be employed include: a signaling system that will comply with the requirements for PTC under 49 U.S.C. 20157 and be installed throughout the TCRR system (including trainset maintenance facilities) and used at all speeds; a dedicated, fully fenced (except for elevated structures), grade-separated right-of-way; an intrusion detection system; a right-of-way barrier plan to protect against unauthorized incursions into the right-of-way and from adjacent highway and freight rail operations; and wind, rain, and flood hazard detectors located at specific sites along the right-of-way.

FRA recognizes and appreciates the mitigations that TCRR will have in place under part 299 and that those mitigations are modeled on the very successful Tokaido Shinkansen system. However, even with all the mitigations TCRR is putting in place to avoid any form of accident/incident, it is in the interest of railroad safety to require TCRR to install image recording systems in its high-speed trainsets. Notably, should an event occur despite the mitigations put in place by the railroad, it will be even more crucial to have imagery from the recording system to determine how the event occurred and/or what was occurring in the controlling cab of the trainset in the time before and during the event. See also the discussion under Section II.W of this final rule, noting that FRA cannot consider PTC an adequate ''alternative technology'' to installation of inward- and outward-facing image recording devices for purposes of the statutory exemption. Accordingly, TCRR is not exempt from the requirement to install inward- and outward-facing image recording devices.

Contrary to the discussion in the TCRR NPRM, in which FRA stated it would make appropriate conforming changes to the requirements outlined in the NPRM, essentially making the requirements of § 229.136 applicable to TCRR, FRA is adding § 299.449 to part 299 to contain the specific requirements for the image recording system applicable only to TCRR.[59] Placing the requirements that are specific to TCRR in part 299 allows FRA to properly tailor the requirements to the TCRR system and operation.

Section 299.449, as adopted in this final rule, reflects FRA's efforts to tailor the locomotive image recorder requirement to TCRR's equipment and operation and to address TCRR's comments. Section V, Section-by-Section Analysis, below, contains a discussion of the changes made and codified under §§ 299.5 and 299.449, and under appendix A to part 299, Criteria for Certification of Crashworthy Event Recorder Memory Module. FRA has made both editorial and substantive changes in applying the rule text in § 229.136 and appendix D to part 229 to TCRR's rule of particular applicability, part 299. The changes ease understanding of the various requirements, as applied to TCRR, including clarifying whether a requirement pertains to a component of the image recording system (such as an

[52] *www.railroads.dot.gov.*

[53] *See* 5 U.S.C. 553(b)(A).

[54] *See* 87 FR 15839 (Mar. 21, 2022).

[55] *See Id.*

[56] *See* 85 FR 69700 (Nov. 3, 2020).

[57] *See* 85 FR 14036, 14041 (Mar. 10, 2020); *see* also 84 FR 35712 (Jul. 24, 2019).

[58] *See* Section V.C, Trainset Image Recording System, of the TCRR final rule, 85 FR 69700, 69714.

[59] The TCRR final rule explained that, because the image recording device rulemaking was not finalized at the time the TCRR rule was finalized, FRA would ''make any necessary changes to [the TCRR] regulation as a part of'' the image recording device final rule. 85 FR 69700, 69715 (Nov. 3, 2020).

image recording device) or whether a requirement pertains to the image recording system as a whole. The substantive changes were made to tailor the rule text appropriately for TCRR's system.

V. Section-by-Section Analysis

This section responds to public comments and identifies any changes made from the provisions as proposed in the NPRM. Provisions that received no comment, and are otherwise being finalized as proposed, are not discussed again here.[60]

Amendments to 49 CFR Part 217

Section 217.9 Program of Operational Tests and Inspections; Recordkeeping

In this final rule, FRA is clarifying its intent to exclude freight railroads from these requirements by using the term ''passenger railroad,'' instead of ''railroad,'' throughout paragraphs (b)(3) and (4).

FRA is also adding audio recordings to paragraph (b)(3)(iii). Although proposed paragraph (b)(3)(iii) did not expressly mention audio recordings as subject to the 72-hour limitation on operational tests or inspections after completion of the employee's tour of duty, the omission of audio recordings was inadvertent and not consistent with proposed paragraph (b)(3) as a whole. For instance, proposed paragraph (b)(3)'s introductory text made clear that operational tests and inspections involving inward-facing image or in-cab audio recordings must comply with the conditions in paragraphs (b)(3)(i), (ii), and (iii). Further, it would not make sense for FRA to require passenger railroads to select testing subjects at random for operational testing involving inward-facing locomotive image recordings, but allow the potential for specific employees to be targeted for operational testing with audio recording devices. Therefore, FRA is correcting the inadvertent omission in this final rule. Accordingly, while the final rule does not require passenger railroads to install audio recording devices of any kind, if passenger railroads choose to install such devices and then use them for operational testing, the same protections for operational testing and use of image recorders also apply for operational testing and use of audio recorders.

Amendments to 49 CFR Part 218

Section 218.53 Scope and Definitions

FRA is revising paragraph (d) of this section to make clear that the provisions in §§ 218.59 and 218.61 do not apply to locomotive-mounted image or audio recording equipment on freight locomotives. FRA's use of ''or,'' instead of ''and'' as proposed in the NPRM, is to avoid the potential ambiguity that both image and audio recording equipment on a freight locomotive must be present for the exclusion to apply. It is FRA's intention that §§ 218.59 and 218.61 will not apply to either type of recording device on a freight locomotive, whether alone or in combination.

Section 218.61 Authority To Deactivate Safety Devices

FRA is also revising subsection (c) of this section to read that the requirements of this section do not apply to inward- or outward-facing image recording devices that are installed on freight locomotives, instead of inward- and outward-facing image recording devices on freight locomotives. Like its revision in § 218.53, FRA is substituting the word ''and'' with ''or'' to avoid the potential ambiguity that both an inward- and outward-facing image recording device must be present on a freight locomotive to avoid the application of this section, when the presence of either an inward- or outward-facing image recording device is sufficient to avoid the section's requirements.

Amendments to 49 CFR Part 229

Section 229.5 Definitions

Although proposed in the NPRM, FRA is not amending this section to add a definition for ''NTSB'' as the acronym for the National Transportation Safety Board, an independent U.S. government investigative agency responsible for civil transportation accident investigation. The term is not used in any of the amended or new language being added to part 229 by this final rule.

Section 229.21 Inspections and Tests

FRA is making conforming changes to § 229.21 to reflect the allowance for movement beyond a calendar day inspection point of a lead locomotive in long-distance intercity passenger train service with a locomotive image recorder system or device defect. See the discussion in the Section-by-Section analysis of § 229.136, below, as well as Section II.I (Repairing, Replacing, or Removing Locomotive Image Recording Devices From Service) within the Discussion of Specific Comments and Conclusions, above. Although not expressly proposed in the NPRM, these changes are limited only to such long-distance intercity passenger trains led by locomotives subject to this final rule's locomotive image recorder requirements—and only to the handling of such locomotive image recording systems or devices. FRA intends no other changes to this section's application or effect.

Section 229.22 Passenger Locomotive Inspection and Repair Record

FRA has added this section in preparing the final rule to establish use of new Form FRA F 6180–49AP (Passenger Locomotive Inspection and Repair Record) to collect Federally required locomotive inspection, testing, and repair information for lead locomotives in commuter or intercity passenger train service, including information for locomotive recording devices. This new form is based on existing Form FRA F 6180–49A (Locomotive Inspection and Repair Record), which has been used for many years as the centralized record of Federally required inspection, testing, and repair information for all locomotives, as defined broadly in § 229.5. Form FRA F 6180–49AP, as the new counterpart to Form FRA F 6180–49A, will include a designated row for entering information about annual testing of locomotive image recording devices required under § 229.136, consistent with the designated row on Form FRA F 6180–49A (as well as new Form FRA F 6180–49AP) for entering information about required locomotive event recorder testing. Form FRA F 6180–49AP will also continue to be organized to fit on one double-sided page, for ease of use and printing and copying.

Establishing use of the new F 6180–49AP form for lead locomotives in commuter or intercity passenger train service will help avoid any potential confusion for freight railroad operators as to the application of locomotive recording device requirements under this rule, and also conserve valuable space on the existing F 6180–49A form. Freight railroads operate the vast majority of locomotives, and the locomotive recording device requirements in this rule do not apply to locomotives in freight service, or to locomotives used in switching service. Nor will the rule affect use of the F 6180–49A form by non-lead locomotives in commuter or intercity passenger train service.

To phase-in use of new Form FRA F 6180–49AP for lead locomotives in commuter or intercity passenger train service, § 229.22 expressly permits continued use and maintenance of Form FRA F 6180–49A until October 12,

[60] 84 FR 35,712.

2027, when all such locomotives will be required to be equipped with image recording devices compliant with § 229.136. In providing broad flexibility, § 229.22 also makes clear that railroads may adopt use of Form FRA F 6180–49AP earlier than required.

Section 229.136 Locomotive Image and Audio Recording Devices

FRA is making changes in this section's regulatory text from the NPRM. In various paragraphs, the changes remove redundant words or phrases from the proposed language to streamline the final rule. Where these and other purely stylistic textual changes do not modify the meaning or requirements of the paragraphs or this section, they will not be addressed in the analysis below.

FRA is modifying the headings for paragraphs (b), (c), (d), and (e) by inserting the word ''lead'' into each paragraph heading, to clarify that only passenger locomotives in the lead position must comply with these paragraphs' requirements. FRA is also adding clarifying text to avoid any confusion as to the applicability of this section's requirements to recording devices or systems voluntarily installed in locomotives. FRA has therefore inserted ''as required under paragraph (a)(1) or (2) of this section'' to make clear that the corresponding text applies only to locomotives required to be equipped with recording devices or systems under paragraph (a)(1) or (2) of this section.

In paragraph (a)(3), FRA has changed the name of the form referenced in this paragraph from ''Form FRA F 6180–49A'' to ''Form FRA F 6180–49AP,'' as FRA has created this new form specifically for passenger locomotives subject to the requirements in this final rule. Passenger railroads must still note the presence of any image or audio recording system in the REMARKS section; however, passenger railroads must use new Form FRA F 6180–49AP for their lead locomotives used in commuter or intercity passenger train service.

In paragraph (a)(5), FRA is adding language making clear that locomotive recording device data can be stored on a certified crashworthy event recorder memory module or an alternative, remote storage system that provides equivalent data protections if approved by FRA. See Section II.E.2 (Potential Exemptions From the Crashworthy Memory Module Requirements) for a detailed discussion of FRA's considerations in approving a remote storage system as part of the locomotive recording system approval process. FRA has added paragraphs (a)(5)(i) and (ii) to clarify when required image recording and voluntarily installed audio recording devices on lead locomotives must comply with the paragraph's requirements. Paragraph (a)(5)(i) references paragraphs (a)(1) and (2) for when image recording devices on lead locomotives must comply with this paragraph's requirements, while paragraph (a)(5)(ii) specifies when voluntarily installed audio recording devices on lead locomotives must comply with the same requirements. FRA added these paragraphs because the NPRM was unclear when voluntarily installed audio recording devices on lead locomotives in commuter or intercity passenger service would be required to record their data to a certified crashworthy event recorder memory module or FRA-approved remote storage system.

FRA is not adopting the language proposed in paragraph (c)(1)(i) specifying that the locomotive inward-facing camera system have sufficient resolution to record whether a crewmember is physically incapacitated and whether a crewmember is complying with the indicators of a signal system or other operational control system. Instead, FRA is simply retaining the requirement that the inward-facing camera system have sufficient resolution to record crewmember actions, without the more prescriptive language. FRA reiterates that this paragraph does not require the real-time monitoring of passenger train crews. Please see the above discussion in Section II.G (Inward-Facing Locomotive Image Recording Systems and Devices).

FRA is also renumbering paragraph (c) for clarity. The proposed regulatory language in paragraph (c)(1)(ii) is now contained in paragraphs (c)(1)(ii) and (iii) in this final rule. Similarly, the regulatory language in proposed paragraphs (c)(2), (3), and (4) is now found in paragraphs (c)(1)(iv), (2), and (3), respectively. In addition, FRA is adding the phrase ''on image recordings'' in paragraph (c)(1)(iv) for clarity.

FRA is modifying and broadening paragraph (d) from the proposal in the NPRM to make clear that, in addition to unauthorized downloads, passenger railroads must also take necessary protective measures against unauthorized access to the recording system and its recordings that could lead to the deletion or alteration of data. Likewise, paragraph (d)'s heading now refers to ''protection requirements,'' rather than ''download protection requirements,'' to make clear this paragraph's requirements address measures to protect the integrity of the recording system more than just protecting against unauthorized downloads. In addition, as stated above in Section II.R (Download and Security Features of Locomotive Recording Systems), the reference to standard memory modules in this paragraph was proposed in error and has not been retained.

FRA is also adding paragraphs (d)(1) and (2) to clarify when required image recording and voluntarily installed audio recording devices on lead locomotives must comply with paragraph (d)'s requirements. Paragraph (d)(1) includes requirements for image recording devices on lead locomotives, while paragraph (d)(2) addresses requirements for voluntarily installed audio recording devices on the same locomotives. The language FRA is adopting in paragraphs (d)(1) and (2) is nearly identical to that which FRA is adopting in paragraphs (a)(5)(i) and (ii). Similar to those new paragraphs, which are discussed above, FRA is adding these paragraphs to paragraph (d) because the NPRM was unclear when voluntarily installed audio recording devices on lead locomotives in commuter or intercity passenger service would have to meet the paragraph's requirements.

In paragraph (e), FRA is modifying paragraph (e)(1) so that it directly references the requirements in paragraph (i) for the removal from service and handling for repair of inward- and outward-facing image recording systems. FRA had initially proposed referencing the daily inspection requirements in § 229.21 (Daily inspection). However, as discussed in Section II.I (Repairing, Replacing, or Removing Locomotive Image Recording Devices From Service), FRA has modified the requirements for the removal from service and handling for repair of inward- and outward-facing image recording systems on long-distance intercity passenger trains, as specified in paragraph (i) of this section.

FRA is also modifying paragraph (e)(2)'s requirements based on comments it received, which are discussed above in Section II.S (Self-Monitoring and Self-Reporting Systems or Devices on Locomotive Image Recording Systems). Specifically, paragraph (e)(2) makes clear that the required sample download(s) must be taken directly from the image recording system's crashworthy memory module, or FRA-approved remote storage system, to confirm proper operation of the system. Paragraph (e)(2) also now provides for taking the required sample

download(s) during a locomotive's annual test required under § 229.27, Annual tests.

Information concerning the results of this annual test must be entered on new Form FRA F 6180–49AP in a row specifically dedicated for this purpose. The added row on the new form parallels, and is directly below, the row for entering information concerning the results of event recorder tests required by §§ 229.25(d) and 229.27(c), and provides for entering the same information as for other required tests.

In paragraph (f), the exception to a railroad's use of image or audio recording device data in paragraph (f)(2)(ii) applies by direction of FRA or ''another Federal agency,'' including but not limited to the NTSB. This change is consistent with the use of similar forms of ''another Federal agency'' throughout paragraph (f)(2) and clarifies that another Federal agency is not limited to the NTSB. FRA is also modifying the language in paragraph (f)(3)(vii) to make clear that a railroad may perform inspection, testing, maintenance, or repair activities on an ''image or audio recorder,'' and not only an ''inward-facing image recorder'' as stated in the NPRM, to ensure proper installation and functioning. Passenger railroads may of course perform such activities on inward- or outward locomotive image or audio recording devices at any time.

In paragraph (g), FRA is requiring a ''description'' of the technical aspects of any locomotive image recording system intended to comply with this section, rather than a ''written description'' as proposed in the NPRM. In addition, paragraph (g) specifies an email address rather than a mailing address for submitting the description to FRA. FRA has made these changes to encourage and promote the electronic submission of the information to FRA. This final rule also clarifies that railroads should submit to FRA a description of the technical aspects of any locomotive image recording system ''intended'' to comply with the section, rather than after a recording system has been ''installed,'' as stated in the NPRM. FRA revised this language as it is rational that railroads would seek FRA's approval of their locomotive image recording systems before spending money to install a potentially non-approved system on their locomotives.

Further, FRA is correcting paragraph (g)(2)'s submission date requirements, to address an inadvertent error in the proposed rule, and also modifying paragraph (g)(3) to make clear that FRA must review a railroad's submission and approve any locomotive image recording system before the system can be installed or put into service in compliance with this section. Please see Section II.J (FRA Approval Process for Locomotive Image Recording Systems and Devices) above, for more detailed discussion of these revisions.

In paragraph (i), FRA is inserting the word ''alone'' into the regulatory text to clarify that a locomotive with only an out-of-service image recording device is not considered to be in an improper condition, unsafe to operate, or a non-complying locomotive under §§ 229.7 and 229.9. However, as unchanged from the NPRM, paragraph (i) also makes clear that a railroad must remove the device from service if the railroad knows the device is not properly recording. Further, when a railroad removes a locomotive image recording device from service, a qualified person must record the date the device was removed from service under the REMARKS section of Form FRA F 6180–49AP—not Form FRA F 6180–49A. For a more extensive discussion of this requirement, please see Sections II.H (Notice Provided When Locomotive Recording Devices Are Present) and II.I.3 (Documenting When a Locomotive Image Recording Device Has Been Removed From Service), above.

In addition, except for long-distance intercity passenger trains, a locomotive with a defective image recording device may remain as the lead locomotive only until the next calendar-day inspection required under § 229.21. This includes a lead locomotive in a commuter train with an image recording device found defective at an outlying inspection point, which may remain as the train's lead locomotive only until the next calendar-day inspection required under § 229.21. As discussed above in Section II.I (Repairing, Replacing, or Removing Locomotive Image Recording Devices From Service), FRA has expanded the movement-for-repair allowance for a long-distance intercity passenger train's lead locomotive with a defective image recording device so that it may remain as the lead locomotive until arrival at its destination terminal or its nearest forward point of repair, whichever occurs first.

FRA notes that the rule does not specify how a railroad shall indicate on the F 6180–49AP form when a locomotive image recording device is returned to service. This is intended to provide railroads the flexibility to denote this information in the REMARKS or the REPAIRS section of the F 6180–49AP form, or in an equivalent location.

FRA is adding paragraph (l) to exclude from compliance with the requirements of this section freight locomotives acting as passenger locomotives when they are performing rescue operations for intercity or commuter passenger trains. Please see the above discussion in Section II.A.3 (Application of Requirements to Freight Locomotives Performing Rescue Operations).

Finally, FRA is revising the introductory paragraph of appendix D to part 229 to clarify that data from image and voluntarily-installed audio recording systems must be recorded on a certified crashworthy memory module or on an alternative, remote storage system that provides equivalent data protections and is approved by FRA.

Amendments to 49 CFR Part 299

Section 299.5 Definitions

Consistent with the revisions made to part 229 in this final rule, FRA is adding three new definitions to part 299: ''Event recorder memory module'', ''Image recording system'', and ''Recording device''. These define key components of what comprises the image recording system and are substantively similar to the definitions of the same terms in § 229.5. The definitions in part 299 differ only slightly from those in part 229 to reflect editorial revisions to harmonize the definitions with the rest of part 299.

Section 299.449 Trainset Image and Audio Recording System

Section 299.449 is based on § 229.136. Similar to § 229.136, FRA is requiring all TCRR high-speed passenger trainsets used in revenue service to be equipped with an image recording system as described under § 299.449 prior to commencing revenue operations. However, because TCRR is not yet operating, it does not need to avail itself of an implementation period for this requirement, as in § 229.136(a), and FRA has not included one.

As provided in § 229.136(a)(3), if a locomotive is equipped with an image or audio recording system, that fact must be annotated on the locomotive's Form FRA F 6180–49AP. FRA is not including this annotation requirement in § 299.449, however, as TCRR is not required to use Form FRA F 6180–49AP.

FRA has also revised the language in § 299.449(a)(4) to clarify that TCRR's locomotive image recording device data must recorded on either a certified crashworthy memory module or an alternative, remote storage system that provides at least equivalent data protections and has been approved by FRA under § 299.449(g).

In commenting on the TCRR NPRM, TCRR stated that the resolution

requirements for both outward- and inward-facing image recording devices proposed in § 229.136(b) were quite prescriptive and should be reexamined for high-speed operations. As adopted in this final rule, § 229.136(b) requires the outward-facing image recording device to record at a minimum frame rate of 15 fps and have sufficient resolution to record the position of switch points 50 feet in front of the leading locomotive. TCRR questioned the underlying rationale and the benefit of such a requirement on a system that would have a PTC system capable of preventing a trainset from operating through a misaligned switch. Further, TCRR noted that for a trainset operating at 205 mph (330 km/h) the trainset would travel 20 feet between frames using an image recording device with a minimum frame rate of 15 fps and would pass a switch that is located 50 feet in front of the trainset within ⅙ of a second. TCRR also commented that for its trainsets, the outward-facing image recording device would be mounted at least 12.5 feet back from the front of the trainset, and thus the proposal would effectively require the image recording device to have a resolution capable of detecting the position of switch points 62.5 feet in advance of the switch.

FRA notes that TCRR raises issues that were not fully considered for an exclusive, high-speed passenger rail system. Accordingly, and consistent with FRA's approach to regulating TCRR as a system, FRA is requiring the railroad to develop and define certain image recording system requirements for inclusion in its inspection, testing, and maintenance program. Specifically, § 299.449(b)(4) requires TCRR to define the resolution requirements for outward-facing image recording devices in its inspection, testing, and maintenance program. TCRR must ensure such requirements provide sufficient resolution to determine the position of switch points 50 feet in advance of the trainset (wherever the outward-facing image recording device may be located) while operating at speeds of 170 km/h (106 mph) or below (TCRR track class H4 and below), and to capture images in daylight or with normal nighttime illumination from the trainset's headlight, required by § 299.433. As the resolution requirements adopted under § 229.136(b)(1)(iii) are not specifically attuned to exclusively higher speed passenger rail operations as contemplated by TCRR, FRA has taken into account the conditions under which the outward-facing image recording devices are expected to operate. FRA notes that, with respect to switches, facing-point diverging moves present an increased risk of derailment, or other accident/incident, compared to other types of moves through a switch, and TCRR's outward-facing image recording devices must therefore be able to capture the position of the switch points. However, FRA is also sensitive to TCRR's concern that at the proposed maximum operating speeds of 330 km/h (205 mph), it may be difficult for an image recording device to capture useful images so close to the leading edge of the trainset. Further, under TCRR's proposed system, facing-point (switch) diverging moves would occur most commonly when entering a station location, at lower speeds. Thus, FRA believes it has harmonized the requirements for outward-facing image recording devices so that they are suitable for TCRR while still capturing images of the more crucial movements along TCRR's right-of-way.

Additionally, § 299.449(c)(1)(i) provides that TCRR will define the resolution requirements for its inward-facing image recording devices in its inspection, testing, and maintenance program, ensuring sufficient resolution to record crewmember actions, including under the lighting conditions specified in § 299.449(c)(1)(iii).

TCRR commented on the periodic inspection and download requirements in proposed paragraph § 229.136(e)(2) to take sample downloads of the image recording system to confirm operation of the system. TCRR agreed with APTA's comment on the part 229 proposal,[61] in which APTA stated that railroads should be allowed to establish their own inspection processes for the image recording system. TCRR stated that such sampling of the image recording system, how often and by whom, should be established under TCRR's inspection, testing, and maintenance program. With respect to TCRR, FRA agrees that such requirements should be developed and defined as part of TCRR's inspection, testing, and maintenance program, consistent with FRA's overall approach to the systems-based use of TCRR's inspection, testing, and maintenance program. Accordingly, § 299.449(e)(2) requires TCRR to define, as part of its inspection, testing, and maintenance program for its rolling stock under § 299.445, the requirements for periodic inspection of and taking sample downloads from its trainset image recording system. FRA also expects that TCRR's training program developed under 49 CFR part 243 will include appropriate training and qualification requirements for the personnel who will be responsible for inspecting and taking sample downloads from the image recording system.

Finally, § 299.449(i) addresses the removal of an image recording system or device from service and handling for repair. In commenting on proposed § 229.136(i), the part 229 counterpart to this section, TCRR essentially echoed APTA's comments on the proposal.[62] Specifically, APTA commented that for semi-permanently coupled trainsets, prohibiting the use of the trainset due to a non-functioning image recording device or system could lead to an entire trainset being taken out of service, because individual cars in such trainsets are not typically uncoupled or freely switched; accordingly, if it is not possible to repair or replace the defective image recording device or system by the next calendar day inspection (or, for TCRR, the next pre-service inspection), the proposal could lead to removing an entire trainset from service. TCRR therefore suggested that the regulatory language mirror the statutory language in 49 U.S.C. 20168(j), allowing the image recording device or system to be repaired or replaced ''as soon as practicable,'' rather than by the next pre-service inspection.

Initially, FRA notes that a requirement to repair or replace a defective image recording device or system by the next pre-service inspection would mirror the requirement for event recorders under § 299.439(d). Additionally, FRA is treating the image recording system as a safety device under part 218 and, accordingly, expects that the railroad will make preparations to be able to repair or replace a non-functioning image recording device or system within the timeframe permitted under the regulation. FRA is also treating TCRR trainsets similar to Amtrak's semi-permanently coupled, high-speed trainsets operated exclusively in a designated rail corridor, which are not subject to § 229.136(i)'s exception for long-distance intercity passenger trains.[63] Moreover, FRA makes clear that § 299.449 does not prohibit TCRR from using a trainset in revenue service beyond the next pre-service inspection that has only one cab end with a non-

[61] *See* Docket No. FRA–2016–0036, Docket ID. FRA–2016–0036–0014 at 5–6.

[62] *See* Docket No. FRA–2016–0036, Docket ID. FRA–2016–0036–0014.

[63] Section 229.136(i) cross-references the definition of long-distance intercity passenger train in § 238.5, which excludes passenger trains operated exclusively on Amtrak's Northeast Corridor regardless of the distance between large cities serviced.

functioning image recording device, provided the system is properly functioning in the cab end that is the leading end of the trainset. Accordingly, § 299.449(i) as adopted in this final rule makes this distinction clear. For clarity, FRA provides two examples to illustrate application of this rule text.

• *Example 1 (Trainset A, with cab ends 1 and 2):* Trainset A is found to have a non-functioning image recording device in cab end 1 (its outward-facing image recording device), and TCRR has it properly taken out service under § 299.449(i)(2). The inward-facing recording device in cab end 1 is still fully functional, along with the event recorder and all image recording devices in cab end 2. After the image recording device in cab end 1 is taken out of service, cab end 1 can remain the leading cab end of the trainset only until the next pre-service inspection required under the railroad's inspection, testing, and maintenance program, and then the railroad would be required to repair or replace the image recording device before cab end 1 could be used as the leading end for trainset A in revenue service. However, should the railroad elect, the railroad could keep trainset A in service beyond the next pre-service inspection so long as all image recording devices in cab end 2 remained fully functional, along with the event recorder and all other required components. The railroad is limited to using only cab end 2 for trainset A as the leading end for all revenue service movements.

• *Example 2 (Trainset A, with cab ends 1 and 2):* In this example, the trainset's entire image recording system has been discovered as non-functional (either each cab end has non-functional image recording devices, or some other failure is affecting the image recording system's functionally as a whole), and has been properly taken out of service under § 299.449(i)(2). Trainset A can remain in service only until the next pre-service inspection required under the railroad's inspection, testing, and maintenance program, and then the railroad would be required to repair or replace the image recording system for trainset A before returning it to revenue service.

The distinction between the above examples is that in Example 2, there is no cab end that can serve as the leading end for trainset A while operating in revenue service.

Finally, FRA has added paragraphs (k)(1) and (2) to provide the same employee protections as described under § 217.9(b)(3) and (4). As the rationale for the requirements is the same as discussed under § 217.9(b)(3) and (4), FRA will rely on that discussion without repeating here. FRA's omission of paragraph (k) in the NPRM to provide these protections expressly was inadvertent, and notes that there are some minor differences between paragraph (k) and § 217.9(b)(3) and (4) only to harmonize the language with that used in part 299 for TCRR.

Appendix A to Part 299—Criteria for Certification of Crashworthy Event Recorder Memory Module

FRA is revising the introductory paragraph of appendix A to part 299 to harmonize the language of the appendix with the introductory paragraph of appendix D to part 229, reflecting the changes made in this final rule.

VI. Regulatory Impact and Notices

A. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

This final rule was designated as significant by the Office of Information and Regulatory Affairs. The final rule follows the direction of Executive Order 13563, which emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. However, FRA was unable to determine how effective locomotive image recording devices will be at reducing accidents. Thus, instead of presenting the quantifiable benefits, FRA presents the benefits qualitatively, as discussed further below. Details on the estimated costs of this final rule can be found in the rule's economic analysis.

This final rule directly responds to the Congressional mandate in section 11411 of the FAST Act that FRA, by delegation from the Secretary, require each railroad that provides intercity rail passenger or commuter rail passenger transportation to install image recording devices on the controlling locomotives of its passenger trains. The requirements of this final rule, as applied to passenger trains, are directly or implicitly required by the Statute and will promote railroad safety.

FRA has prepared and placed an RIA addressing the economic impact of this final rule in the rulemaking docket (Docket no. FRA–2016–0036). The RIA provides estimates of the costs of this final rule that are likely to be incurred over a ten-year period. FRA estimates the low- and high-range costs of this final rule using discount rates of 3 and 7 percent in the tables below.

TABLE 1—TOTAL 10-YEAR COSTS OF LOCOMOTIVE IMAGE RECORDING DEVICES, LOW RANGE

[Costs are in 2018 dollars, in millions]

	Discounted at 7%	Discounted at 3%	Annualized at 7%	Annualized at 3%
Costs	$42.2	$46.2	$6.0	$5.4
Cost Savings	2.0	2.4	0.3	0.3
Net Costs	40.2	43.9	5.7	5.1

TABLE 2—TOTAL 10-YEAR COSTS OF LOCOMOTIVE IMAGE RECORDING DEVICES, HIGH RANGE

[In millions]

	Discounted at 7%	Discounted at 3%	Annualized at 7%	Annualized at 3%
Costs	$87.3	$94.0	$12.4	$11.0
Cost Savings	2.0	2.4	0.3	0.3
Net Costs	85.3	91.6	12.1	10.7

As discussed in the preamble above, FRA may consider crashworthiness protection requirements unnecessary (or met) in the future for passenger locomotive image recording device memory modules if recorded data is stored at a remote location away from a locomotive consist, safe from accident destruction. FRA did not require this option because the agency does not believe current technology would reliably allow for such remote transmission and storage in all instances, and such a system would likely be much costlier to develop in order to transfer the recorded data to a centralized location.

In the 2015 Amtrak accident in Philadelphia, Pennsylvania, image recording devices could have helped provide additional causal information during the post-accident investigation. Causal data is especially critical for the prevention of future accidents when no apparent accident cause can be determined through other means. Further, images can become key to identifying new safety concerns that otherwise would be difficult to research or identify, which could lead FRA and the railroad industry to better understand areas in which safety could be improved. Other safety benefits will also primarily accrue from the deterrence of unsafe behaviors that cause railroad accidents. For instance, the presence of locomotive image recording devices could have deterred the engineer from text messaging while operating the Metrolink train involved in the 2008 accident at Chatsworth, California. In the RIA, FRA discusses and provides examples of how the deterrent effect of locomotive image recording devices could reduce negative behavior because train crews know their actions are being recorded.[64]

The primary source of expected benefits is the potential reduction in safety risk. FRA conducted a literature review to determine the effectiveness rate of inward- and outward-facing recording devices, but was unable to determine an appropriate rate. The benefits for the final rule are qualitatively discussed. The reduction in safety risk is expected to come primarily from the change in crew behavior. Railroads can deter unsafe behavior if crewmembers realize their actions may be observed on a frequent, but random, basis by railroad supervisors. Locomotive image recorders cannot directly prevent an accident from occurring, but rather can provide investigators with information after an accident occurs that can help to prevent future accidents of that type from occurring.

Although FRA is declining to require locomotive recording devices in freight locomotives, many freight railroads have informed FRA the above reasons are why railroads install camera systems even without an FRA regulation. FRA's analysis shows there are many factors that are difficult to quantify that combine to warrant the final rule.

Tables: Costs of the final rule:

TABLE 3—10-YEAR COSTS AND COST SAVINGS (LOW RANGE)

[In millions]

	Undiscounted	Discounted at 7%	Discounted at 3%	Annualized at 7%	Annualized at 3%
Costs:					
Camera	$40.6	$34.6	$37.7	$4.9	$4.4
Crashworthiness	9.2	7.5	8.4	1.1	1.0
Administrative Costs	0.1	0.1	0.1	0.0	0.0
Governmental Costs	0.004	0.004	0.004	0.0006	0.0005
Total Costs	49.9	42.2	46.2	6.0	5.4
Cost Savings:					
Operational Testing	2.7	2.0	2.4	0.3	0.3
Net Costs	47.2	40.2	43.9	5.7	5.1

TABLE 4—10-YEAR COSTS AND COST SAVINGS (HIGH RANGE)

[In millions]

	Undiscounted	Discounted at 7%	Discounted at 3%	Annualized at 7%	Annualized at 3%
Costs:					
Camera	$90.6	$79.7	$85.5	$11.3	$10.0
Crashworthiness	9.2	7.5	8.4	1.1	1.0
Administrative Costs	0.1	0.1	0.1	0.0	0.0
Governmental Costs	0.004	0.004	0.004	0.0006	0.0005
Total Costs	99.9	87.3	94.0	12.4	11.0
Cost Savings:					
Operational Testing	2.7	2.0	2.4	0.3	0.3
Net Costs	97.2	85.3	91.6	12.1	10.7

[64] *See* Benefits, Section VIII, of the RIA for more information.

B. Regulatory Flexibility Act and Executive Order 13272; Certification

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) and Executive Order 13272 (67 FR 53461, Aug. 16, 2002) require agency review of proposed and final rules to assess their impacts on small entities. An agency must prepare a Final Regulatory Flexibility Analysis (FRFA) unless it determines and certifies that a rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. As discussed below, FRA does not believe this final rule will have a significant economic impact on a substantial number of small entities.

Under section 312 of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, FRA has issued a final policy statement that formally establishes ''small entities'' as railroads that meet the line-haulage revenue requirements of a Class III railroad, which is $20 million or less in inflation-adjusted annual revenues, and commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less. *See* 49 CFR part 209, app. C.

This final rule will apply to railroad carriers that provide regularly scheduled intercity rail or commuter rail passenger transportation to the public. FRA notes that one passenger railroad is considered a small entity: the Hawkeye Express (operated by the Iowa Northern Railway Company). All other passenger railroad operations in the United States are part of larger governmental entities whose service jurisdictions exceed 50,000 in population, and, based on the definition, are not considered small entities. Hawkeye Express is a short-haul passenger railroad that does not provide commuter or intercity passenger service, and therefore will not be affected by the final rule. Additionally, the Hawkeye Express has not been in operation for at least the past two years. FRA does not believe that the provisions of the final rule will significantly impact a substantial number of small entities.

FRA invited all interested parties to submit comments, data, and information demonstrating the potential economic impact on any small entity that would result from the adoption of the final rule. During the NPRM comment period, FRA did not receive any comments from the public or stakeholders regarding the impact that the final rule would have on small entities.

Accordingly, the FRA Administrator hereby certifies this rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements in this final rule are being submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The sections that contain the new information and current information collection requirements and the estimated time to fulfill each requirement are as follows:

CFR section [65]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [66]
217.7(a)—Operating rules; filing and recordkeeping—Filing of code of operating rules, timetables, and timetable special instructions by Class I, Class II, Amtrak, and commuter railroads with FRA.	2 new railroads	2 documents	1 hour	2	$154
—(b) Amendments to code of operating rules, timetables, and timetable special instructions by Class I, Class II, Amtrak, and commuter railroads with FRA.	53 railroads	312 revised documents.	20 minutes	104	8,008
—(c) Class III and other railroads—Copy of code of operating rules, timetables, and timetable special instructions at system headquarters.	2 new railroads	2 documents	1 hour	2	154
—(c) Class III and other railroads—Amendments to code of operating rules, timetables, and timetable special instructions at system headquarters.	714 railroads	1,596 amendments	15 minutes	399	30,723
217.9(b)(2)—Program of operational tests and inspections; recordkeeping—Written records documenting qualification of each railroad testing officer.	765 railroads	4,732 records	2 minutes	158	12,166
—(b)(3) Development and adoption of procedure ensuring random selection of employees by railroads utilizing inward-facing locomotive and in-cab audio recordings to conduct operational tests and inspections (New requirement).	36 railroads	12 adopted procedures.	24 hours	288	34,560
—(c) Written program of operational tests and inspections.	2 new railroads	2 programs	10 hours	20	2,400
—(d)(1) Records of operational tests/inspections	765 railroads	9,120,000 test records and updates.	5 minutes	760,000	58,520,000
—(d)(2) Railroad copy of current program operational tests/inspections—Amendments.	53 railroads	159 program revisions	70 minutes	186	14,322
—(e)(1)(i) Written quarterly review of operational tests/inspections by RRs other than passenger RRs.	8 (Amtrak + 7 Class I) railroads.	32 reviews	2 hours	64	4,928
—(e)(1)(ii) 6-month review of operational tests/inspections/naming of officer.	7 Class I railroads	14 reviews	2 hours	28	2,156
—(e)(2) 6-month review by passenger railroads designated officers of operational testing and inspection data.	35 (Amtrak + 34 passenger) railroads.	70 reviews	2 hours	140	10,780
—(e)(3) Records of periodic reviews	50 railroads	116 records	1 minute	2	154
—(f)–(g) Annual summary of operational tests and inspections.	50 railroads	71 summary records	1 hour	71	5,467
—(h)(1)(i) RR amended program of operational tests/inspections.	765 railroads	6 revised programs	30 minutes	3	231
—(h)(1)(ii) FRA disapproval of RR program of operational tests/inspections and RR written response in support of program.	765 railroads	6 supporting documents.	1 hour	6	462
217.11(a)—RR periodic instruction of employees on operating rules—New railroads.	2 new railroads	2 written programs	8 hours	16	1,232

CFR section [65]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [66]
217.11(b)—RR copy of amendment of program for periodic instruction of employees.	765 railroads	110 modified written programs.	30 minutes	55	4,235
218.95(a)(5)–(b)—Instruction, training, examination—Employee records.	765 railroads	85,600 employees' records.	1 minute	1,427	109,879
—(c)(1)(i) Amended RR program of instruction, testing, examination.	765 railroads	5 amended programs	30 minutes	3	231
218.97(b)(4)—RR copy of good faith challenge procedures.	765 railroads	4,732 copies to new employees.	6 minutes	473	36,421
218.97(c)(1) and (c)(4)—RR employee good faith challenge of RR directive.	10 workers	10 gd. faith challenges	15 minutes	3	231
—(c)(5) RR resolution of employee good faith challenge.	2 new railroads	5 responses	15 minutes	1	77
—(d)(1) RR officer immediate review of unresolved good faith challenge.	2 new railroads	3 reviews	30 minutes	2	154
—(d)(2) RR officer explanation to employee that Federal law may protect against employer retaliation for refusal to carry out work if employee refusal is a lawful, good faith act.	2 new railroads	3 answers	15 minutes	1	77
—(d)(3) Employee written/electronic protest of employer final decision.	2 new railroads	3 written protests	15 minutes	1	77
—(d)(3) Employee copy of protest	2 new railroads	3 copies	1 minute	0.1	8
—(d)(4) Employer further review of good faith challenge after employee written request.	2 new railroads	2 further reviews	15 minutes	0.5	39
—(d)(4) RR verification decision to employee in writing.	2 new railroads	2 decisions	15 minutes	0.5	39
—(e) Recordkeeping and record retention—Employer's copy of written procedures at division headquarters.	765 railroads	765 copies	5 minutes	64	4,928
218.99(a)—Shoving or pushing movement—RR operating rule complying with section's requirements.	2 new railroads	2 rule modifications	1 hour	2	154
218.101(a)–(c)—Leaving equipment in the clear—Operating rule that complies with this section.	2 new railroads	2 rule modifications	30 minutes	1	77
218.103(a)(1)—Hand-Operated Switches—Operating Rule that Complies with this section.	2 new railroads	2 rule modifications	30 minutes	1	77
229.22—Locomotive image recording systems—Form FRA F 6180–49AP (New requirements) [67].	36 railroads	4,500 passenger locomotives.	15 minutes	1,125	86,625
229.136(f)(1)—Passenger railroads adoption and development of chain of custody (c of c) procedures (New requirements).	36 railroads	12 c of c procedures	48 hours	576	44,352
—(f)(2)–(3) Passenger railroad preservation of accident/incident data of image and audio recording system from locomotive using such system at time of accident/incident (includes voluntary freight railroads & restates previous requirement under section 229.135(e)) (New requirements).	36 railroads	140 saved recordings	10 minutes	23	1,771
—(g) Locomotive image recording system approval process—Description of technical aspects any locomotive image recording system to FRA for approval (New requirements).	36 railroads	12 descriptions/plans	20 hours	240	18,480
Total	765 railroads	9,223,047 responses	N/A	765,488	58,955,829

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information.

For information or a copy of the paperwork package submitted to OMB, contact Ms. Arlette Mussington, Information Collection Clearance Officer, at email: *Arlette.Mussington@dot.gov* or telephone: (571) 609–1285 or Ms. Joanne Swafford, Information Collection Clearance Officer, at email: *Joanne.Swafford@dot.gov* or telephone: (757) 897–9908.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to Ms. Arlette Mussington, Information Collection Clearance Officer, at email: *Arlette.Mussington@dot.gov* or telephone: (571) 609–1285 or Ms. Joanne Swafford, Information Collection Clearance Officer, at email: *Joanne.Swafford@dot.gov* or telephone: (757) 897–9908.

OMB must make a decision concerning the collection of information requirements contained in this rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. FRA received two public comments on the information collection requirements contained in the NPRM.

FRA is not authorized to impose a penalty on persons for violating information collection requirements that do not display a current OMB control number, if required. The current OMB control number for this rule is 2130–0035.

D. Federalism Implications

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States,

[65] FRA anticipates that no procedures will be disapproved under § 217.9(b)(4). Additionally, the burdens associated under § 299.449 and appendix A to part 299 have been accounted for under the burden associated with § 229.136(f) and (g).

[66] The dollar equivalent cost is derived from the Surface Transportation Board's Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes 75-percent overhead charges.

[67] The burdens for §§ 229.21, 229.136(a)(3), (e)(2), and 229.139(i) are covered under § 229.22.

on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

FRA has analyzed this final rule under the principles and criteria contained in Executive Order 13132. This final rule could affect State and local governments to the extent that they sponsor, or exercise oversight of, passenger railroads. Because this final rule is required by Federal statute for passenger railroads under 49 U.S.C. 20168, the consultation and funding requirements of Executive Order 13132 do not apply. However, this final rule could have preemptive effect by operation of law under certain provisions of the Federal railroad safety statutes, specifically the former Locomotive Inspection Act and the former Federal Railroad Safety Act of 1970, repealed and recodified at 49 U.S.C. 20701 *et seq.* and 49 U.S.C. 20106, respectively. Section 20701 governs all ''parts and appurtenances'' of locomotives, and has been held to occupy the field.[68] Section 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the ''essentially local safety or security hazard'' exception to section 20106.

In sum, FRA has analyzed this final rule under the principles and criteria in Executive Order 13132. As explained above, FRA has determined this final rule has no federalism implications, other than the possible preemption of State laws under Federal railroad safety statutes, specifically 49 U.S.C. 20701 *et seq.* and 49 U.S.C. 20106. Therefore, preparation of a federalism summary impact statement for this final rule is not required.

E. Environmental Impact

Consistent with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality's NEPA implementing regulations at 40 CFR parts 1500 through 1508, and FRA's NEPA implementing regulations at 23 CFR part 771, FRA has evaluated this final rule and determined that it is categorically excluded from environmental review and therefore does not require the preparation of an environmental assessment (EA) or environmental impact statement (EIS). Categorical exclusions (CEs) are actions identified in an agency's NEPA implementing regulations that do not normally have a significant impact on the environment and therefore do not require either an EA or EIS.[69] Specifically, FRA has determined that this final rule is categorically excluded from detailed environmental review pursuant to 23 CFR 771.116(c)(15), ''[p]romulgation of rules, the issuance of policy statements, the waiver or modification of existing regulatory requirements, or discretionary approvals that do not result in significantly increased emissions of air or water pollutants or noise.''

The purpose of this rulemaking is to require commuter and intercity passenger railroads to install recording devices on locomotives in compliance with this rule and use those devices to help investigate and prevent railroad accidents. This rule does not directly or indirectly impact any environmental resources and will not result in significantly increased emissions of air or water pollutants or noise. In analyzing the applicability of a CE, FRA must also consider whether unusual circumstances are present that would warrant a more detailed environmental review.[70] FRA has concluded that no such unusual circumstances exist with respect to this final rule and it meets the requirements for categorical exclusion under 23 CFR 771.116(c)(15).

Pursuant to Section 106 of the National Historic Preservation Act and its implementing regulations, FRA has determined this undertaking has no potential to affect historic properties.[71] FRA has also determined that this rulemaking will not approve a project resulting in a use of a resource protected by Section 4(f).[72] Further, FRA reviewed this final rule and found it consistent with Executive Order 14008, Tackling the Climate Crisis at Home and Abroad.

F. Executive Order 12898 (Environmental Justice)

Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, and DOT Order 5610.2C (require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority populations and low-income populations. The DOT Order instructs DOT agencies to address compliance with Executive Order 12898 and requirements within the DOT Order in rulemaking activities, as appropriate. FRA has evaluated this final rule under Executive Order 12898 and the DOT Order and has determined it will not cause disproportionately high and adverse human health and environmental effects on minority populations or low-income populations.

G. Executive Order 13175 (Tribal Consultation)

FRA has evaluated this final rule under the principles and criteria in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, dated November 6, 2000. The final rule will not have a substantial direct effect on one or more Indian tribes, will not impose substantial direct compliance costs on Indian Tribal Governments, and will not preempt tribal laws. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply, and a tribal summary impact statement is not required.

H. Unfunded Mandates Reform Act of 1995

Under Section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in

[68] *See, e.g., Napier* v. *Atlantic Coastline RR. Co.,* 272 U.S. 605 (1926).

[69] *See* 40 CFR 1508.4.

[70] *See* 23 CFR 771.116(b).

[71] *See* 54 U.S.C. 306108.

[72] *See* Department of Transportation Act of 1966, as amended (Pub. L. 89–670, 80 Stat. 931); 49 U.S.C. 303.

law).'' Section 202 of the Unfunded Mandates Reform Act (2 U.S.C. 1532) further requires that before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement detailing the effect on State, local, and Tribal Governments and the private sector. This final rule will not result in the expenditure, in the aggregate, of $100,000,000 or more (as adjusted annually for inflation) in any one year, and thus preparation of such a statement is not required.

I. Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [73] FRA evaluated this final rule in accordance with Executive Order 13211 and determined that this regulatory action is not a ''significant energy action'' within the meaning of the Executive order.

J. Trade Impact

The Trade Agreements Act of 1979 (Pub. L. 96–39, 19 U.S.C. 2501 *et seq.*) prohibits Federal agencies from engaging in any standards setting or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. FRA has assessed the potential effect of this final rule on foreign commerce and believes that its requirements are consistent with the Trade Agreements Act of 1979. The requirements are safety standards, which, as noted, are not considered unnecessary obstacles to trade.

K. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs did not designate this rule as a ''major rule'' as defined by 5 U.S.C. 804(2).

[73] 66 FR 28355 (May 22, 2001).

List of Subjects

49 CFR Part 217

Occupational safety and health, Penalties, Railroad employees, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 218

Locomotives, Occupational safety and health, Penalties, Railroad employees, Railroad safety, and Tampering.

49 CFR Part 229

Locomotives, Penalties, Railroad employees, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 299

High-speed rail, Railroad safety, Reporting and recording requirements, Tokaido Shinkansen.

The Final Rule

For the reasons discussed in the preamble, FRA is amending chapter II, subtitle B of title 49, Code of Federal Regulations, as follows:

PART 217—RAILROAD OPERATING RULES

The authority citation for part 217 is revised to read as follows:

■ 1. Authority: 49 U.S.C. 20103, 20107, 20168, 28 U.S.C. 2461, note; and 49 CFR 1.89.

Subpart A—General

■ 2. In § 217.9, add paragraphs (b)(3) and (4) to read as follows:

§ 217.9 Program of operational tests and inspections; recordkeeping.

* * * * *

(b) * * *

(3) A passenger railroad that utilizes inward-facing locomotive image or in-cab audio recordings to conduct operational tests and inspections shall adopt and comply with a procedure in its operational tests and inspections program that ensures employees are randomly subject to such operational tests and inspections involving image or audio recordings. The procedure adopted by a passenger railroad must:

(i) Establish objective, neutral criteria to ensure every employee subject to such operational tests and inspections is selected randomly for such operational tests and inspections within a specified time frame;

(ii) Not permit subjective factors to play a role in selection, *i.e.,* no employee may be selected based on the exercise of a railroad's discretion; and

(iii) Require that any operational test or inspection using locomotive image or audio recordings be performed within 72 hours of the completion of the employee's tour of duty that is the subject of the operational test. Any operational test performed more than 72 hours after the completion of the tour of duty that is the subject of the test is a violation of this section. The 72-hour limitation does not apply to investigations of railroad accidents/incidents or to violations of Federal railroad safety laws, regulations, or orders, or any criminal laws.

(4) FRA may review a passenger railroad's procedure implementing paragraph (b)(3) of this section, and, for cause stated, may disapprove such procedure under paragraph (h) of this section.

* * * * *

PART 218—RAILROAD OPERATING PRACTICES

■ 3. The authority citation for part 218 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20131, 20138, 20144, 20168; 28 U.S.C. 2461 note; and 49 CFR 1.89.

Subpart D—Prohibition Against Tampering With Safety Devices

■ 4. In § 218.53, revise paragraph (c) and add paragraph (d) to read as follows:

§ 218.53 Scope and definitions.

* * * * *

(c) *Safety Device* means any locomotive-mounted equipment used either to assure the locomotive engineer is alert, not physically incapacitated, and aware of and complying with the indications of a signal system or other operational control system, or a system used to record data concerning the operations of that locomotive or the train it is powering. See appendix C to this part for a statement of agency policy on this subject.

(d) The provisions in §§ 218.59 and 218.61 do not apply to locomotive-mounted image or audio recording equipment on freight locomotives.

■ 5. Revise § 218.61(c) to read as follows:

§ 218.61 Authority to deactivate safety devices.

* * * * *

(c) If a locomotive in commuter or intercity passenger service is equipped with a device to record data concerning the operation of that locomotive or the train it is powering, that device may be deactivated only under the provisions of § 229.135 of this chapter. Inward- and outward-facing image recording devices on commuter or intercity passenger

locomotives may be deactivated only under the provisions of § 229.136 of this chapter. This section does not apply to inward- or outward-facing image recording devices that are installed on freight locomotives.

■ 6. In appendix C to part 218, revise the fifth sentence of the fourth paragraph of appendix C to part 218 to read as follows:

Appendix C—Statement of Agency Enforcement Policy on Tampering

* * * * *

Safety Devices Covered by This Rule

* * * This regulation applies to a variety of devices including equipment known as ''event recorders,'' ''alerters,'' ''deadman controls,'' ''automatic cab signal,'' ''cab signal whistles,'' ''automatic train stop equipment,'' ''automatic train control equipment,'' ''positive train control equipment,'' and ''passenger locomotive-mounted image and audio recording equipment.'' * * *

* * * * *

PART 229—RAILROAD LOCOMOTIVE SAFETY STANDARDS

■ 7. The authority citation for part 229 is revised to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20133, 20137–38, 20143, 20168, 20701–03, 21301–02, 21304, 28 U.S.C. 2461, note; and 49 CFR 1.89.

Subpart A—General

■ 8. In § 229.5, revise the definition of ''Event recorder memory module'' and add, in alphabetical order, definitions of ''Image recording system'' and ''Recording device'' to read as follows:

§ 229.5 Definitions.

* * * * *

Event recorder memory module means that portion of an event recorder used to retain the recorded data as described in §§ 229.135(b) and 229.136(a) through (c).

* * * * *

Image recording system means a system of cameras or other electronic devices that record images as described in § 229.136, and any components that convert those images into electronic data transmitted to, and stored on, a memory module.

* * * * *

Recording device means a device that records images or audible sounds, as described in § 229.136.

* * * * *

Subpart B—Inspections and Tests

■ 9. In § 229.21, revise paragraphs (a) and (b) to read as follows:

§ 229.21 Daily inspection.

(a) Except for MU locomotives, each locomotive in use shall be inspected at least once during each calendar day. A written report of the inspection shall be made. This report shall contain the name of the carrier; the initials and number of the locomotive; the place, date and time of the inspection; a description of the non-complying conditions disclosed by the inspection; and the signature of the employee making the inspection. Except as provided in §§ 229.9, 229.136, 229.137, and 229.139, any conditions that constitute non-compliance with any requirement of this part shall be repaired before the locomotive is used. Except with respect to conditions that do not comply with §§ 229.136, 229.137, or 229.139, a notation shall be made on the report indicating the nature of the repairs that have been made. Repairs made for conditions that do not comply with §§ 229.136, 229.137, or 229.139 may be noted on the report, or in electronic form. The person making the repairs shall sign the report. The report shall be filed and retained for at least 92 days in the office of the carrier at the terminal at which the locomotive is cared for. A record shall be maintained on each locomotive showing the place, date and time of the previous inspection.

(b) Each MU locomotive in use shall be inspected at least once during each calendar day and a written report of the inspection shall be made. This report may be part of a single master report covering an entire group of MU locomotives. If any non-complying conditions are found, a separate, individual report shall be made containing the name of the carrier; the initials and number of the locomotive; the place, date, and time of the inspection; the non-complying conditions found; and the signature of the inspector. Except as provided in §§ 229.9, 229.136, 229.137, and 229.139, any conditions that constitute non-compliance with any requirement of this part shall be repaired before the locomotive is used. Except with respect to conditions that do not comply with §§ 229.136, 229.137, or 229.139, a notation shall be made on the report indicating the nature of the repairs that have been made. Repairs made for conditions that do not comply with §§ 229.136, 229.137, or 229.139 may be noted on the report, or in electronic form. A notation shall be made on the report indicating the nature of the repairs that have been made. The person making the repairs shall sign the report. The report shall be filed in the office of the carrier at the place where the inspection is made or at one central location and retained for at least 92 days.

* * * * *

■ 10. Add § 229.22 to read as follows:

§ 229.22 Passenger locomotive inspection and repair record.

(a) *Application.* This section applies only to lead locomotives of trains used in commuter or intercity passenger service, *i.e.,* locomotives subject to the requirements of § 229.136.

(b) *Dates.* (1) Each locomotive subject to the requirements of § 229.136 shall use and maintain Form FRA F 6180–49AP in accordance with the requirements of § 229.136, except that Form FRA F 6180–49A may fulfill any requirement in § 229.136 with respect to Form FRA F 6180–49AP until October 12, 2027.

(2) For purposes of complying with the inspection, testing, and repair recordkeeping requirements in §§ 229.23, 229.27, 229.29, 229.31, 229.33, 229.55, 229.103, 229.105, 229.114, 229.123, and 229.135 with respect to Form FRA F 6180–49A, each locomotive subject to the requirements of § 229.136 shall instead use and maintain Form FRA F 6180–49AP no later than October 12, 2027.

(c) *Earlier adoption.* Railroads may adopt use of Form FRA F 6180–49AP earlier than required for locomotives subject to the requirements of § 229.136.

(d) *Effect.* Nothing in this section affects the requirements in this part for use of Form FRA F 6180–49A for locomotives not subject to the requirements of § 229.136.

Subpart C—Safety Requirements

■ 11. Add § 229.136 to read as follows:

§ 229.136 Locomotive image and audio recording devices.

(a) *Duty to equip and record.* (1) Effective October 12, 2027, each lead locomotive of a train used in commuter or intercity passenger service must be equipped with an image recording system to record images of activities ahead of the locomotive in the direction of travel (outward-facing image recording device), and of activities inside the cab of the locomotive (inward-facing image recording device).

(i) If the lead locomotive is equipped with an image recording system, the system must be turned on and recording whenever a train is in motion, at all train speeds.

(ii) If operating circumstances cause the controlling locomotive to be other than the lead locomotive, railroads must

also record images of activities inside the cab of the controlling locomotive.

(iii) Both cabs of a dual-cab locomotive shall be equipped with inward- and outward-facing image recording systems. Image recordings for only a dual-cab locomotive's active cab and the leading end of the locomotive's movement are required to be made and retained.

(2) Image recording systems installed after October 12, 2024, on new, remanufactured, or existing lead locomotives used in commuter or intercity passenger service shall meet the requirements of this section. Lead locomotives used in commuter or intercity passenger service must be equipped with an image recording system meeting the requirements of this section no later than October 12, 2027.

(3) For lead locomotives in commuter or intercity passenger service, railroads must note the presence of any image or audio recording systems in the REMARKS section of Form FRA F 6180–49AP in the locomotive cab.

(4) As required under paragraph (a)(1) or (2) of this section, the image recording system shall record at least the most recent 12 hours of operation of a lead locomotive in commuter or intercity passenger service.

(5) Locomotive recording device data for each lead locomotive used in commuter or intercity passenger service shall be recorded on a memory module meeting the requirements for a certified crashworthy event recorder memory module described in appendix D to this part, or on an alternative, remote storage system that provides at least equivalent data protections and is approved by FRA under paragraph (g) of this section.

(i) Paragraph (a)(5) of this section applies to locomotive image recording systems as required under paragraph (a)(1) or (2) of this section.

(ii) Audio recording systems installed after October 12, 2024, on new, remanufactured, or existing lead locomotives used in commuter or intercity passenger service shall meet the requirements of paragraph (a)(5) of this section. Audio recording systems installed on lead locomotives in commuter or intercity passenger service must meet the requirements of paragraph (a)(5) of this section no later than October 12, 2027.

(b) *Outward-facing recording system requirements for lead locomotives in commuter or intercity passenger service.* (1) As required under paragraph (a)(1) or (2) of this section, the image recording system shall:

(i) Include an image recording device aimed parallel to the centerline of tangent track within the gauge on the front end of the locomotive;

(ii) Be able to distinguish the signal aspects displayed by wayside signals;

(iii) Record at a minimum frame rate of 15 frames per second (or its equivalent) and have sufficient resolution to record the position of switch points 50 feet in front of the locomotive;

(iv) Be able to capture images in daylight or with normal nighttime illumination from the headlight of the locomotive; and

(v) Include an accurate time and date stamp on image recordings.

(2) If a lead locomotive in commuter or intercity passenger service experiences a technical failure of its outward-facing image recording system, then the system shall be removed from service and handled in accordance with paragraph (i) of this section.

(c) *Inward-facing image recording system requirements for lead locomotives in commuter or intercity passenger service.* (1) As required under paragraph (a)(1) or (2) of this section, the image recording system shall include an image recording device positioned to provide complete coverage of all areas of the controlling locomotive cab where a crewmember typically may be positioned, including complete coverage of the instruments and controls required to operate the controlling locomotive in normal use, and:

(i) Have sufficient resolution to record crewmember actions;

(ii) Record at a minimum frame rate of 5 frames per second;

(iii) Be capable of using ambient light in the cab, and when ambient light levels drop too low for normal operation, automatically switch to infrared or another operating mode that enables the recording sufficient clarity to comply with the requirements of this paragraph (c)(1); and

(iv) Include an accurate time and date stamp on image recordings.

(2) No image recordings may be made of any activities within a locomotive's sanitation compartment as defined in § 229.5, and no image recording device shall be installed in a location where the device can record activities within a sanitation compartment.

(3) If a lead locomotive in commuter or intercity passenger service experiences a technical failure of its inward-facing image recording system, the system shall be removed from service and handled in accordance with paragraph (i) of this section.

(d) *Image and audio recording system protection requirements for lead locomotives in commuter or intercity passenger service.* Railroads must provide convenient wired or wireless connections to allow authorized railroad personnel to download audio or image recordings from any certified crashworthy event recorder memory module in a lead locomotive in commuter or intercity passenger service. The railroads must use electronic security measures, and apply appropriate cybersecurity measures, to prevent unauthorized access to, and download, deletion, or alteration of, the recording system or its recordings.

(1) Paragraph (d) of this section applies to locomotive image recording systems as required under paragraph (a)(1) or (2) of this section.

(2) Audio recording systems installed after October 12, 2024, on new, remanufactured, or existing lead locomotives used in commuter or intercity passenger service shall meet the requirements of paragraph (d) of this section. Audio recording devices installed on lead locomotives in commuter or intercity passenger service must meet the requirements of paragraph (d) of this section no later than October 12, 2027.

(e) *Inspection, testing, and maintenance for image recording systems on lead locomotives in commuter or intercity passenger service.* As required under paragraph (a)(1) or (2) of this section, the image recording system shall have self-monitoring features to assess whether the system is operating properly, including whether the system is powered on.

(1) If a fault with the image recording system is detected, the locomotive may be used in the lead position only in accordance with paragraph (i) of this section.

(2) As required under paragraph (a)(1) or (2) of this section, at each annual test required under § 229.27, the railroad conducting the inspection shall take sample download(s) from the image recording system's crashworthy event recorder memory module, or an FRA-approved equivalent under paragraph (g) of this section, to confirm proper operation of the system, and, if necessary, repair the system to full operation.

(f) *Handling of recordings*—(1) *Chain-of-custody procedure.* Each railroad with locomotives in commuter or intercity passenger service subject to this section shall adopt, maintain, and comply with a chain-of-custody procedure governing the handling and the release of the locomotive image recordings described in paragraphs (a) through (c) of this section and any locomotive audio recordings. The chain-of-custody procedure must specifically address the preservation and handling

requirements for post-accident/incident recordings provided to FRA or other Federal agencies under paragraph (f)(2) of this section.

(2) *Accident/incident preservation.* If any locomotive in commuter or intercity passenger service equipped with an image or audio recording system is involved in an accident/incident that must be reported to FRA under part 225 of this chapter, the railroad that was using the locomotive at the time of the accident shall, to the extent possible, and to the extent consistent with the safety of life and property, preserve the data recorded by each such device for analysis by FRA or other Federal agencies. A railroad must either provide the image and/or audio data in a format readable by FRA or other Federal agencies; or make available to FRA or other Federal agencies any platform, software, media device, etc., that is required to play back the image and/or audio data. This preservation requirement shall expire one (1) year after the date of the accident, unless FRA or another Federal agency notifies the railroad in writing that it must preserve the recording longer. Railroads may extract and analyze such data for the purposes described in paragraph (f)(3) of this section, only if:

(i) The original downloaded data file, or an unanalyzed exact copy of it, is retained in secure custody under the railroad's procedure adopted under paragraph (f)(1) of this section; and

(ii) The original downloaded data file, or an unanalyzed exact copy of it, is not utilized for any other purpose, except by direction of FRA or another Federal agency.

(3) *Recording uses.* A railroad may use the image and audio recordings from a locomotive in commuter or intercity passenger service subject to this section to:

(i) Investigate an accident/incident that is required to be reported to FRA under part 225 of this chapter;

(ii) Investigate a violation of a Federal railroad safety law, regulation, or order, or a railroad's operating rules and procedures;

(iii) Conduct an operational test under § 217.9 of this chapter;

(iv) Monitor for unauthorized occupancy of a locomotive's cab or a control cab locomotive's operating compartment;

(v) Investigate a violation of a criminal law;

(vi) Assist Federal agencies in the investigation of a suspected or confirmed act of terrorism; or

(vii) Perform inspection, testing, maintenance, or repair activities to ensure the proper installation and functioning of an image or audio recorder.

(g) *Locomotive image recording system approval process.* Each railroad with locomotives in commuter or intercity passenger service subject to this section must provide the FRA Associate Administrator for Railroad Safety and Chief Safety Officer with a description of the technical aspects of any locomotive image recording system installed to comply with this section. The required description must be submitted via electronic mail to the following email address: *FRARRSMPE@dot.gov.*

(1) The description must include information specifically addressing the image recording system's:

(i) Minimum 12-hour continuous recording capability;

(ii) Crashworthiness; and

(iii) Post-accident accessibility of the system's recordings.

(2) The railroad must submit the statement not less than 90 days before the installation of such image recording system, or, for existing systems, not more than 60 days after November 13, 2023.

(3) The FRA Associate Administrator for Railroad Safety and Chief Safety Officer will review a railroad's submission and must approve any locomotive image recording system intended to comply with this section before the system can be installed or put into service. FRA may disapprove any locomotive image recording systems that do not meet the requirements of this section.

(h) *Relationship to other laws.* Nothing in this section is intended to alter the legal authority of law enforcement officials investigating potential violation(s) of State criminal law(s), and nothing in this section is intended to alter in any way the priority of investigations under 49 U.S.C. 1131 and 1134, or the authority of the Secretary of Transportation to investigate railroad accidents under 49 U.S.C. 5121, 5122, 20107, 20111, 20112, 20505, 20702, 20703, and 20902.

(i) *Removal of device from service and handling for repair.* A railroad may remove from service an image recording device on a locomotive in commuter or intercity passenger service, and must remove the device from service if the railroad knows the device is not properly recording. When a railroad removes a locomotive image recording device from service, a qualified person shall record the date the device was removed from service on Form FRA F 6180–49AP, under the REMARKS section. Except as provided in this paragraph, a locomotive on which an image recording device has been taken out of service as provided in this paragraph may remain as the lead locomotive only until the next calendar-day inspection required under § 229.21. A locomotive with an inoperative image recording device alone is not deemed to be in an improper condition, unsafe to operate, or a non-complying locomotive under §§ 229.7 and 229.9. A locomotive in a long-distance intercity passenger train, as defined in § 238.5 of this chapter, with a non-operational image recording device may remain as the lead locomotive until arrival at its destination terminal or its nearest forward point of repair, whichever occurs first.

(j) *Disabling or interfering with locomotive-mounted audio and video recording equipment.* Any individual who willfully disables or interferes with the intended functioning of locomotive-mounted image or audio recording system equipment on a passenger locomotive, or who tampers with or alters the data recorded by such equipment, is subject to a civil penalty and to disqualification from performing safety-sensitive functions on a railroad as provided in parts 209 and 218 of this chapter.

(k) *As used in this section—Train* means (1) A single locomotive;

(2) Multiple locomotives coupled together; or

(3) One or more locomotives coupled with one or more cars.

(l) *Freight rescue locomotives.* The requirements of this section do not apply to a freight locomotive when used to haul a passenger train due to the failure of a passenger locomotive.

■ 12. Revise the introductory paragraph of appendix D to part 229 to read as follows:

Appendix D to Part 229—Criteria for Certification of Crashworthy Event Recorder Memory Module

Section 229.135(b) requires railroads to equip certain locomotives with an event recorder that includes a certified crashworthy event recorder memory module. Section 229.136(a)(1) requires passenger railroads to install locomotive-mounted image recording systems in every lead locomotive used in commuter or intercity passenger service. As required by § 229.136(a)(5), data from these image and voluntarily installed audio recording systems must be recorded on a certified crashworthy memory module or on an alternative, remote storage system that provides at least equivalent data protections and is approved by FRA under § 229.136(g). This appendix prescribes the requirements for certifying an event recorder memory module (ERMM) or a locomotive-mounted audio and/or image recording device memory module as crashworthy. For purposes of this

appendix, a locomotive-mounted audio or image recording device memory module is also considered an ERMM. This appendix includes the performance criteria and test sequence for establishing the crashworthiness of the ERMM and marking the event recorder or locomotive-mounted image or audio recording system containing the crashworthy ERMM.

* * * * *

PART 299—TEXAS CENTRAL RAILROAD HIGH-SPEED RAIL SAFETY STANDARDS

■ 13. The authority citation for part 299 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20133, 20141, 20302–20303, 20306, 20701–20702, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 14. In § 299.5, add definitions for the terms ''Event recorder memory module,'' ''Image recording system'', and ''Image recording device'' to read as follows:

§ 299.5 Definitions.

* * * * *

Event recorder memory module means that portion of an event recorder used to retain the recorded data as described in §§ 299.439(c) and 299.449(a) through (c).

* * * * *

Image recording device means a device that records images, as described in § 299.449.

Image recording system means a system of electronic devices capable of recording images as described in § 299.449, and any components that convert those images into electronic data transmitted to, and stored on, a certified crashworthy memory module as described in appendix A to this part.

* * * * *

■ 15. Add § 299.449 to read as follows:

§ 299.449 Trainset image and audio recording system.

(a) *Duty to equip and record.* (1) Each trainset used in revenue service must be equipped with an image recording system comprised of—

(i) Outward-facing image recording devices capable of recording images of the right-of-way ahead of the trainset in the direction of travel as further described in paragraph (b) of this section; and,

(ii) Inward-facing image recording devices capable of recording images of crewmember activities inside the leading trainset cab as further described in paragraph (c) of this section.

(2) The image recording system must be turned on and recording whenever a trainset is in motion, at all speeds. If operating circumstances cause the controlling cab to be other than the cab of the leading end of the trainset, the railroad must also record images of activities inside the controlling cab.

(3) The trainset image recording system shall record at a minimum the most recent 12 hours of operation of a leading trainset cab used in revenue service.

(4) Image recording device data for each leading trainset cab used in revenue service shall be recorded on a memory module meeting the requirements for a certified crashworthy event recorder memory module described in appendix A to this part or on an alternative, remote storage system that provides at least equivalent data protections and is approved by FRA under paragraph (g) of this section.

(b) *Outward-facing recording device requirements for leading trainset cabs used in revenue service.* The image recording system shall—

(1) Include an image recording device aimed parallel to the centerline of tangent track within the gauge on the leading end of the trainset;

(2) Be able to distinguish the signal aspects displayed by go/no-go signals;

(3) Record at a minimum frame rate of 15 frames per second (or its equivalent);

(4) Have sufficient resolution, as defined by the railroad in the railroad's inspection, testing, and maintenance program under § 299.445, to record the position of switch points in advance of the trainset at speeds of 170 km/h (106 mph) and below, and to capture images in daylight or with normal nighttime illumination from the headlight of the trainset; and

(5) Include an accurate time and date stamp on image recordings.

(c) *Inward-facing image recording device requirements for leading trainset cabs used in revenue service.* (1) The image recording system shall include an image recording device positioned to provide complete coverage of all areas of the leading trainset cab where a crewmember typically may be positioned, including complete coverage of the instruments and controls required to operate the trainset in normal use, and—

(i) Have sufficient resolution, as defined in the railroad's inspection, testing, and maintenance program under § 299.445, to record crewmember actions;

(ii) Record at a minimum frame rate of 5 frames per second;

(iii) Be capable of using ambient light in the cab, and when ambient light levels drop too low for normal operation, automatically switch to infrared or another operating mode that enables the recording sufficient clarity to comply with the requirements of this paragraph (c)(1); and

(iv) Include an accurate time and date stamp on image recordings.

(2) Inward-facing image recording devices shall not be installed in a location where the device can record activities within a trainset cab's sanitation compartment, as defined in § 229.5 of this chapter, and shall not be used to make recordings of any activities within a trainset cab's sanitation compartment.

(3) If a leading trainset cab used in revenue service experiences a technical failure of its inward-facing image recording system, then the system shall be removed from service and handled in accordance with paragraph (i) of this section.

(d) *Image recording system protection requirements for leading trainset cabs used in revenue service.* The railroad must provide convenient wired or wireless connections to allow authorized railroad personnel to download audio or image recordings from any certified crashworthy event recorder memory module in leading trainset cabs used in revenue service. The railroad also must use electronic security measure(s), and apply appropriate cybersecurity measures, to prevent unauthorized access to, and download, deletion, or alteration of, the recording system or its recordings.

(e) *Inspection, testing, and maintenance for image recording systems in leading trainset cabs used in revenue service.* (1) The image recording system in trainsets used in revenue service shall have self-monitoring features to assess whether the system is operating properly, including whether the system is powered on.

(2) Periodic inspection requirements for the trainset image recording system shall be defined in the railroad's inspection, testing, and maintenance program required under § 299.445. As part of the periodic inspection, the railroad shall take sample download(s) from the image recording system's crashworthy memory module to confirm proper operation of the system, and, if necessary, repair the system to full operation.

(f) *Handling of recordings.* (1) *Chain-of-custody procedure.* The railroad shall develop, adopt, maintain, and comply with a chain-of-custody procedure governing the handling and the release of the image recordings described in paragraphs (a) through (c) of this section and any audio recordings. The chain-of-custody procedure must specifically address the preservation and handling requirements for post-accident/incident

recordings provided to FRA or other Federal agencies under paragraph (f)(2) of this section.

(2) *Accident/incident preservation.* If any trainset equipped with an image or audio recording system is involved in an accident/incident that must be reported to FRA under part 225 of this chapter, the railroad shall, to the extent possible, and to the extent consistent with the safety of life and property, preserve the data recorded by the system for analysis by FRA or other Federal agencies. The railroad must either provide the image and/or audio data in a format readable by FRA or other Federal agencies; or make available to FRA or other Federal agencies any platform, software, media device, etc., that is required to play back the image and/or audio data. This preservation requirement shall expire one year after the date of the accident unless FRA or another Federal agency notifies the railroad in writing that it must preserve the recording longer. The railroad may extract and analyze such data for the purposes described in paragraph (f)(3) of this section, only if—

(i) The original downloaded data file, or an unanalyzed exact copy of it, is retained in secure custody under the railroad's procedure adopted under paragraph (f)(1) of this section; and

(ii) It is not utilized for analysis or any other purpose, except by direction of FRA or another Federal agency.

(3) *Recording uses.* Subject to the conditions specified in paragraph (f)(2) of this section, the railroad may use image and audio recordings from a leading trainset cab used in revenue service subject to this section to—

(i) Investigate an accident/incident that is required to be reported to FRA under part 225 of this chapter;

(ii) Investigate a violation of a Federal railroad safety law, regulation, or order, or the railroad's operating rules and procedures;

(iii) Conduct an operational test under § 299.505;

(iv) Monitor for unauthorized occupancy of a trainset's cab or operating compartment;

(v) Investigate a violation of a criminal law;

(vi) Assist Federal agencies in the investigation of a suspected or confirmed act of terrorism; or

(vii) Perform inspection, testing, maintenance, or repair activities to ensure the proper installation and functioning of an image or audio recorder as required under paragraph (e)(2) of this section.

(g) *Image recording system approval process.* The railroad must submit for approval a description of the technical aspects of its trainset image recording system installed pursuant this section. The required description must be submitted via electronic mail to the following email address: *FRARRSMPE@dot.gov.*

(1) The description must specifically address the image recording system's—

(i) Minimum 12-hour continuous recording capability;

(ii) Crashworthiness; and

(iii) Post-accident accessibility of the system's recordings.

(2) The railroad must submit the written statement not less than 90 days before the installation of such image recording system.

(3) The Associate Administrator will review the railroad's description and may approve, or disapprove, the image recording system if it does not meet the requirements of this section. FRA may disapprove any recording systems that do not meet the requirements of this section.

(h) *Relationship to other laws.* Nothing in this section is intended to alter the legal authority of law enforcement officials investigating potential violation(s) of State criminal law(s), and nothing in this section is intended to alter in any way the priority of investigations under 49 U.S.C. 1131 and 1134, or the authority of the Secretary of Transportation to investigate railroad accidents under 49 U.S.C. 5121, 5122, 20107, 20111, 20112, 20505, 20702, 20703, and 20902.

(i) *Removal of an image recording system or device from service and handling for repair.* (1) Notwithstanding the duty established in paragraph (a) of this section to equip trainsets cabs used in revenue service with an image recording system, the railroad—

(i) May remove from service the entire image recording system or an image recording device in a leading trainset cab used in revenue service for any reason.

(ii) Must remove from service the entire image recording system or an image recording device in a leading trainset cab used in revenue service if the railroad knows the system or device is not properly recording.

(2) When a railroad removes the entire image recording system or an image recording device in a leading trainset cab used in revenue service from service, a qualified person shall record the date the system or device was removed from service in the trainset's maintenance records.

(3) A trainset on which the entire image recording system, or an image recording device in a leading trainset cab used in revenue service, has been taken out of service as provided in paragraphs (i)(1)(i) or (ii) of this section may be used as a leading trainset cab in revenue service only until the next pre-service inspection required under the railroad's inspection, testing, and maintenance program.

(4) A trainset with an image recording device that has been taken out of service on only one cab end may be used in revenue service beyond the next pre-service inspection without repair provided the other cab end is the leading end of the trainset and the image recording system is otherwise operative for that cab end.

(5) A trainset with an inoperative image recording device alone is not deemed to be in an improper condition, unsafe to operate, or non-complying under § 299.447. However, a trainset with an entire image record system taken out of service or image recording devices taken out service in both cab ends, may not be used in revenue service beyond the next pre-service inspection required under the railroad's inspection, testing, and maintenance program without repair or replacement of the non-operative system or devices.

(j) *Disabling or interfering with locomotive-mounted audio and video recording equipment.* Any individual who willfully disables or interferes with the intended functioning of image or audio recording system equipment mounted in a leading trainset cab used in revenue service, or who tampers with or alters the data recorded by such equipment, is subject to a civil penalty and to disqualification from performing safety-sensitive functions on a railroad as provided in parts 209 and 218 of this chapter.

(k) *Employee protections.* (1) If inward-facing image or in-cab audio trainset recordings are utilized to conduct operational tests and inspections under § 299.505, the railroad shall adopt and comply with a procedure in its operational tests and inspections program that ensures employees are randomly subject to such operational tests and inspections involving image or audio recordings. The procedure adopted must:

(i) Establish objective, neutral criteria to ensure every employee subject to such operational tests and inspections is selected randomly for such operational tests and inspections within a specified time frame;

(ii) Not permit subjective factors to play a role in selection, *i.e.,* no employee may be selected based on the exercise of the railroad's discretion; and

(iii) Require that any operational test or inspection using trainset image or audio recordings be performed within 72 hours of the completion of the

employee's tour of duty that is the subject of the operational test. Any operational test performed more than 72 hours after the completion of the tour of duty that is the subject of the test is a violation of this section. The 72-hour limitation does not apply to investigations of railroad accidents/incidents or to violations of Federal railroad safety laws, regulations, or orders, or any criminal laws.

(2) FRA may review the railroad's procedure implementing paragraph (k)(1) of this section, and, for cause stated, may disapprove such procedure under § 299.505(h).

■ 16. Revise the introductory paragraph of appendix A to part 299 to read as follows:

Appendix A to Part 299—Criteria for Certification of Crashworthy Event Recorder Memory Module

Section 299.439(c) requires that trainsets be equipped with an event recorder that includes a certified crashworthy event recorder memory module. Section 299.449(a)(1) requires the railroad to install an image recording system in its trainsets used in revenue service. As required by § 299.449(a)(4), data from these image recording systems must be recorded on a certified crashworthy memory module or an alternative, remote storage system that provides at least equivalent data protections and is approved by FRA under § 299.15. This appendix prescribes the requirements for certifying an event recorder memory module (ERMM) or a trainset-mounted audio and/or image recording device memory module as crashworthy. For purposes of this appendix, a trainset-mounted audio or image recording system memory module is also considered an ERMM. This appendix includes the performance criteria and test sequence for establishing the crashworthiness of the ERMM as well as the marking of the event recorder containing the crashworthy ERMM.

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Issued in Washington, DC.

Amitabha Bose,

Administrator.

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Part IV

Department of Health and Human Services

42 CFR Chapter I
Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter I

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Issuance of mandatory guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') has revised the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), which published in the **Federal Register** of January 23, 2017.

DATES: The mandatory guidelines are effective February 1, 2024.

FOR FURTHER INFORMATION CONTACT: Eugene D. Hayes, Ph.D., MBA, SAMHSA, CSAP, DWP; 5600 Fishers Lane, Room 16N02, Rockville, MD 20857, by telephone (240) 276–1459 or by email at *Eugene.Hayes@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

These revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) establish a process whereby the Department annually publishes the authorized drug testing panel (*i.e.,* drugs, analytes, or cutoffs) to be used for Federal workplace drug testing programs; revise the definition of a substituted specimen to include specimens with a biomarker concentration inconsistent with that established for a human specimen, establish a process whereby the Department publishes an authorized biomarker testing panel (*i.e.,* biomarker analytes and cutoffs) for Federal workplace drug testing programs; update and clarify the oral fluid collection procedures; revise the confirmatory test cutoff for morphine; revise the Medical Review Officer (MRO) verification process for positive codeine and morphine specimens; and require MROs to submit semiannual reports to the Secretary or designated HHS representative on Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. In addition, some wording changes have been made for clarity and for consistency with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) or to apply to any authorized specimen type.

The Department is publishing a separate Federal Register Notification (FRN) elsewhere in this issue of the **Federal Register** with the revised OFMG, which include the same or similar revisions as the UrMG, where appropriate.

Background

Pursuant to its authority under section 503 of Public Law 100–71, 5 U.S.C. 7301, and Executive Order 12564, HHS establishes the scientific and technical guidelines for Federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for Federal agencies.

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates that 275,000 urine specimens are tested annually by Federal agencies. No Federal agencies are testing hair or oral fluid specimens at this time.

HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (hereinafter referred to as Guidelines or Mandatory Guidelines) in the **Federal Register** (FR) on April 11, 1988 (53 FR 11979). The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 (59 FR 29908), September 30, 1997 (62 FR 51118), November 13, 1998 (63 FR 63483), April 13, 2004 (69 FR 19644), and November 25, 2008 (73 FR 71858). SAMHSA published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) on January 23, 2017 (82 FR 7920), and published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) on October 25, 2019 (84 FR 57554). SAMHSA published proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair (HMG) on September 10, 2020 (85 FR 56108), and proposed revisions to the UrMG (87 FR 20560) and OFMG (87 FR 20522) on April 7, 2022.

There was a 60-day public comment period following publication of the proposed UrMG, during which 22 commenters submitted 93 comments on the UrMG. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at *https://www.regulations.gov/.* All comments were reviewed and taken into consideration in the preparation of the Guidelines. The issues and concerns raised in the public comments for the UrMG are set forth below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

The following comments were directed to the information and questions in the preamble.

Authorized Drug Testing Panel

The Department requested comments on its proposal to publish the drug testing panel separately from the UrMG in a **Federal Register** Notification (FRN) each year. Sixteen commenters submitted a total of 35 comments on this topic for the UrMG.

Eight commenters disagreed with publishing a revised drug testing panel without a public comment period, expressing concerns that stakeholders including individuals subject to federally regulated drug testing would not be given the opportunity to provide comment and that the Department would miss valuable input including information on costs and burden. Some of these commenters suggested alternate ways to permit public comment while enabling a quicker response to testing panel changes (*e.g.,* setting a shorter comment period, publishing the Guidelines as an interim final rule or issuing an advance notice of proposed rulemaking). The Department has reviewed these comments and suggestions and determined that no changes to the proposed Guidelines are needed. The Department has developed procedures which will allow review and comment before testing panel changes are published, as described below.

Consistent with current procedures, prior to making a change to the drug or biomarker testing panel, the Department will conduct a thorough review of the scientific and medical literature, and will solicit review and input from subject matter experts such as Responsible Persons (RPs) of HHS-certified laboratories, Medical Review Officers (MROs), research scientists, manufacturers of collection devices and/or immunoassay kits, as well as Federal partners such as the Department of Transportation (DOT), the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA). Further, the Department plans to provide notice and opportunity for public comment regarding any proposed changes to the drug and biomarker testing panels as part of Drug Testing Advisory Board (DTAB) meetings and procedures.

Information regarding any proposed changes to the drug analyte and biomarker testing panels and a request for public comment will be included in an advance notice of the DTAB meeting published in the **Federal Register**, along with the timeframe and method(s) for comment submission. During the meeting, the Department will present the basis for adding or removing analytes (*i.e.,* including technical and scientific support for the proposed changes), as well as a discussion of related costs and benefits. This information will be provided in advance to DTAB members. The Department will review all submitted public comments and will share information during a DTAB session prior to DTAB's review of SAMHSA's recommendation to the Secretary regarding each proposed change.

The Department will make the final decision on any panel changes and include the effective date(s) in the annual Notification, to allow time for drug testing service providers (*e.g.,* immunoassay kit manufacturers, oral fluid collection device manufacturers) to develop or revise their products, and for HHS-certified laboratories to develop or revise assays, complete validation studies, and revise procedures.

Four commenters disagreed that HHS is exempt from the Administrative Procedure Act (APA) requirements. Two of these specifically stated that the Guidelines are subject to APA requirements because DOT is required to use the Guidelines for their transportation industry drug testing programs. The Department explained why the APA does not apply under the *Regulatory Impact and Notices* section of the current UrMG (82 FR 7920) and has repeated the same information in that section below.

Ten commenters were concerned that the Department will not allow sufficient time for stakeholders to implement changes (*e.g.,* time for Food and Drug Administration [FDA] clearance for new or revised products, information technology [IT] changes, process development and/or changes, contractual changes, and training). Some of these commenters suggested that the Department set a standard time period (*e.g.,* 90 days) for implementation of changes or based on the complexity of the change (*e.g.,* between 90 and 365 days). The Department will establish a reasonable time for implementation based on the change, rather than setting a standard time period for all changes. As noted above, the Department will solicit information from stakeholders to assist in decision making.

In regard to the use of FDA-cleared immunoassay initial tests, two commenters suggested that federally regulated drug testing could fall under what they referred to as the FDA's Employment and Insurance exemption. The Department notes that, while some drugs of abuse test systems intended for employment and insurance testing are, under certain circumstances, exempt from the premarket notification procedures in 21 CFR part 807, subpart E, such exemptions do not apply to test systems intended for Federal drug testing programs. See 21 CFR part 862, subpart D. Applicant and HHS-certified test facilities must verify that test systems subject to FDA regulations are approved or otherwise cleared by FDA and, in addition, must validate test systems prior to use in accordance with requirements specified in the National Laboratory Certification Program (NLCP) Manuals for Urine Laboratories and Initial Instrumented Test Facilities (IITFs).

One commenter appeared to misinterpret the Department's testing panel proposal, objecting to the Department making changes to the testing panels each year. The Department plans to issue an annual Notification with the current testing panels and required nomenclature, but will make changes only when needed to ensure the continued effectiveness of Federal workplace drug testing programs, which may not be every year.

Four commenters specifically agreed with the need to streamline and improve processes for making changes to the testing panels. Three of these commenters expressed concern over the process for testing panel review and who would be involved, and suggested involving other stakeholders (*e.g.,* HHS-certified laboratories, DTAB, FDA). As noted above, the Department will use multiple methods and involve subject matter experts from various stakeholder groups to determine testing panel changes, and will provide opportunity for public review and comment before changes are made. FDA, DOT, and other Federal partners will also have opportunities to review and provide input.

The other commenter suggested that the Department include additional prescriptive language in each annual Notification (*e.g.,* street names, detection times, pharmacological information on added drugs for MROs; Custody and Control Form (CCF) instructions for collectors). The Department has determined that no changes to the proposed Guidelines are needed. Relevant information and guidance will be included in the MRO Guidance Manual, Case Studies, Guidance for Using the Federal Custody and Control Form (CCF), and Specimen Collection Handbook. These documents are posted on SAMHSA's website, *https://www.samhsa.gov/workplace.*

One commenter stated that testing panel changes would lead to an increase in incorrect information on the Federal CCF. The Department disagrees, noting that the Federal CCF does not include preprinted analyte names.

One of the commenters agreed with posting a Notification without a public comment period for added drugs, but disagreed with removing drugs from the testing panel without public comment. The commenter noted that entities (*e.g.,* DOT, some states) are required by law to use the Guidelines testing panel should be able to continue testing those drugs, even if Federal agencies will not. The Department has determined that no changes to the proposed Guidelines are needed to address these concerns.

See additional comments under Section 3.4 below.

Authorized Biomarker Testing Panel

The Department requested comments on its proposal to publish the biomarker testing panel separately from the UrMG in the **Federal Register** each year. Five commenters submitted a total of 12 comments on this topic for the UrMG.

Two commenters disagreed with publishing a biomarker testing panel without a public comment period, expressing concerns that stakeholders would not be given the opportunity to provide comment and that the Department would miss valuable input including information on costs and burden.

Two other commenters specifically agreed with the need to streamline and improve processes for making changes to the testing panels, but suggested involving other stakeholders (*e.g.,* HHS-certified laboratories, DTAB). The Department has reviewed these comments and determined that no changes to the proposed Guidelines are needed. The Department has developed procedures which will allow review and comment before testing panel changes are published, as described under *Authorized drug testing panel* above.

One commenter disagreed that HHS is exempt from the APA requirements. The Department has reviewed the comment and determined that no change is needed to the proposed Guidelines. The Department explained why the APA does not apply under the *Regulatory Impact and Notices* section of the current UrMG (82 FR 7920) and has repeated the same information in that section below.

Two commenters were concerned that the Department will not allow sufficient time for stakeholders to implement changes (*e.g.,* time for information technology [IT] changes, process development and/or changes, training). The commenters suggested that the Department set a standard time for implementation of all changes (*e.g.,* 90 days, six months). As noted under *Authorized drug testing panel* above, the Department will establish a reasonable time for implementation based on the change, rather than setting a standard time period for all changes, and will solicit information from multiple sources to assist in decision making.

Two commenters suggested that the Department require all HHS-certified laboratories to perform standardized specimen validity and biomarker tests on all federally regulated specimens, and allow laboratories to choose whether to offer additional specialized tests upon MRO request on a case-by-case basis. This is consistent with current UrMG requirements for specimen validity testing. The Department is not requiring all certified laboratories to conduct biomarker testing at this time. However, if the drug testing industry identifies a need for such tests and an HHS-certified laboratory chooses to offer a biomarker test to their regulated clients, the Department will ensure that the tests provide scientifically valid and forensically defensible results and will revisit the need for requiring the test on all specimens.

Medical Review Officer (MRO) Verification of Codeine and Morphine Test Results

The Department removed the additional decision point for codeine and morphine, adjusted the confirmatory test cutoff for morphine from 2,000 to 4,000 ng/mL, and removed the additional requirement for clinical evidence of illegal opioid use. The Department received one comment agreeing with these changes to the UrMG.

Medical Review Officer (MRO) Semiannual Reports

In Section 13.11, the Department added requirements for each MRO performing medical review services for Federal agencies to submit semiannual reports, in January and July of each year, of Federal agency specimens that were reported as positive for a drug or drug metabolite by the laboratory and verified as negative by the MRO, along with the reason for the negative verification (*e.g.,* a valid prescription for a drug). Six commenters submitted six comments on this topic for the UrMG.

Four commenters disagreed, stating that HHS had not clearly described the reason and the process for such reports. One commenter noted that the Department had not presented data documenting that MROs were incorrectly reporting specimens, and it was unclear how the reports could be matched to laboratory report information submitted to the National Laboratory Certification Program (NLCP). Another commenter was concerned that donors would be identifiable, and that ''a database of legal drug use'' would violate donor privacy. One of the commenters expressed concern over ''unintended consequences'' for DOT and state workplace drug testing programs, without further explanation.

One commenter disagreed on the basis of added costs and burden to MROs (*e.g.,* system revisions, increased staff workload).

One commenter agreed that such reports could be beneficial, but suggested that MROs provide the same information as provided by laboratories to the NLCP. The commenter incorrectly stated that laboratories do not provide specimen identification numbers to the NLCP.

The Department has reviewed the comments and determined that no change is needed to the proposed Guidelines. To clarify, this reporting policy is only for Federal agency specimens, not DOT-regulated specimens. Further, the reports are not for all positive specimens, only for those specimens that were reported as positive by the laboratory and verified as negative by the MRO. The requested MRO information is sufficient to enable matching to HHS-certified laboratory information provided to the NLCP without identifying the donor. At this time, there is no system-wide mechanism for identifying MRO verification practices for Federal agency specimens that are inconsistent with the Mandatory Guidelines, so data on incorrect reporting is not available. The Department is not planning to share MRO-specific information, but may share statistical information and deidentified examples of incorrect reporting by various means (*e.g.,* DTAB meeting presentations, revisions to the MRO Guidance Manual and/or Case Studies). The Department will also provide this information to HHS-approved MRO certification organizations to share with their certified MROs and to update training materials and examinations as needed.

Marijuana Testing

The Department did not propose any changes to the UrMG in regard to marijuana testing, but received three comments from three commenters disagreeing with the current requirements. Two commenters supported medical use of marijuana. One commenter supported legalization of marijuana in general.

Current Federal law requires Federal agencies to test for marijuana under E.O. 12564 in their workplace drug testing programs. The Department also edited Section 13.5(c) to clarify that only prescription medications can be offered as a legitimate medical explanation for a positive drug test (as described under Section 13.5 below). No further edits are required at this time.

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or for minor wording changes (*e.g.,* edits for clarity, typographical or grammatical corrections).

Subpart A—Applicability

Section 1.5 What do the terms used in these Guidelines mean?

Two commenters agreed and one disagreed with the Department's proposed revision to the Substituted Specimen definition in Section 1.5 to include specimens tested for a biomarker. The commenter who disagreed stated that there are situations in which a legitimate specimen may be reported as outside the standards for human specimens, and these should be reported as invalid. The Department has reviewed the comment and determined that no change is needed to the proposed Guidelines. The Department will follow the procedures summarized under *Authorized drug testing panel* above to enable public comment and review, and will ensure that a biomarker test is scientifically supported and forensically sound to identify specimens as substituted before allowing its use with federally regulated drug testing. Specimens that do not meet established criteria for the biomarker test will not be reported as substituted.

Section 1.7 What is a refusal to take a federally regulated drug test?

In Section 1.7(a), the Department proposed to remove two exceptions for reporting a refusal to test for a pre-employment test: a donor who fails to appear in a reasonable time and a donor who leaves the collection site before the collection process begins. Seven

commenters submitted seven comments on this proposal.

Five commenters disagreed with the changes, noting that an applicant may fail to appear because they have taken a different job offer. The commenters noted that a refusal to test in the individual's record could prevent individuals from taking other job offers and/or require them to undergo unnecessary return-to-duty testing. The Department has reviewed the comments and determined that no change is needed. As stated in this section, the Federal agency determines a reasonable time for the donor to take the test, consistent with applicable agency regulations, and directs the individual accordingly. At the time an applicant is scheduled for a pre-employment drug test, or before, Federal agencies should provide the applicant with instructions on how to notify the agency in the event that they decide to withdraw their application or to not accept a job offer. Such instructions will allow the agency to cancel the drug test and help applicants avoid a refusal to test result.

One commenter noted that the Guidelines should state that the designated employer representative (DER) makes the determination of a refusal to test. The Department has reviewed the comment and determined that no change is needed. As stated in this section, the Federal agency takes action consistent with applicable agency regulations.

Subpart C—Urine Specimen Tests

Section 3.4 What are the drug and biomarker test analytes and cutoffs for urine?

The Department revised Section 3.4 to describe the annual publication of the drug testing and biomarker testing panels and the nomenclature required for laboratory and MRO reports. Three commenters submitted four comments on the required nomenclature required for laboratory and MRO reports, which are addressed below. Comments on the testing panels are addressed under *Authorized drug testing panel* and *Authorized biomarker testing panel* above.

In regard to the required nomenclature specified in the annual **Federal Register** Notification, two commenters noted it is difficult and requires substantial effort for stakeholders to make such changes to their information technology (IT) systems. These commenters suggested that HHS convene a working group for review and input on nomenclature changes, to include employers, third party administrators, providers of electronic Federal Custody and Control Forms (ECCF providers), laboratories, and MROs. One commenter agreed with publishing the required nomenclature for each change to the testing panel, but suggested that nomenclature not be changed after publication to avoid increased costs and confusion. One commenter recommended a minimum of one-year implementation period after nomenclature changes are published.

The Department will establish required terminology based on correct scientific nomenclature for added analytes. As described under *Authorized drug testing panel* above, the Department has developed procedures to allow public notice and comment on proposed drug analyte changes through DTAB meetings and procedures. The Department will publish separate nomenclature lists for urine and oral fluid analytes.

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.2 What happens if the correct Office of Management and Budget (OMB)-approved Federal CCF is not available or is not used?

One commenter stated that the Department should specify what constitutes an incorrect form, how a collector's signed memorandum must be submitted to correct submission of an incorrect CCF, and what actions an HHS-certified laboratory must take in response to an incorrect CCF. The Department has determined that no changes to the Guidelines are needed. The Department issues Guidance for Using the Federal CCF as part of the OMB-approved package and provides information and guidance specific to the current and expired versions of the Federal CCF, rather than including them in these Guidelines.

Subpart H—Urine Specimen Collection Procedure

8.3 What are the preliminary steps in the urine specimen collection procedure?

There were no comments on this section; however, the Department added a sentence in item h stating that a donor is not required to remove any items worn for faith-based reasons. This requirement will be specified for all authorized specimen types.

Subpart K—Laboratory

Section 11.20 How long must an HHS-certified laboratory retain specimens?

The Department did not propose any changes to this section. One commenter submitted a comment specifically agreeing with the existing UrMG requirement for laboratories to maintain substituted urine specimens for a period of one year after reporting. The comment appeared to be in response to DOT's February 28, 2022 notice of proposed rulemaking (NPRM) for transportation industry drug testing programs.

Subpart M—Medical Review Officer (MRO)

Section 13.3 What training is required before a physician may serve as an MRO?

The Department did not propose any changes to this section; however, one commenter indicated that this section is unclear and needs substantial clarification regarding additional MRO training (*e.g.,* what must training consist of, must the MRO take another certification exam, would this be required for annual panel changes). The commenter also suggested that MROs register with SAMHSA to get updates/announcements and acknowledge review of that information.

The Department has reviewed these comments and edited item b of this section to clarify that MROs must be trained on any revisions to the drug and biomarker testing panels. In regard to training, SAMHSA relies on the approved MRO certification entities to ensure that MROs certified by their organizations meet Guidelines requirements. Current documents on the SAMHSA website *https://www.samhsa.gov/workplace* include the HHS Medical Review Officer Guidance Manual, MRO Cases Studies for Urine, and MRO Case Studies for Urine which address most of the suggested topics. The Department does not maintain an email list, but sends a notice through the NLCP to HHS-approved MRO certification organizations for dissemination to their certified MROs. The Department also sends additional guidance to HHS-certified laboratories to share with MROs, clients, and collectors as applicable.

Section 13.5 What must an MRO do when reviewing a urine specimen's test results?

The Department revised Section 13.5(d)(2) to clarify that passive exposure to any drug (not just marijuana smoke) and ingestion of food products containing a drug (not just those containing marijuana) are not acceptable medical explanations for a positive drug test. The Department also added Section 13.5(d)(2)(iii) to clarify that only prescription medications can be offered as a legitimate medical explanation for

a positive drug test. Two commenters disagreed with the addition of Section 13.5(d)(2)(iii), maintaining that a physician's recommendation for medical marijuana should be considered a legitimate medical explanation for a positive test. The Department has evaluated these comments and determined that no change is needed at this time. Although an increased number of States have authorized marijuana use for medical purposes, marijuana remains a Schedule I controlled substance and cannot be prescribed under Federal law. For purposes of the Federal drug free workplace program, Federal law pertaining to marijuana control supersedes State marijuana laws, and therefore, a physician's recommendation for marijuana use is not a legitimate medical explanation for a positive marijuana test. Also see comments under *Marijuana testing* above.

In addition to the changes described above, the Department reordered UrMG Sections 13.8 and 13.9 to reflect the procedural order (*i.e.,* requirements for an MRO to report a primary specimen test result are now in Section 13.8, and requests for a test of the split specimen are addressed in Section 13.9).

Regulatory Impact and Notices

The potential impact that these Guidelines have on the Department of Transportation (DOT) and/or Nuclear Regulatory Commission (NRC) regulated industries depends on the extent to which these agencies incorporate the UrMG revisions into their regulatory programs. Therefore, analysis of the potential impact of these Guidelines on such programs falls under the regulatory purview of DOT and NRC.

Executive Order 14094, 13563, and 12866

Executive Order 14094 of April 6, 2023 (Modernizing Regulatory Review) reaffirms the statement set forth in 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) that ''Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.'' Consistent with this mandate, Executive Order 13563 requires agencies to tailor ''regulations to impose the least burden on society, consistent with obtaining regulatory objectives.'' Executive Order 13563 also requires agencies to ''identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice'' while selecting ''those approaches that maximize net benefits.'' The regulatory approach in this document will reduce burdens to providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the Guidelines under Executive Order 12866, as amended by Executive Order 14094, which directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

According to Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as one that is likely to result in a rule that may meet any one of a number of specified conditions, including: (1) have an annual effect on the economy of $200 million or more in any one year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern Federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

Costs and Benefits

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the April 7, 2022 **Federal Register** Notification for the proposed UrMG (87 FR 20560), and requested public comment on all estimates and assumptions. Two commenters submitted comments concerning the Department's costs and benefits analysis.

One commenter noted that the Department did not consider the application of the Guidelines to DOT testing, and recommended reanalysis of the costs and burden of the proposed changes with consideration of the impact on testing by the transportation industry. Please see the first paragraph of the Regulatory Impact and Notices section above.

The other commenter disagreed with the Department's statement in the preamble to the proposed UrMG that ''implementation costs would be lower for laboratories that already offer the drug test'' compared to those laboratories that do not test for the added drug. The commenter indicated that the list of cost impacts for any change should include the laboratory's assay validation, materials management, and updates to IT systems (*e.g.,* laboratory information management system [LIMS], recipient systems, and electronic ordering systems). This commenter indicated that these additional costs should be considered, and that they will be dependent on the complexity and adaptability of these systems. The Department agrees that costs will depend on the change and noted that in the preamble to the proposed UrMG. The Department will continue to proactively solicit cost information from stakeholders when conducting a cost analysis. As described under *Authorized drug testing panel* above, the Department will include a discussion of related costs and benefits when presenting a proposed panel change during a DTAB meeting.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for Federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget

(OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form (Federal CCF) used to document the collection and chain of custody of urine and oral fluid specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination; the National Laboratory Certification Program (NLCP) application; the NLCP Laboratory Information Checklist; and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect.

In support of the Government Paperwork Reduction Act (PRA), the Department revised the Federal CCF to enable its use as an electronic form (78 FR 42091, July 15, 2013) and developed requirements and oversight procedures to ensure that HHS-certified test facilities and other service providers (*e.g.,* collection sites, MROs) using an electronic version of the Federal CCF (ECCF) maintain the accuracy, security, and confidentiality of electronic drug test information. Before a Federal ECCF can be used for Federal agency specimens, HHS-certified test facilities must submit detailed information and proposed standard operating procedures (SOPs) to the NLCP for SAMHSA review and approval, and undergo an NLCP inspection focused on the proposed ECCF.

Since 2013, SAMHSA has encouraged the use of Federal ECCFs and other electronic processes in HHS-certified test facilities, when practicable, for federally regulated testing operations. In accordance with section 8108(a) of the SUPPORT for Patients and Communities Act, SAMHSA originally set a deadline of August 31, 2023 for all HHS-certified laboratories to submit a request for approval of a digital (paperless) electronic Federal CCF. The Department subsequently extended the deadline to August 31, 2026, to enable sufficient time for all HHS-certified laboratories to identify and contract with an ECCF supplier or to develop an ECCF.

The title and description of the information collected and respondent description are shown in the following paragraphs with an estimate of the annual reporting, disclosure, and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine.

Description: The Mandatory Guidelines establish the scientific and technical guidelines for Federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions.

Description of Respondents: Individuals or households, businesses, or other-for-profit and not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 38,000 donors who apply for employment or are employed in testing designated positions, 100 collectors, 25 urine specimen testing laboratories, 1 IITF, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory or IITF required to submit application for certification.	10	1	3	30
9.12(a)(3)	Materials to submit to become an HHS inspector.	10	1	2	20
11.3	Laboratory submits qualifications of responsible person (RP) to HHS.	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.22	Specifications for laboratory semiannual statistical report of test results to each Federal agency.	10	5	0.5	25
12.3(a)	IITF [1] submits qualifications of RT to HHS	1	1	1	1
12.4(c)	IITF [1] submits information to HHS on new RT or alternate RT.	1	1	1	1
12.19	Specifications for IITF [1] semiannual statistical report of test results to each Federal agency.	1	1	1	1
13.8 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the Federal agency.	100	14	0.05 (3 min)	70
13.11	Specifications for MRO semiannual report to the Secretary or designated representative for Federal agency specimen results that were laboratory-positive and MRO-verified negative.	100	2	0.5	100
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review.	1	1	50	50

ESTIMATE OF ANNUAL REPORTING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total		259			395

[1] Although IITFs are allowed under the UrMG, SAMHSA has not received any IITF application for certification to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF (Sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (Section 10.3(a)); MRO notifies the Federal agency and HHS when an error occurs on a blind sample (Section 10.4(d)); and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide a urine specimen. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(a), 8.5(f)(2)(iii), 8.6(b)(2).	Collector must contact Federal agency point of contact.	100	1	0.05 (3 min)	5
11.23, 11.24	Information on drug test that laboratory must provide to Federal agency upon request or to donor through MRO.	25	10	3	750
12.20, 12.21	Information on drug test that IITF must provide to Federal agency upon request or to donor through MRO.	1	1	1	1
13.9(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	14	3	4,200
Total		226			4956

The following disclosure requirements are also included in the Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the basic collection procedure to the donor and answer any questions (Section 8.3(e) and (g)). SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.5, 8.8	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,660
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	38,000	1	0.08 (5 min)	3,040
11.8(a) & 11.19	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	25	1,520	0.05 (3 min)	1,900
12.8(a) & 12.15	IITF completes Federal CCF upon receipt of specimen and before reporting result.	1	1	1	1
13.4(d)(4), 13.8(c), 14.7(c).	MRO completes Federal CCF before reporting the primary or split specimen result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested.	100	2	0.05 (3 min)	10
Total		38,326			9,511

The Guidelines contain several recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual

to be a collector (Section 4.3(a)(3)) and the documentation must be maintained in the collector's training file (Section 4.3(c)). SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a Federal agency specimen, the collector is required to provide a statement (Section 6.2(b)) explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H (Sections 8.4(c), 8.5(d)(2) and (e)(1) and (2)) requires collectors to enter any information on the Federal CCF of any unusual findings during the urine specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subpart K describes a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* Sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.11(a); 11.14(a); 11.17; 11.21(a), (b), and (c); 11.22; 11.23(a); and 11.24). These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. These practices are integrated in the current processes and, therefore, SAMHSA does not consider these standard business practices to be an additional burden for disclosure. Thus, the total annual response burden associated with the testing of urine specimens by the laboratories and IITFs is estimated to be 14,862 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of the proposed Guidelines to OMB for its review. Comments on the information collection requirements were specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: September 27, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens

Subpart A—Applicability

Subpart B—Urine Specimens

Subpart C—Urine Specimen Tests

Subpart D—Collectors

Subpart E—Collection Sites

Subpart F—Federal Drug Testing Custody and Control Form

Subpart G—Urine Specimen Collection Containers and Bottles

Subpart H—Urine Specimen Collection Procedure

Subpart A—Applicability

Section 1.1 To whom do these Guidelines apply?

(a) These Guidelines apply to:

(1) Executive agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3), but excluding the Armed Forces as defined in 5 U.S.C. 2101(2);

(3) Any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories and instrumented initial test facilities (IITFs) that provide drug testing services to the Federal agencies;

(6) Collectors who provide specimen collection services to the Federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the Federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

Section 1.2 Who is responsible for developing and implementing these Guidelines?

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for Federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How does a Federal agency request a change from these Guidelines?

(a) Each Federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a Federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How are these Guidelines revised?

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) Revisions to these Guidelines will be published in final as a notification in the **Federal Register**.

Section 1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Accessioner. The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of a normal constituent (*e.g.,* nitrite in urine).

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Responsible Technician. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF when the responsible technician is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Biomarker Testing Panel. The panel published in the **Federal Register** that includes the biomarkers authorized for testing, with analytes and cutoffs for initial and confirmatory biomarker tests, as described under Section 3.4.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the Federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or the specimen has been rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Container. A receptacle used to collect a donor's drug test specimen.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support an initial specimen validity test result.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The analytical value (*e.g.,* drug, drug metabolite, or biomarker concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

Dilute Specimen. A urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

Donor. The individual from whom a specimen is collected.

Drug Testing Panel. The panel published in the **Federal Register** that includes the drugs authorized for testing, with analytes and cutoffs for initial and confirmatory drug tests, as described under Section 3.4.

External Service Provider. An independent entity that performs services related to Federal workplace drug testing on behalf of a Federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or (for urine) an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic (digital), or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

Gender Identity. Gender identity means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is adulterated, invalid, substituted, or (for urine) dilute.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.9 when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection (LOD). The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the Federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmatory test cutoff.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2).

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

Responsible Technician (RT). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified IITF.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Urine). A collection in which the specimen collected is divided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.

Substituted Specimen. A specimen that has been submitted in place of the donor's specimen, as evidenced by the absence of a biomarker or a biomarker concentration inconsistent with that established for a human specimen, as indicated in the biomarker testing panel, or (for urine) creatinine and specific gravity values that are outside the physiologically producible ranges of human urine, in accordance with the criteria to report a specimen as substituted in Section 3.7.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101 through 24.104, all agency contracts with laboratories, IITFs, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of section 503 of Public Law 100–71. Each Federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, subparts A and E, may be applicable to certain health care providers with whom a Federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *https://www.hhs.gov/hipaa/index.html.*

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test within a reasonable time, as determined by the Federal agency, consistent with applicable agency regulations, after being directed to do so by the Federal agency;

(2) Fail to remain at the collection site until the collection process is complete;

(3) Fail to provide a specimen (*i.e.,* urine or another authorized specimen type) for any drug test required by these Guidelines or Federal agency regulations;

(4) In the case of a direct observed or monitored collection, fail to permit the observation or monitoring of your provision of a specimen when required as described in Sections 8.9 and 8.10;

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(6) Fail or decline to participate in an alternate specimen collection (*e.g.,* oral fluid) as directed by the Federal agency or collector (*i.e.,* as described in Section 8.6);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the Federal agency. In the case of a Federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the Federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (*e.g.,* refuse to empty pockets when directed by the collector, disrupt the collection process, fail to wash hands after being directed to do so by the collector);

(9) For an observed collection, fail to follow the observer's instructions related to the collection process;

(10) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(11) Attempt to adulterate, substitute, or dilute the specimen;

(12) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(13) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) A refusal to take a test may result in the initiation of disciplinary or adverse action for a Federal employee, up to and including removal from Federal employment. An applicant's refusal to take a pre-employment test may result in non-selection for Federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test, the collector must terminate the collection process and take action as described in Section 8.13. Required action includes immediately notifying the Federal agency's designated representative by any means (*e.g.,* telephone, email, or secure facsimile [fax] machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting

the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the Federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Urine Specimens

Section 2.1 What type of specimen may be collected?

A Federal agency may collect urine and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using urine must follow these Guidelines.

Section 2.2 Under what circumstances may a urine specimen be collected?

A Federal agency may collect a urine specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each urine specimen collected?

Each urine specimen is collected as a split specimen as described in Section 2.5.

Section 2.4 What volume of urine is collected?

A donor is expected to provide at least 45 mL of urine for a specimen.

Section 2.5 How does the collector split the urine specimen?

The collector pours at least 30 mL into a specimen bottle that is designated as A (primary) and then pours at least 15 mL into a specimen bottle that is designated as B (split).

Section 2.6 When may an entity or individual release a urine specimen?

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable Federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.9.

Subpart C—Urine Specimen Tests

Section 3.1 Which tests are conducted on a urine specimen?

A Federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine metabolites as provided in the drug testing panel described under Section 3.4;

(b) Is authorized to test each specimen for other Schedule I or II drugs as provided in the drug testing panel;

(c) Must ensure that the following specimen validity tests are conducted on each urine specimen:

(1) Determine the creatinine concentration on every specimen;

(2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH on every specimen; and

(4) Perform one or more specimen validity tests for oxidizing adulterants on every specimen.

(d) Is authorized to test each specimen for one or more biomarkers as provided in the biomarker testing panel; and

(e) May perform additional testing if a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis.

Section 3.2 May a specimen be tested for drugs other than those in the drug testing panel?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a Federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a Federal agency employee may be tested by the Federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The Federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the Federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in the drug testing panel described under Section 3.4. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under Section 3.2(a).

Section 3.3 May any of the specimens be used for other purposes?

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with subpart C of these Guidelines. Use of specimens by donors, their designees, or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable Federal law.

(b) These Guidelines are not intended to prohibit Federal agencies specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the drug and biomarker test analytes and cutoffs for urine?

The Secretary will publish the drug and biomarker test analytes and cutoffs (*i.e.,* the ''drug testing panel'' and ''biomarker testing panel'') for initial and confirmatory drug and biomarker tests in the **Federal Register** each year. The drug and biomarker testing panels will also be available on the internet at *https://www.samhsa.gov/workplace.*

This drug testing panel will remain in effect until the effective date of a new drug testing panel published in the **Federal Register**:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff
Marijuana metabolite (THCA) [2]	50 ng/mL [3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL [3]	Benzoylecgonine	100 ng/mL.
Codeine/Morphine	2000 ng/mL	Codeine	2000 ng/mL.
		Morphine	4000 ng/mL.
Hydrocodone/Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA [4]/MDA [5]	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

[1] For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff): *Immunoassay:* The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group. *Alternate technology:* Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

[3] *Alternate technology (THCA and benzoylecgonine):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 15 ng/mL for THCA, 100 ng/mL for benzoylecgonine).

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

(a) The drug testing panel will include drugs authorized for testing in Federal workplace drug testing programs, with the required test analytes and cutoffs;

(b) The biomarker testing panel will include biomarkers authorized for testing in Federal workplace drug testing programs, with the required test analytes and cutoffs; and

(c) HHS-certified IITFs, HHS-certified laboratories, and Medical Review Officers must use the nomenclature (*i.e.,* analyte names and abbreviations) published in the **Federal Register** with the drug and biomarker testing panels to report Federal workplace drug test results.

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* tetrahydrocannabivarin, specimen validity tests). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of d,l stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report a urine specimen as adulterated?

An HHS-certified laboratory reports a primary (A) specimen as adulterated when:

(a) The pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(b) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(c) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(d) The presence of a halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or great than 200 mcg/mL nitrite-equivalent cutoff or an equal to or great than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(e) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (*e.g.,* GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(f) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(g) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(h) The presence of any other adulterant not specified in paragraphs (b) through (g) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report a urine specimen as substituted?

An HHS-certified laboratory reports a primary (A) specimen as substituted when:

(a) The creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests on two separate aliquots (*i.e.,* the same colorimetric test may be used to test both aliquots) and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory specific gravity tests on two separate aliquots (*i.e.,* a refractometer is used to test both aliquots), or

(b) A biomarker is not detected or is present at a concentration inconsistent with that established for human urine for both the initial (first) test and the confirmatory (second) test on two separate aliquots (*i.e.,* using the test analytes and cutoffs listed in the biomarker testing panel).

Section 3.8 What criteria are used to report a urine specimen as dilute?

A dilute result may be reported only in conjunction with the positive or negative drug test results for a specimen.

(a) An HHS-certified laboratory or an HHS-certified IITF reports a primary (A) specimen as dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003 on a single aliquot.

(b) In addition, an HHS-certified laboratory reports a primary (A) specimen as dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030.

Section 3.9 What criteria are used to report an invalid result for a urine specimen?

An HHS-certified laboratory reports a primary (A) specimen as an invalid result when:

(a) Inconsistent creatinine concentration and specific gravity results are obtained (*i.e.,* the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(b) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(c) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(d) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(e) The possible presence of a halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(f) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(g) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(h) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(i) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(j) Interference with the confirmatory drug test occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(k) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments;

(l) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(m) A specimen validity test (*i.e.,* other than the tests listed above) on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect urine specimens in accordance with these Guidelines.

(b) The immediate supervisor of a Federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a Federal agency applicant may only collect that Federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A Federal agency employee who is in a testing designated position and subject to the Federal agency drug testing rules must not be a collector for co-workers in the same testing pool or

who work with that employee on a daily basis.

(b) A Federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory or IITF must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or be a personal friend of the employee (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the Federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to the collection procedure described in these Guidelines;

(3) Is trained and qualified to collect a urine specimen. Training must include the following:

(i) All steps necessary to complete a urine collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include one uneventful collection scenario, one insufficient specimen quantity scenario, one temperature out of range scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen bottle tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in Section 4.3(a).

(c) The collector must maintain the documentation of their training and provide that documentation to a Federal agency when requested.

(d) An individual may not collect specimens for a Federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be an observer for a direct observed collection?

(a) An individual may serve as an observer for a direct observed collection when the individual has satisfied the requirements:

(1) Is knowledgeable about the direct observed collection procedure described in Section 8.9;

(2) Is knowledgeable about any guidance provided by the Federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to the direct observed collection procedure described in these Guidelines;

(3) Has received training on the following subjects:

(i) All steps necessary to perform a direct observed collection; and

(ii) The observer's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring that the observation is done in a professional manner that minimizes the discomfort to the employee so observed, ensuring the security of the specimen by maintaining visual contact with the collection container until it is delivered to the collector, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(b) The gender of the observer must be the same as the donor's gender, which is determined by the donor's gender identity. The observer selection process is described in Section 8.10(b).

(c) The observer is not required to be a trained collector.

Section 4.5 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors and may train others to collect urine specimens when they have completed the following:

(1) Qualified as a trained collector and regularly conducted urine drug test collections for a period of at least one year; or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, Federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that documentation to a Federal agency when requested.

Section 4.6 What must a Federal agency do before a collector is permitted to collect a specimen?

A Federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, Federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the Federal agency representative.

Subpart E—Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a urine specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory or IITF;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies;

(f) A restricted access area for the secure storage of records; and

(g) The ability to restrict the donor access to potential diluents in accordance with Section 8.2.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory or IITF are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory or IITF.

Section 5.6 What are the privacy requirements when collecting a urine specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What Federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-Federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory or IITF to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a Federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory or IITF must handle and test the specimen as a Federal agency specimen.

(c) If the HHS-certified laboratory, HHS-certified IITF, or MRO discovers that the collector used an incorrect form, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory or IITF reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory or IITF must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Urine Specimen Collection Containers and Bottles

Section 7.1 What is used to collect a urine specimen?

A single-use collection container with a means (*i.e.,* thermometer) to measure urine temperature and two specimen bottles must be used.

Section 7.2 What are the requirements for a urine collection container and specimen bottles?

(a) The collection container, the thermometer, and the specimen bottles must not substantially affect the composition of drugs and/or metabolites in the urine specimen.

(b) The two specimen bottles must be sealable and non-leaking, and must maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory or IITF for the presence of drugs or their metabolites.

(c) The two specimen bottles must be sufficiently transparent (*e.g.,* translucent) to enable an objective assessment of specimen appearance and identification of abnormal physical characteristics without opening the bottle.

Section 7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?

(a) The collection container must be capable of holding at least 55 mL and have a volume marking clearly noting a level of 45 mL.

(b) One of the two specimen bottles must be capable of holding at least 35 mL and the other at least 20 mL, and each must have a volume marking clearly noting the appropriate level (30 mL for the primary specimen and 15 mL for the split specimen).

(c) The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings from 32–38 °C/90–100 °F. Alternatively, the collector may use another technology to measure specimen temperature (*e.g.,* thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

Subpart H—Urine Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing a urine specimen?

The following privacy requirements apply when a donor is providing a urine specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor. The gender of the observer for purposes of a direct observed collection (*i.e.,* as described in Section 8.10) must be the same as the donor's gender, which is determined by the donor's gender identity. The gender of the monitor for a monitored collection (*i.e.,* as described in Section 8.12) must be the same as the donor's gender, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).

(c) The collector must give the donor visual privacy while providing the specimen. The donor is allowed to provide a urine specimen in an enclosed

stall within a multi-stall restroom or in a single person restroom during a monitored collection.

Section 8.2 What must the collector ensure at the collection site before starting a urine specimen collection?

The collector must deter the dilution or substitution of a specimen at the collection site by:

(a) Placing a toilet bluing agent in a toilet bowl or toilet tank, so the reservoir of water in the toilet bowl always remains blue. If no bluing agent is available or if the toilet has an automatic flushing system, the collector shall turn the water supply off to the toilet and flush the toilet to remove the water in the toilet when possible.

(b) Secure other sources of water (*e.g.,* shower or sink) in the enclosure where urination occurs. If the enclosure has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.11.

Section 8.3 What are the preliminary steps in the urine specimen collection procedure?

The collector must take the following steps before beginning a urine specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the Federal agency policy or contact the Federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because the donor states that they are unable to urinate or an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a Federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the Federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(e) The collector explains the basic collection procedure to the donor.

(f) The collector provides the instructions for completing the Federal CCF for the donor's review, and informs the donor that the instructions are available upon request.

(g) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

(h) The collector asks the donor to remove any unnecessary outer garments (*e.g.,* coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the urine specimen. The collector must ensure that all personal belongings (*e.g.,* purse or briefcase) remain with the outer garments. The donor may retain the donor's wallet. The donor is not required to remove any items worn for faith-based reasons.

(i) The collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(1) If no items are present that can be used to adulterate, substitute, or dilute the specimen, the collector instructs the donor to return the items to their pockets and continues the collection procedure.

(2) If an item is present whose purpose is to adulterate, substitute, or dilute the specimen (*e.g.,* a commercial drug culture product or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13.

(3) If an item that could be used to adulterate, substitute, or dilute the specimen (*e.g.,* common personal care products such as eyedrops, mouthwash, or hand sanitizer) appears to have been inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) If the donor refuses to show the collector the items in their pockets, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13.

(j) The collector shall instruct the donor to wash and dry the donor's hands prior to urination. After washing the donor's hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate or substitute the specimen.

(k) If the donor refuses to wash their hands when instructed by the collector, this is considered a ''refusal to test.'' The collector must stop the collection and report the refusal to test as described in Section 8.13.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?

(a) The collector will provide or the donor may select a specimen collection container that is clean, unused, wrapped/sealed in original packaging and compliant with subpart G of these Guidelines. The specimen collection container package will be opened in view of the donor.

(b)The collector instructs the donor to provide the specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collector directs the donor to provide a specimen of at least 45 mL, to not flush the toilet, and to return with the specimen as soon as the donor has completed the void.

(1) Except in the case of a direct observed collection (*i.e.,* as described in Section 8.10) or a monitored collection (*i.e.,* as described in Section 8.12), neither the collector nor anyone else may go into the room with the donor.

(2) The collector may set a reasonable time limit for specimen collection.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), the collector must report a refusal to test in accordance with Section 8.13.

Section 8.5 What steps does the collector take during and after the urine specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the urine specimen:

(a) The collector must inform the donor that, once the collection procedure has begun, the donor must remain at the collection site (*i.e.,* in an area designated by the collector) until the collection is complete and that failure to follow these instructions will be reported as a refusal to test. This includes the wait period (*i.e.,* up to 3 hours) if needed to provide a sufficient specimen as described in Sections 8.5(f)(2) and 8.6.

(b) After providing the specimen, the donor gives the specimen collection container to the collector. Both the donor and the collector must keep the specimen container in view at all times until the collector seals the specimen bottles as described in Section 8.8.

(c) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash the donor's hands and the donor may flush the toilet.

(d) The collector must measure the temperature of the specimen within 4 minutes of receiving the specimen from the donor. The collector records on the Federal CCF whether or not the temperature is in the acceptable range of 32°–38°C/90°–100 °F.

(1) The temperature measuring device must accurately reflect the temperature of the specimen and not contaminate the specimen.

(2) If the temperature of the specimen is outside the range of 32°–38°C/90°–100 °F, that is a reason to believe that the donor may have adulterated or substituted the specimen. Another specimen must be collected under direct observation in accordance with Section 8.9. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(e) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid urine specimen (*e.g.,* unusual color, presence of foreign objects or material, unusual odor).

(1) The collector notes any unusual finding on the Federal CCF. A specimen suspected of not being a valid urine specimen must be forwarded to an HHS-certified laboratory for testing.

(2) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under direct observation in accordance with Section 8.10. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(f) The collector must determine the volume of urine in the specimen container. The collector must never combine urine collected from separate voids to create a specimen.

(1) If the volume is at least 45 mL, the collector will proceed with steps described in Section 8.8.

(2) If the volume is less than 45 mL, the collector discards the specimen and immediately collects a second specimen using the same procedures as for the first specimen (including steps in Section 8.5(c) and (d)).

(i) The collector may give the donor a reasonable amount of liquid to drink for this purpose (*e.g.,* an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). However, the donor is not required to drink any fluids during this waiting time.

(ii) If the donor provides a sufficient urine specimen (*i.e.,* at least 45 mL), the collector proceeds with steps described in Section 8.8.

(iii) If the employee has not provided a sufficient specimen (*i.e.,* at least 45 mL) within three hours of the first unsuccessful attempt to provide the specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the Federal agency's designated representative for authorization to collect an alternate specimen, and sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency's designated representative. The Federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

(g) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in Section 8.5(d)(2) or (e)(2), refuses to provide a second specimen as required in Section 8.5(f)(2), or refuses to provide an alternate specimen as authorized in Section 8.5(f)(2)(iii), the collector stops the collection and reports the refusal to test in accordance with Section 8.13.

Section 8.6 What procedure is used when the donor states that they are unable to provide a urine specimen?

(a) If the donor states that they are unable to provide a urine specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a urine specimen.

(b) The donor demonstrates their inability to provide a specimen when he or she comes out of the stall with an empty collection container.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a reasonable amount of liquid to drink for this purpose (*e.g.,* an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). If the donor simply needs more time before attempting to provide a urine specimen, the donor may choose not to drink any fluids during the 3 hour wait time.

(2) If the donor states that they are unable to provide a urine specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the Federal agency's designated representative for authorization to collect an alternate specimen, and sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency's designated representative. The Federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

Section 8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the Federal agency.

Section 8.8 How does the collector prepare the urine specimens?

(a) All Federal agency collections are to be split specimen collections.

(b) The collector, in the presence of the donor, pours the urine from the collection container into two specimen bottles to be labeled ''A'' and ''B''. The collector pours at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B, and caps each bottle.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over each specimen bottle cap. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen bottle. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all required information is included on the Federal CCF.

(f) The collector asks the donor to read and sign a statement on the Federal

CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Bottle A and Bottle B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory or IITF that will be testing the Bottle A urine specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory or IITF, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

(j) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: the collector may use excess urine to conduct clinical tests (*e.g.,* protein, glucose) if the collection was conducted in conjunction with a physical examination required by Federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

Section 8.9 When is a direct observed collection conducted?

A direct observed collection procedure must be conducted when:

(a) The agency has authorized a direct observed collection because:

(1) The donor's previous drug test result was reported by an MRO as positive, adulterated, or substituted; or

(2) The HHS-certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not a legitimate medical explanation for the result; or

(3) The MRO reported to the agency that the primary (A) specimen was positive, adulterated, or substituted but the test was cancelled because the split (B) specimen could not be tested or the split specimen failed to reconfirm the primary specimen result; or

(b) At the collection site, an immediate collection of a second urine specimen is required because:

(1) The temperature of the specimen collected during a routine collection is outside the acceptable temperature range; or

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (*e.g.,* abnormal physical characteristic such as unusual color and/or odor, and/or excessive foaming when shaken).

(c) The collector must contact a collection site supervisor to review and concur in advance with any decision by the collector to obtain a specimen under direct observation.

(d) If the donor declines to have a direct observed collection, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

Section 8.10 How is a direct observed collection conducted?

(a) A direct observed collection procedure is the same as that for a routine collection, except an observer watches the donor urinate into the collection container. The observer's gender must be the same as the donor's gender, which is determined by the donor's gender identity, with no exception to this requirement.

(b) Before an observer is selected, the collector informs the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity (as defined in Section 1.5). The collector then selects the observer to conduct the observation:

(i) The collector asks the donor to identify the donor's gender on the Federal CCF and initial it.

(ii) The donor will then be provided an observer whose gender matches the donor's gender.

(iii) The collector documents the observer's name and gender on the Federal CCF.

(c) If there is no collector available of the same gender as the donor's gender, the collector or collection site supervisor shall select an observer trained in direct observed specimen collection as described in Section 4.4. The observer may be an individual that is not a trained collector.

(d) At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps:

(1) The observer enters the restroom with the donor;

(2) The observer must directly watch the urine go from the donor's body into the collection container (the use of mirrors or video cameras is not permitted);

(3) The observer must not touch or handle the collection container unless the observer is also serving as the collector;

(4) After the donor has completed urinating into the collection container:

(i) If the same person serves as the observer and collector, that person may receive the collection container from the donor while they are both in the restroom;

(ii) If the observer is not serving as the collector, the donor and observer leave the restroom and the donor hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the donor hands the container to the collector.

(5) The collector checks the box for an observed collection on the Federal CCF and writes the name of the observer and the reason for an observed collection on the Federal CCF; and

(6) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.11 When is a monitored collection conducted?

(a) In the event that an agency-designated collection site is not available and there is an immediate requirement to collect a specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

(b) If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted.

(c) If the donor declines to permit a collection to be monitored when required, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

Section 8.12 How is a monitored collection conducted?

A monitored collection is the same as that for a routine collection, except that a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen. A person of the same gender as the donor shall serve as the monitor, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The same procedures used for selecting an observer of the appropriate gender in Section 8.10(b) must be used to select the monitor for the purposes of Section 8.12, unless the monitor is a medical professional as described above. The monitor may be an individual other than the collector and need not be a qualified collector.

(a) The collector secures the restroom being used for the monitored collection so that no one except the employee and

the monitor can enter the restroom until after the collection has been completed.

(b) The monitor enters the restroom with the donor.

(c) The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt by the donor to tamper with a specimen, there must be an additional collection under direct observation in accordance with Section 8.9.

(d) The monitor must not touch or handle the collection container unless the monitor is also the collector.

(e) After the donor has completed urinating into the collection container:

(1) If the same person serves as the monitor and collector, that person may receive the collection container from the donor while they are both in the restroom;

(2) If the monitor is not serving as the collector, the donor and monitor leave the restroom and the donor hands the collection container directly to the collector. The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) If the monitor is not serving as the collector, the collector writes the name of the monitor on the Federal CCF.

(g) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.13 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any urine collected and reports the refusal to test by:

(a) Notifying the Federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test including the reason on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the Federal agency's designated representative.

Section 8.14 What are a Federal agency's responsibilities for a collection site?

(a) A Federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H of these Guidelines.

(b) A Federal agency (or only one Federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A Federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory or IITF) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Urine Specimens for Federal agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories and IITFs

Section 9.1 Who has the authority to certify laboratories and IITFs to test urine specimens for Federal agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory or IITF including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory or IITF to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory or IITF is prohibited from stating or implying that it is certified by HHS under these Guidelines to test urine specimens for Federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory or IITF to become HHS-certified?

(a) A laboratory or IITF seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory or IITF provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for Federal agencies.

Section 9.3 What is the process for a laboratory or IITF to maintain HHS certification?

(a) To maintain HHS certification, a laboratory or IITF must:

(1) Successfully participate in both the maintenance PT and inspection programs (*i.e.,* successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory or IITF does not maintain its HHS certification?

(a) A laboratory or IITF that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.20, 11.21, 12.18, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.23, 11.24, 12.20, and 12.21 and subpart P of these Guidelines; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in subpart P of these Guidelines that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in the drug testing panel and must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from Section 9.5(a)(1)(i) and (ii) for a special purpose.

(2) A PT sample may contain an interfering substance, an adulterant, or other substances for special purposes, or may satisfy the criteria for a substituted specimen, dilute specimen, or invalid result.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) PT samples used to evaluate specimen validity tests shall satisfy, but are not limited to, one of the following criteria:

(1) The nitrite concentration will be at least 20 percent above the cutoff;

(2) The pH will be between 1.5 and 5.0 or between 8.5 and 12.5;

(3) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(4) The creatinine concentration will be between 0 and 20 mg/dL; or

(5) The specific gravity will be less than or equal to 1.0050 or between 1.0170 and 1.0230.

(c) For each PT cycle, the set of PT samples going to each HHS-certified laboratory or IITF will vary but, within each calendar year, each HHS-certified laboratory or IITF will analyze essentially the same total set of samples.

(d) The laboratory or IITF must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What are the PT requirements for an applicant laboratory that seeks to perform urine testing?

(a) An applicant laboratory that seeks certification under these Guidelines to perform urine testing must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean; and

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Do not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range, or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to satisfy these requirements will result in the denial of the laboratory's application for HHS certification to perform urine testing.

Section 9.7 What are the PT requirements for an HHS-certified urine laboratory?

(a) A laboratory certified under these Guidelines to perform urine testing must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group means;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each

individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean;

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Do not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any PT sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range, or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the PT requirements for an applicant IITF?

(a) An applicant IITF that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Correctly identify at least 90 percent of the total drug challenges over the three sets of PT samples;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over the three sets of PT samples;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over the three sets of PT samples that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration or ±0.002 specific gravity units for specific gravity.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.9 What are the PT requirements for an HHS-certified IITF?

(a) An IITF certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Correctly identify at least 90 percent of the total drug challenges over two consecutive PT cycles;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified IITF's certification.

Section 9.10 What are the inspection requirements for an applicant laboratory or IITF?

(a) An applicant laboratory or IITF is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's or IITF's testing procedures and facilities using an inspection checklist.

Section 9.11 What are the maintenance inspection requirements for an HHS-certified laboratory or IITF?

(a) An HHS-certified laboratory or IITF must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory or IITF is inspected by two or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's or IITF's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory or IITF must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.12 Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in subpart K of these Guidelines or as a responsible technician for an HHS-certified IITF as described in subpart L of these Guidelines;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance

consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory or IITF.

(b) The Secretary or a Federal agency may conduct an inspection at any time.

Section 9.13 What happens if an applicant laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory or IITF fails to satisfy the requirements established for the initial certification process, the laboratory or IITF must start the certification process from the beginning.

Section 9.14 What happens if an HHS-certified laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory or IITF fails to satisfy the minimum requirements for certification, the laboratory or IITF is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's or IITF's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's or IITF's certification is revoked or suspended in accordance with the process described in subpart P of these Guidelines, the laboratory or IITF is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory or IITF has successfully completed the certification requirements as a new applicant laboratory or IITF.

Section 9.15 What factors are considered in determining whether revocation of a laboratory's or IITF's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory or IITF in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug and specimen validity test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug and specimen validity tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory or IITF by a Federal agency using the laboratory's or IITF's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory or IITF; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory or IITF to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

Section 9.16 What factors are considered in determining whether to suspend a laboratory's or IITF's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's HHS certification to conduct drug testing for Federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.17 How does the Secretary notify an HHS-certified laboratory or IITF that action is being taken against the laboratory or IITF?

(a) When laboratory's or IITF's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory or IITF with written notice of the suspension or proposed revocation by fax, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory or IITF will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory or IITF received the notice, or if expedited review is requested, within 3 days of the date the laboratory or IITF received the notice. Subpart P of these Guidelines contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory or IITF that has its certification revoked or suspended under Section 9.13 or 9.14, respectively, and the name of any HHS-certified laboratory or IITF that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory or IITF that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart P of these Guidelines.

Section 9.18 May a laboratory or IITF that had its HHS certification revoked be recertified to test Federal agency specimens?

Following revocation, a laboratory or IITF may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.17 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory or IITF which has had its certification revoked may reapply for HHS certification as an applicant laboratory or IITF.

Section 9.19 Where is the list of HHS-certified laboratories and IITFs published?

(a) The list of HHS-certified laboratories and IITFs is published monthly in the **Federal Register**. This notice is also available on the internet at *https://www.samhsa.gov/workplace.*

(b) An applicant laboratory or IITF is not included on the list.

Subpart J—Blind Samples Submitted by an Agency

Section 10.1 What are the requirements for Federal agencies to submit blind samples to HHS-certified laboratories or IITFs?

(a) Each Federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory or IITF that the collector sends employee specimens.

(b) Each Federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative, 15 percent must be positive for one or more drugs, and 10 percent must either be adulterated or substituted.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must contain one or more of the drugs or metabolites listed in the drug testing panel.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) A blind sample that is adulterated must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is an adulterated sample at the time of validation.

(d) A blind sample that is substituted must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is a substituted sample at the time of validation.

(e) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory or IITF, and must provide the information upon request to the MRO, the Federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory or IITF?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory or IITF uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory or IITF reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory or IITF reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory or IITF and attempt to determine if the laboratory or IITF made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory or IITF;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the Federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the Federal agency. The Secretary shall ensure notification of the finding as appropriate to other Federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified

laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of Federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.,* for the Department, a Federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What test(s) does an HHS-certified laboratory conduct on a urine specimen received from an IITF?

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

Section 11.10 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay; or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.12.

Section 11.11 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff, using samples at several concentrations between 0 and 150 percent of the cutoff;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.12 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.13 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification (*e.g.,* gas chromatography-mass spectrometry [GC–MS], liquid chromatography-mass spectrometry [LC–MS], GC–MS/MS, LC–MS/MS) or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of a urine specimen when identifying and quantifying drugs or their metabolites.

Section 11.14 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff;

(5) The accuracy (bias) and precision at 40 percent of the cutoff;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.15 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff;

(2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.16 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid, adulterated, or substituted specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results (required specimen validity tests are addressed in Section 11.18); and

(c) Controls must be analyzed concurrently with specimens.

Section 11.17 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.18 What are the requirements for conducting each specimen validity test?

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test;

(2) The initial creatinine test must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;

(iii) A control in the range of 3 mg/dL to 20 mg/dL; and

(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(3) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL; and

(iii) A control in the range of 3 mg/dL to 4 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with initial creatinine test results greater than 5 mg/dL and less than 20 mg/dL, laboratories may perform a screening test using a refractometer that measures urine specific gravity to at least three decimal places to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be subjected to an initial specific gravity test using a four decimal place refractometer when the initial creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002.

(2) The screening specific gravity test must have the following calibrators and controls:

(i) A calibrator or control at 1.000;

(ii) One control targeted at 1.002;

(iii) One control in the range of 1.004 to 1.018.

(3) For the initial and confirmatory specific gravity tests, the refractometer must report and display specific gravity to four decimal places. The refractometer must be interfaced with a laboratory information management system (LIMS), computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the specific gravity test results;

(4) The initial and confirmatory specific gravity tests must have the following calibrators and controls:

(i) A calibrator or control at 1.0000;

(ii) One control targeted at 1.0020;

(iii) One control in the range of 1.0040 to 1.0180; and

(iv) One control equal to or greater than 1.0200 but not greater than 1.0250.

(c) Requirements for measuring pH are as follows:

(1) Colorimetric pH tests that have the dynamic range of 3 to 12 to support the 4 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper (*i.e.,* screening tests) that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH specimen validity test must be performed;

(2) For the initial and confirmatory pH tests, the pH meter must report and display pH to at least one decimal place. The pH meter must be interfaced with a LIMS, computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results;

(3) pH screening tests must have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use;

(4) An initial colorimetric pH test must have the following calibrators and controls:

(i) One calibrator at 4;

(ii) One calibrator at 11;

(iii) One control in the range of 3 to 3.8;

(iv) One control in the range 4.2 to 5;

(v) One control in the range of 5 to 9;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(5) An initial pH meter test, if a pH screening test is not used, must have the following calibrators and controls:

(i) One calibrator at 3;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 3 to 3.8;

(v) One control in the range 4.2 to 5;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(6) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test indicates that the pH is below the lower decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One control in the range of 3 to 3.8; and

(iv) One control in the range 4.2 to 5; and

(7) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test indicates that the pH is above the upper decision point in use:

(i) One calibrator at 7;

(ii) One calibrator at 10;

(iii) One control in the range of 10 to 10.8; and

(iv) One control in the range of 11.2 to 12.

(d) Requirements for performing oxidizing adulterant tests are as follows:

(1) The initial test must include an appropriate calibrator at the cutoff specified in Section 11.19(d)(2), (3), or (4) for the compound of interest, a control without the compound of interest (*i.e.,* a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and

(2) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory test batch must include an appropriate calibrator, a control without the compound of interest (*i.e.,* a certified negative control), and a control with the compound of interest at a measurable concentration.

(e) The requirements for measuring the nitrite concentration are that the initial and confirmatory nitrite tests must have a calibrator at the cutoff, a control without nitrite (*i.e.,* certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

Section 11.19 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report, as described in items p and q below. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug

testing, and the specimen does not meet invalid criteria as described in Section 11.19(h)(1) through (13).

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with the cutoffs listed in the drug testing panel.

(d) A primary (A) urine specimen is reported adulterated when:

(1) The pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(4) The presence of halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory method (*e.g.,* GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory method (*e.g.,* GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in Section 11.19(d)(2) through (7) is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (A) urine specimen is reported substituted when:

(1) The creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory creatinine tests (*i.e.,* the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (*i.e.,* a refractometer is used to test both aliquots) on two separate aliquots; or

(2) A biomarker is not present or is present at a concentration inconsistent with that established for human urine.

(f) A primary (A) urine specimen is reported dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(g) For a specimen that has an invalid result for one of the reasons stated in Section 11.19(h)(4) through (13), the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive, adulterated, or substituted result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(h) A primary (A) urine specimen is reported as an invalid result when:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (*i.e.,* the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(5) The possible presence of a halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(8) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(10) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(12) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(13) A specimen validity test (*i.e.,* other than the tests listed above) on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

(i) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(j) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for a urine specimen. For example, a specimen can be positive for a drug and adulterated.

(k) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(l) An HHS-certified laboratory must report numerical values of the specimen validity test results that support an adulterated, substituted, or invalid result (as appropriate).

(m) An HHS-certified laboratory must report results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

(n) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(o) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* fax, computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(p) HHS-certified laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(q) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.20 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) Retained urine specimens must be kept in secured frozen storage (-20°C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period following the laboratory's reporting of the specimen.

Section 11.21 How long must an HHS-certified laboratory retain records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A Federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.23) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The Federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?

(a) HHS-certified laboratories must provide to each Federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personally identifiable information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test;

(10) Number of specimens reported positive;

(11) Number of specimens reported positive for each drug and drug metabolite;

(12) Number of specimens reported adulterated;

(13) Number of specimens reported substituted; and

(14) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the Federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a Federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.23 What HHS-certified laboratory information is available to a Federal agency?

(a) Following a Federal agency's receipt of a positive, adulterated, or substituted drug test report, the Federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.24 What HHS-certified laboratory information is available to a Federal employee?

Federal applicants or employees who are subject to a workplace drug test may submit a written request through the MRO and/or the Federal agency requesting copies of any records relating to their drug test results or a documentation package as described in Section 11.23(b) and any relevant certification, review, or revocation of certification records. Federal applicants or employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.25 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a Federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a Federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Section 11.26 What type of relationship can exist between an HHS-certified laboratory and an HHS-certified IITF?

An HHS-certified laboratory can enter into any relationship with an HHS-certified IITF.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 What must be included in the HHS-certified IITF's standard operating procedure manual?

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified IITF operations. When followed, the SOP manual ensures that all specimens are tested consistently using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for two years.

Section 12.2 What are the responsibilities of the responsible technician (RT)?

(a) Manage the day-to-day operations of the HHS-certified IITF even if another individual has overall responsibility for alternate areas of a multi-specialty facility.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified IITF. The RT must ensure the continued competency of IITF personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified IITF, and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RT when procedures are first placed into use or changed or when a new individual assumes responsibility for the management of the HHS-certified IITF. The SOP must be reviewed and documented by the RT annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified IITF in response to the following: quality control systems not within performance specifications, errors in result reporting or in analysis of performance testing samples, and inspection deficiencies. The RT must ensure that specimen results are not

reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 12.3 What qualifications must the RT have?

An RT must:

(a) Have at least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(b) Have training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF;

(c) Have training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise;

(d) Be found to fulfill RT responsibilities and qualifications, as demonstrated by the HHS-certified IITF's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying technician.

Section 12.4 What happens when the RT is absent or leaves an HHS-certified IITF?

(a) HHS-certified IITFs must have an RT and an alternate RT. When an RT is absent, an alternate RT must be present and qualified to fulfill the responsibilities of the RT.

(1) If an HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, business trip), the HHS-certified IITF may continue operations and testing of Federal agency specimens under the direction of a certifying technician.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all specimens if the IITF does not have an RT or alternate RT for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RT or alternate RT.

(b) If the RT leaves an HHS-certified IITF:

(1) The HHS-certified IITF may maintain certification and continue testing federally regulated specimens under the direction of an alternate RT for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RT's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all federally regulated specimens if the IITF does not have a permanent RT within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RT.

(c) To nominate an individual as the RT or alternate RT, the HHS-certified IITF must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RT qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified IITF.

(d) The HHS-certified IITF must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RT.

Section 12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?

A certifying technician must have:

(a) Training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 12.6 What qualifications and training must other personnel of an HHS-certified IITF have?

(a) All HHS-certified IITF staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified IITF must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 12.7 What security measures must an HHS-certified IITF maintain?

(a) An HHS-certified IITF must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times except for individuals conducting inspections (*i.e.,* for the Department, a Federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for the access to the secured area.

Section 12.8 What are the IITF chain of custody requirements for specimens and aliquots?

(a) HHS-certified IITFs must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the IITF through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified IITFs must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 12.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay; or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified IITF must validate an initial drug test before testing specimens;

(c) Initial drug tests must be accurate and reliable for the testing of urine specimens when identifying drugs or their metabolites.

(d) An HHS-certified IITF may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 12.11.

Section 12.10 What must an HHS-certified IITF do to validate an initial drug test?

(a) An HHS-certified IITF must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff, using samples at several concentrations between 0 and 150 percent of the cutoff;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 12.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following calibrators and controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 12.12 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each specimen validity test result must be based on performing a single test on one aliquot;

(b) The HHS-certified IITF must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results in accordance with Section 12.14; and

(c) Controls must be analyzed concurrently with specimens.

Section 12.13 What must an HHS-certified IITF do to validate a specimen validity test?

An HHS-certified IITF must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 12.14 What are the requirements for conducting each specimen validity test?

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on the test;

(2) The creatinine test must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;

(iii) A control in the range of 3 mg/dL to 20 mg/dL; and

(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with creatinine test results greater than 5 mg/dL and less than 20 mg/dL, an IITF must perform a screening test using a refractometer to identify specific gravity values that are acceptable (equal to or greater than1.003) or dilute (equal to or greater than1.002 and less than1.003). Specimens must be forwarded to an HHS-certified laboratory when the creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result is less than 1.002.

(2) The screening specific gravity test must have the following calibrators and controls:

(i) A calibrator or control at 1.000;

(ii) One control targeted at 1.002; and

(iii) One control in the range of 1.004 to 1.018.

(c) The requirements for measuring pH are as follows:

(1) The IITF may perform the pH test using a pH meter, colorimetric pH test, dipsticks, or pH paper. Specimens must be forwarded to an HHS-certified laboratory when the pH is less than 4.5 or equal to or greater than 9.0.

(2) The pH test must have, at a minimum, the following calibrators and controls:

(i) One control below 4.5;

(ii) One control between 4.5 and 9.0;

(iii) One control above 9.0; and

(iv) One or more calibrators as appropriate for the test. For a pH meter: calibrators at 4, 7, and 10.

(d) The requirements for measuring the nitrite concentration are that the nitrite test must have a calibrator at 200 mcg/mL nitrite, a control without nitrite (*i.e.,* certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL. Specimens with a nitrite concentration equal to or greater than 200 mcg/mL must be forwarded to an HHS-certified laboratory; and,

(e) Requirements for performing oxidizing adulterant tests are that the test must include an appropriate calibrator at the cutoff specified in Section 11.19(d)(3), (4), or (6) for the compound of interest, a control without the compound of interest (*i.e.,* a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration. Specimens with an oxidizing adulterant result equal to or greater than the cutoff must be forwarded to an HHS-certified laboratory.

Section 12.15 What are the requirements for an HHS-certified IITF to report a test result?

(a) An HHS-certified IITF must report a test result to the agency's MRO within an average of 3 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying technician.

(b) A primary (A) specimen is reported negative when each drug test is negative and each specimen validity test result indicates that the specimen is a valid urine specimen.

(c) A primary (A) urine specimen is reported dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003.

(d) An HHS-certified IITF shall reject a urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified IITF will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(e) An HHS-certified IITF must report results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

(f) HHS-certified IITFs may transmit test results to the MRO by various electronic means (*e.g.,* fax, computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. IITFs and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(g) HHS-certified IITFs must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The

computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(h) For rejected specimens, IITFs must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 12.16 How does an HHS-certified IITF handle a specimen that tested positive, adulterated, substituted, or invalid at the IITF?

(a) The remaining specimen is resealed using a tamper-evident label/seal;

(b) The individual resealing the remaining specimen initials and dates the tamper-evident label/seal; and

(c) The resealed specimen and split specimen and the Federal CCF are sealed in a leak-proof plastic bag, and are sent to an HHS-certified laboratory under chain of custody within one day after completing the drug and specimen validity tests.

Section 12.17 How long must an HHS-certified IITF retain a specimen?

A specimen that is negative, negative/dilute, or rejected for testing is discarded.

Section 12.18 How long must an HHS-certified IITF retain records?

(a) An HHS-certified IITF must retain all records generated to support test results for at least 2 years. The IITF may convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months.

(b) A Federal agency may request the HHS-certified IITF to maintain a documentation package (as described in Section 12.20) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The Federal agency's request to the IITF must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified IITF may retain records other than those included in the documentation package beyond the normal two-year period of time.

Section 12.19 What statistical summary reports must an HHS-certified IITF provide?

(a) HHS-certified IITFs must provide to each Federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personally identifiable information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified IITF name and address;

(3) Federal agency name;

(4) Total number of specimens tested;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test; and

(10) Number of specimens forwarded to an HHS-certified laboratory for testing.

(b) An HHS-certified IITF must make copies of an agency's test results available when requested to do so by the Secretary or by the Federal agency for which the IITF is performing drug-testing services.

(c) An HHS-certified IITF must ensure that a qualified individual is available to testify in a proceeding against a Federal employee when the proceeding is based on a test result reported by the IITF.

Section 12.20 What HHS-certified IITF information is available to a Federal agency?

(a) Following a Federal agency's receipt of a positive, adulterated, or substituted drug test report from a laboratory, the Federal agency may submit a written request for copies of the IITF records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified IITF must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified IITF, and a copy of the electronic report (if any) generated by the HHS-certified IITF;

(4) A brief description of the HHS-certified IITF's drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of all test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the tests; and

(6) Copies of the résumé or curriculum vitae for the RT and for the certifying technician of record.

Section 12.21 What HHS-certified IITF information is available to a Federal employee?

A Federal employee who is the subject of a drug test may provide a written request through the MRO and/or the Federal agency requesting access to any records relating to the employee's drug test results or a documentation package (as described in Section 12.20) and any relevant certification, review, or revocation of certification records.

Section 12.22 What types of relationships are prohibited between an HHS-certified IITF and an MRO?

An HHS-certified IITF must not enter into any relationship with a Federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a Federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified IITF for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified IITF or have any agreement with an HHS-certified IITF that may be construed as a potential conflict of interest.

Section 12.23 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?

An HHS-certified IITF can enter into any relationship with an HHS-certified laboratory.

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for Federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notification in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notification is also available on the internet at *https://www.samhsa.gov/workplace.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect Federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for Federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any Federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines including any changes to the drug and biomarker testing panels prior to their effective date, to continue serving as an MRO for Federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.19(g) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the Federal agency.

(e) The MRO must maintain records for a minimum of two years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen and an alternate specimen was not collected, as addressed in Sections 8.6 and 13.6.

Section 13.5 What must an MRO do when reviewing a urine specimen's test results?

(a) When the HHS-certified laboratory or HHS-certified IITF reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory or HHS-certified IITF reports a negative/dilute result for the primary (A) urine specimen, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.

(1) If the recollected specimen provides a negative or negative/dilute result, the MRO reports a negative result to the agency, with no further action required.

(2) If the recollected specimen provides a result other than negative or negative/dilute, the MRO follows the procedures in Section 13.5(c) through (f) for the recollected specimen.

(c) When the HHS-certified laboratory reports multiple results for the primary (A) urine specimen, the MRO must follow the verification procedures described in Section 13.5(d) through (f) and:

(1) The MRO reports all verified positive and/or refusal to test results to the Federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, the MRO does not report the verified invalid result to the Federal agency at this time. The MRO takes action for the verified invalid result(s) for the primary (A) specimen as described in Section 13.5(f) only when:

(i) The MRO verifies the positive, adulterated, or substituted result as negative based on a legitimate medical explanation as described in Section 13.5(d)(2) and (e)(1); or

(ii) The split (B) specimen is tested and reported as a failure to reconfirm the positive, adulterated, or substituted result as described in Section 14.6(m).

(d) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor admits unauthorized use of the drug(s) that caused the positive result, the MRO reports the test result as positive to the agency. The MRO must document the donor's admission of unauthorized drug use in the MRO records and in the MRO's report to the Federal agency.

(2) If the donor provides documentation (*e.g.,* a valid prescription) to support a legitimate

medical explanation for the positive result, the MRO reports the test result as negative to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor. The MRO follows the procedures in Section 13.5(b)(1) or (2) for the recollected specimen.

(i) Passive exposure to a drug (*e.g.,* exposure to marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing a drug (*e.g.,* products containing marijuana, poppy seeds containing codeine and/or morphine) is not a legitimate medical explanation for a positive urine drug test result.

(iii) A physician's authorization or medical recommendation for a Schedule 1 controlled substance is not a legitimate medical explanation for a positive drug test result.

(3) If the donor is unable to provide a legitimate medical explanation for the positive result, the MRO reports the positive result to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO may choose not to report the dilute result.

(e) When the HHS-certified laboratory reports an adulterated or substituted result for the primary (A) urine specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the Federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the Federal agency because the urine specimen was adulterated or substituted.

(f) When the HHS-certified laboratory reports an invalid result for the primary (A) urine specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result. In the case of an invalid result based on pH of 9.0 to 9.5, when an employee has no other medical explanation for the pH in this range, the MRO must consider whether there is evidence of elapsed time and high temperature that could account for the pH value. The MRO may contact the collection site, HHS-certified IITF, and/or HHS-certified laboratory to discuss time and temperature issues (*e.g.,* time elapsed from collection to receipt at the testing facility, likely temperature conditions between the time of the collection and transportation to the testing facility, specimen storage conditions).

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medicine) or if the MRO determines that time and temperature account for the pH in the 9.0 to 9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and informs the Federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation or if the MRO determines that time and temperature fail to account for the pH in the 9.0–9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and directs the Federal agency to immediately collect another urine specimen from the donor using a direct observed collection.

(i) If the specimen collected under direct observation provides a valid result, the MRO follows the procedures in Section 13.5(a) through (e).

(ii) If the specimen collected under direct observation provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* oral fluid). If the Federal agency does not authorize collection of another specimen type, the MRO consults with the agency to arrange a clinical evaluation as described in Section 13.7, to determine whether there is a legitimate medical reason for the invalid result.

(g) When two separate specimens collected during the same testing event were sent to the HHS-certified laboratory for testing (*e.g.,* the collector sent a urine specimen out of temperature range and the subsequently collected specimen—urine or another authorized specimen type), as the MRO, you must follow the verification procedures described in Sections 13.4, 13.5, and 13.6, and:

(1) If both specimens were verified negative, report the result as negative.

(2) If one specimen was verified negative and the other was not (*i.e.,* the specimen was verified as negative/dilute or as positive, adulterated, substituted, and/or invalid), report only the verified result(s) other than negative. For example, if you verified one specimen as negative and the other as a refusal to test because the specimen was substituted, report only the refusal to the Federal agency.

(3) If both specimens were verified as positive, adulterated, and/or substituted, report all results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, report the positive and the refusal results to the Federal agency.

(4) If one specimen has been verified and the HHS-certified laboratory has not reported the result(s) of the other specimen,

(i) Report verified result(s) of positive, adulterated, or substituted immediately and do not wait to receive the result(s) of the other specimen.

(ii) Do not report a verified result of negative, negative/dilute, or invalid for the first specimen to the Federal agency. Hold the report until results of both specimens have been received and verified.

(5) When the HHS-certified laboratory reports an invalid result for one or both specimens, follow the procedures in Section 13.5(c).

(h) When the HHS-certified laboratory or HHS-certified IITF reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor. The recollected specimen must be the same type (*i.e.,* urine).

Section 13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?

(a) When another specimen type (*e.g.,* oral fluid) was collected in accordance with Section 8.6, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

(b) When the Federal agency did not authorize the collection of an alternate specimen, the MRO consults with the Federal agency. The Federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition (*e.g.,* a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable

to correction or cure for an extended period of time. Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genitourinary matters. Acute or temporary medical conditions, such as cystitis, urethritis, or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in the previous sentence.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of urine to complete the test;

(ii) The consequences of the appropriate Federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in Section 13.6(b)(3) and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the Federal agency in writing:

(i) A medical condition as defined in Section 13.6(b)(1) has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the Federal agency.

(ii) A permanent or long-term medical condition as defined in Section 13.6(b)(1) has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine and is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the Federal agency and recommend that the agency authorize collection of an alternate specimen type (*e.g.,* oral fluid) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, you must report a refusal to test to the Federal agency.

(4) When a Federal agency receives a report from the MRO indicating that a test is cancelled as provided in Section 13.6(b)(3)(i), the agency takes no further action with respect to the donor. When a test is canceled as provided in Section 13.6(b)(3)(ii), the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the Federal agency plan. The donor remains in the random testing pool.

Section 13.7 What happens when an individual is unable to provide a sufficient amount of urine for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the Federal agency does not authorize collection of an alternate specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of illicit drug use, as the MRO, you must report the result to the Federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* oral fluid) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the Federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the Federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

Section 13.8 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* fax, computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 13.9 Who may request a test of a split (B) specimen?

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B)

specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the Federal agency on the primary (A) specimen.

Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory or an HHS-certified IITF for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or HHS-certified IITF, or have any agreement with the HHS-certified laboratory or the HHS-certified IITF that may be construed as a potential conflict of interest.

Section 13.11 What reports must an MRO provide to the Secretary for urine testing?

(a) An MRO must send to the Secretary or designated HHS representative a semiannual report of Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. The report must not include any personally identifiable information for the donor and must be submitted by mail, fax, or other secure electronic transmission method within 14 working days after the end of the semiannual period (*i.e.,* in January and July). The semiannual report must contain the following information:

(1) Reporting period (inclusive dates);

(2) MRO name, company name, and address;

(3) Federal agency name; and

(4) For each laboratory-reported positive drug test result that was verified as negative by the MRO:

(i) Specimen identification number;

(ii) Laboratory name and address;

(iii) Positive drug(s) or drug metabolite(s) verified as negative;

(iv) MRO reason for verifying the positive drug(s) or drug metabolite(s) as negative (*e.g.,* a donor prescription [the MRO must specify the prescribed drug]);

(v) All results reported to the Federal agency by the MRO for the specimen; and

(vi) Date of the MRO report to the Federal agency.

(b) An MRO must provide copies of the drug test reports that the MRO has sent to a Federal agency when requested to do so by the Secretary.

(c) If an MRO did not verify any positive laboratory results as negative during the reporting period, the MRO should file a report that states that the MRO has no reportable results during the applicable reporting period.

Section 13.12 What are a Federal agency's responsibilities for designating an MRO?

(a) Before allowing an individual to serve as an MRO for the agency, a Federal agency must verify and document the following:

(1) that the individual satisfies all requirements in Section 13.1, including certification by an MRO certification organization that has been approved by the Secretary, as described in Section 13.2; and

(2) that the individual is not an employee, agent of, or have any financial interest in an HHS-certified laboratory or an HHS-certified IITF that tests the agency's specimens, as described in Section 13.10.

(b) The Federal agency must verify and document that each MRO reviewing and reporting results for the agency:

(1) completes training on any revisions to these Guidelines, including any changes to the drug and biomarker testing panels, prior to their effective date;

(2) at least every five years, maintains their certification by completing requalification training and passing a requalification examination; and

(3) provides biannual reports to the Secretary or designated HHS representative as required in Section 13.11;

(c) The Federal agency must ensure that each MRO reports drug test results to the agency in accordance with Sections 13.8 and 14.7.

(1) Before allowing an MRO to report results electronically, the agency must obtain documentation from the MRO to confirm that the MRO and any external service providers ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

Subpart N—Split Specimen Tests

Section 14.1 When may a split (B) urine specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) urine specimen be tested at a different (*i.e.,* second) HHS-certified laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) urine specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory to perform the test), the MRO reports a cancelled test to the Federal agency and the reason for the cancellation. The MRO directs the Federal agency to ensure the immediate recollection of another urine specimen from the donor under direct observation, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified laboratory, a Federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoffs established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

(c) For a split (B) urine specimen, if the second HHS-certified laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first HHS-certified laboratory, the second laboratory must conduct specimen validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same specimen validity tests as it would conduct on a primary (A) urine specimen and reports those results to the MRO.

Section 14.3 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported adulterated?

(a) An HHS-certified laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (B) urine specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (*i.e.,* either less than 4 or equal to or greater than 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff of equal to or greater than 500 mcg/mL;

(3) Surfactant must be measured using the laboratory's confirmatory surfactant test with a cutoff of equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff; or

(4) For adulterants without a specified cutoff (*e.g.,* glutaraldehyde, chromium (VI), pyridine, halogens (such as, chlorine from bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory specimen validity test at an established LOQ to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported substituted?

(a) An HHS-certified laboratory must use the following criteria to reconfirm a substituted result when testing a split (B) urine specimen:

(1) *For substitution based on creatinine and specific gravity testing:* The creatinine must be measured using the laboratory's confirmatory creatinine test with a cutoff of less than 2 mg/dL, and the specific gravity must be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than or equal to 1.0010 or equal to or greater than 1.0200.

(2) *For substitution based on biomarker testing:* The laboratory must test for the biomarker using its confirmatory test (*i.e.,* using the confirmatory test analytes and cutoffs in the biomarker testing panel).

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

Section 14.5 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.6 What action(s) does an MRO take after receiving the split (B) urine specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) urine specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and the specimen was adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and the specimen was substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request additional review or testing as follows:

(1) *For substitution based on creatinine and specific gravity:* request that Laboratory A review the creatinine and specific gravity results for the primary (A) specimen.

(2) *For substitution based on biomarker testing:* request that Laboratory A test the primary (A) specimen using its confirmatory test for the biomarker.

(i) If the primary (A) specimen's test results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency.

(ii) If the primary (A) specimen's results fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and the specimen was not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s]), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was adulterated.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace

program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was not adulterated or substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen had an invalid result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (not adulterated: specifying the adulterant/pH or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm substitution or adulteration and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: specifying the adulterant/pH or not substituted, and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure and notifies the HHS office responsible for coordination of the drug-free workplace program.

(l) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(m) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and not adulterated: specifying the adulterant/pH or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(n) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s] and adulterated) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(o) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s] and not adulterated: specifying the adulterant/pH). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(p) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: specifying the adulterant/pH, and not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(q) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (not adulterated: specifying the adulterant/pH). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(r) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

Section 14.7 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* fax, computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.8 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions, in accordance with Section 11.20. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O—Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a urine specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory or IITF must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken, or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(f) The specimen was received at the HHS-certified laboratory or IITF without a CCF;

(g) The CCF was received at the HHS-certified laboratory or IITF without a specimen;

(h) The collector performed two separate collections using one CCF; or

(i) The HHS-certified laboratory or IITF identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory or IITF must hold the specimen and attempt to obtain a memorandum for record to recover the collector's signature. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory or IITF cannot recover the collector's signature, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the HHS-certified laboratory or IITF must test the specimen and also attempt to obtain a memorandum for record explaining why a non-Federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the report for at least 5 business days, the HHS-certified laboratory or IITF cannot obtain a memorandum for record from the collector, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory or IITF should not cause an HHS-certified laboratory or IITF to reject a urine specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's Social Security Number or employee identification number;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) A ''collection'' box is not marked;

(11) The ''observed'' box is not marked (if applicable);

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the HHS-certified laboratory or IITF copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(19) The collector failed to check the specimen temperature box and the ''Remarks'' line did not have a comment regarding the temperature being out of range. If, after at least 5 business days, the collector cannot provide a memorandum for record to attest to the fact that the collector did measure the specimen temperature, the HHS-certified laboratory or IITF may report the test result for the specimen but indicates that the collector could not provide a memorandum to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory or IITF should not cause an MRO to cancel a test:

(1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory or IITF will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector, HHS-certified laboratory, or HHS-certified IITF (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 What discrepancies may require an MRO to cancel a test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or substituted; or

(3) The electronic report provided by the HHS-certified laboratory or HHS-certified IITF does not contain all the data elements required for the HHS standard laboratory or IITF electronic report for a specimen being reported drug positive, adulterated, invalid result, or substituted.

(b) If the error in Section 15.4(a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If the error in Section 15.4(a)(2) occurs, the MRO must obtain a

statement from the certifying scientist that they forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If the error in Section 15.4(a)(3) occurs, the MRO must contact the HHS-certified laboratory or HHS-certified IITF. If, after at least 5 business days, the laboratory or IITF does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P—Laboratory or IITF Suspension/Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory or IITF be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory or IITF in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory or IITF has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory or IITF which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of the official's employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory or IITF attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period, advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedures are used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at their discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of the official's employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At their discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory or IITF in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory or IITF received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Section 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by fax,

secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by fax, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and Federal holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue their decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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Part V

Department of Health and Human Services

42 CFR Chapter I
Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter I

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Issuance of mandatory guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') has revised the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) which published in the **Federal Register** of October 25, 2019.

DATES: The mandatory guidelines are effective October 10, 2023.

FOR FURTHER INFORMATION CONTACT: Eugene D. Hayes, Ph.D., MBA, SAMHSA, CSAP, DWP; 5600 Fishers Lane, Room 16N02, Rockville, MD 20857, by telephone (240) 276–1459 or by email at *Eugene.Hayes@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

These revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) establish a process whereby the Department annually publishes the authorized drug testing panel (*i.e.,* drugs, analytes, or cutoffs) to be used for Federal workplace drug testing programs; revise the definition of a substituted specimen to include specimens with a biomarker concentration inconsistent with that established for a human specimen, establish a process whereby the Department publishes an authorized biomarker testing panel (*i.e.,* biomarker analytes and cutoffs) for Federal workplace drug testing programs; update and clarify the oral fluid collection procedures; revise the Medical Review Officer (MRO) verification process for positive codeine and morphine specimens; and require MROs to submit semiannual reports to the Secretary or designated HHS representative on Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. In addition, some wording changes have been made for clarity and for consistency with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) or to apply to any authorized specimen type.

The Department is publishing a separate Federal Register Notification (FRN) elsewhere in this issue of the **Federal Register** with the revised UrMG, which include the same or similar revisions as the OFMG, where appropriate.

Background

Pursuant to its authority under section 503 of Public Law 100–71, 5 U.S.C. 7301, and Executive Order 12564, HHS establishes the scientific and technical guidelines for Federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for Federal agencies.

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates that 275,000 urine specimens are tested annually by Federal agencies. No Federal agencies are testing hair or oral fluid specimens at this time.

HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (hereinafter referred to as Guidelines or Mandatory Guidelines) in the **Federal Register** (FR) on April 11, 1988 (53 FR 11979). The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 (59 FR 29908), September 30, 1997 (62 FR 51118), November 13, 1998 (63 FR 63483), April 13, 2004 (69 FR 19644), and November 25, 2008 (73 FR 71858). SAMHSA published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) on January 23, 2017 (82 FR 7920) and published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) on October 25, 2019 (84 FR 57554). SAMHSA published proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair (HMG) on September 10, 2020 (85 FR 56108) and proposed revisions to the UrMG (87 FR 20560) and OFMG (87 FR 20522) on April 7, 2022.

There was a 60-day public comment period following publication of the proposed OFMG, during which 53 commenters submitted 204 comments on the OFMG. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at *https://www.regulations.gov/.* All comments were reviewed and taken into consideration in the preparation of the Guidelines. The issues and concerns raised in the public comments for the OFMG are set forth below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

The following comments were directed to the information and questions in the preamble.

Some submitted comments were specific to transportation industry drug testing which is regulated by the Department of Transportation (DOT). The Department has noted these comments below, but responded only to comments that are relevant to these Guidelines. DOT issued a notice of proposed rulemaking (NPRM) on February 28, 2022 (87 FR 11156). Subsequently, DOT extended the comment period to April 29, 2022 (87 FR 16160), and published the final rule on May 2, 2023 (88 FR 27596).

Authorized Drug Testing Panel

The Department requested comments on its proposal to publish the drug testing panel separately from the OFMG in a Federal Register\[[[[p Notification (FRN) each year. Fifteen commenters submitted a total of 40 comments on this topic for the OFMG.

Nine commenters disagreed with publishing a revised drug testing panel without a public comment period, expressing concerns that stakeholders including individuals subject to federally regulated drug testing would not be given the opportunity to provide comment and that the Department would miss valuable input including information on costs and burden. Some of these commenters suggested alternate ways to permit public comment while enabling a quicker response to testing panel changes (*e.g.,* setting a shorter comment period, publishing the Guidelines as an interim final rule or issuing an advance notice of proposed rulemaking). The Department has reviewed these comments and suggestions and determined that no changes to the proposed Guidelines are needed. The Department has developed procedures which will allow review and comment before testing panel changes are published, as described below.

Consistent with current procedures, prior to making a change to the drug or biomarker testing panel, the Department will conduct a thorough review of the scientific and medical literature, and will solicit review and input from subject matter experts such as Responsible Persons (RPs) of HHS-certified laboratories, Medical Review Officers (MROs), research scientists,

manufacturers of collection devices and/or immunoassay kits, as well as Federal partners such as DOT, the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA). Further, the Department plans to provide notice and opportunity for public comment regarding any proposed changes to the drug and biomarker testing panels as part of Drug Testing Advisory Board (DTAB) meetings and procedures.

Information regarding any proposed changes to the drug and biomarker testing panels and a request for public comment will be included in an advance notice of the DTAB meeting published in the **Federal Register**, along with the timeframe and method(s) for comment submission. During the meeting, the Department will present the basis for adding or removing analytes (*i.e.,* including technical and scientific support for the proposed changes), as well as a discussion of related costs and benefits. This information will be provided in advance to DTAB members. The Department will review all submitted public comments and will share information during a DTAB session prior to DTAB's review of SAMHSA's recommendation to the Secretary regarding each proposed change.

The Department will make the final decision on any panel changes and include the effective date(s) in the annual Notice, to allow time for drug testing service providers (*e.g.,* immunoassay kit manufacturers, oral fluid collection device manufacturers) to develop or revise their products, and for HHS-certified laboratories to develop or revise assays, complete validation studies, and revise procedures.

Three commenters specifically agreed with the need to streamline and improve processes for making changes to the testing panels, but expressed concern over the process for testing panel review and who would be involved. These commenters suggested involving other stakeholders (*e.g.,* HHS-certified laboratories, DTAB, FDA). As noted above, the Department will use multiple methods and involve subject matter experts from various stakeholder groups to determine testing panel changes, and will provide opportunity for public review and comment before changes are made. FDA, DOT, and other Federal partners will have opportunities to review and provide input.

Four commenters disagreed that HHS is exempt from the Administrative Procedure Act (APA) requirements. Two of these specifically stated that the Guidelines are subject to APA requirements because DOT is required to use the Guidelines for their transportation industry drug testing programs. The Department has reviewed these comments and determined that no change is needed to the proposed Guidelines. The Department explained why the APA does not apply under the *Regulatory Impact and Notices* section of the current OFMG (84 FR 57554) and has repeated the same information in that section below.

Two commenters suggested that the Department limit changes to every few years (*e.g.,* four to five years). The Department will not set such time limits for panel changes. The need for more timely testing panel changes was clearly explained in the preamble to the proposed Guidelines.

Eight commenters were concerned that the Department will not allow sufficient time for stakeholders to implement changes (*e.g.,* time for FDA clearance for new or revised products, information technology [IT] changes, process development and/or changes, contractual changes, and training). Some of these commenters suggested that the Department set a standard time for implementation of all changes (*e.g.,* 90 days, six months) or based on the complexity of the change (*e.g.,* between 90 and 365 days). The Department will establish a reasonable time for implementation based on the change, rather than setting a standard time period for all changes. As noted above, the Department will solicit information from multiple sources to assist in decision making.

In regard to the use of FDA-cleared collection devices and immunoassay initial tests, four commenters suggested that federally regulated drug testing could fall under what they referred to as the FDA's Employment and Insurance exemption. The Department notes that, while some drugs of abuse test systems intended for employment and insurance testing are, under certain circumstances, exempt from the premarket notification procedures in 21 CFR part 807, subpart E, such exemptions do not apply to test systems intended for Federal drug testing programs. See 21 CFR part 862, subpart D. Because the Department does not address FDA clearance requirements for test systems in the Mandatory Guidelines, the reference to FDA clearance for oral fluid collection devices has been removed from Section 7.1. Applicant and HHS-certified laboratories must verify that oral fluid collection devices and test systems subject to FDA regulations are approved or otherwise cleared by FDA and, in addition, must validate the oral fluid collection devices and test systems prior to use in accordance with requirements specified in the National Laboratory Certification Program (NLCP) Manual for Oral Fluid Laboratories.

Two commenters appeared to misinterpret the Department's testing panel proposal, objecting to the Department making changes to the testing panels each year. The Department plans to issue an annual Notice with the current testing panels and required nomenclature, but will make changes only when needed to ensure the continued effectiveness of Federal workplace drug testing programs, which may not be every year.

See additional comments under Section 3.4 below.

Authorized Biomarker Testing Panel

The Department requested comments on its proposal to publish the biomarker testing panel separately from the OFMG in a **Federal Register** Notification each year. Seven commenters submitted a total of 14 comments on this topic for the OFMG.

One commenter disagreed with specimen validity or biomarker testing for oral fluid specimens, because all collections are observed and collection devices are required to have volume indicators. The commenter stated these tests would be unnecessary and increase costs. The commenter also noted that the observed collections and required inspection of the oral fluid reduced the risk of adulteration or substitution. Four commenters suggested that the Department require all HHS-certified laboratories to perform standardized specimen validity and biomarker tests on all federally regulated specimens, and allow laboratories to choose whether to offer additional specialized tests upon MRO request on a case-by-case basis. The Department agrees that there are no known effective subversion products for oral fluid specimens at this time; however, such products may be available in the future. The Department has also included examples in the HHS Oral Fluid Specimen Handbook (posted on SAMHSA's website, *https://www.samhsa.gov/workplace*) to assist trained collectors in identifying donor attempts to tamper with the collection of their oral fluid specimen. The Department is not requiring all certified laboratories to conduct oral fluid specimen validity testing or biomarker testing at this time. However, if the drug testing industry identifies a need for such tests and an HHS-certified laboratory chooses to offer them to their regulated clients, the Department will ensure that the tests provide scientifically valid and forensically defensible results and will revisit the

need for requiring the tests on all specimens.

Two commenters disagreed with publishing a biomarker testing panel without a public comment period, expressing concerns that stakeholders would not be given the opportunity to provide comment and that the Department would miss valuable input including information on costs and burden. The Department has reviewed these comments and determined that no changes to the proposed Guidelines are needed. The Department has developed procedures which will allow review and comment before testing panel changes are published, as described under *Authorized drug testing panel* above.

Three commenters specifically agreed with the need to streamline and improve processes for making changes to the testing panels. One of these commenters noted that since there are no currently agreed-upon analytes to assess OF validity and there may be differences in buffered collection devices, determining a biomarker panel may be complex. The other two commenters suggested involving other stakeholders (*e.g.,* HHS-certified laboratories, DTAB). A different commenter recommended that the Department consult with immunoassay manufacturers and OF testing laboratories to understand the scope of making proposed changes, availability of materials/reagents, etc. As noted under *Authorized drug testing panel* above, the Department will use multiple methods and involve subject matter experts from various stakeholder groups to determine testing panel changes, and will provide opportunity for public review and comment before changes are made. Federal partners will also have opportunities to review and provide input.

One commenter disagreed that HHS is exempt from the APA requirements. The Department has reviewed the comment and determined that no change is needed to the proposed Guidelines. The Department explained why the APA does not apply under the *Regulatory Impact and Notices* section of the current OFMG (84 FR 57554) and has repeated the same information in that section below.

Medical Review Officer (MRO) Verification of Codeine and Morphine Test Results

In Section 13.5, the Department removed the requirement for the MRO to report specimens with morphine and/or codeine between the cutoff and 150 ng/mL as positive based on clinical evidence of illicit drug use and, instead, directed the MRO to verify such specimens as negative unless the donor admits to illegal opioid use that could have caused the positive result. Four commenters agreed with this change.

Medical Review Officer (MRO) Semiannual Reports

In Section 13.11, the Department added requirements for each MRO performing medical review services for Federal agencies to submit semiannual reports, in January and July of each year, of Federal agency specimens that were reported as positive for a drug or drug metabolite by the laboratory and verified as negative by the MRO, along with the reason for the negative verification (*e.g.,* a valid prescription for a drug). Six commenters submitted eight comments on this topic for the OFMG.

Three commenters disagreed, stating that HHS had not clearly described the reason and the process for such reports. One commenter noted that the Department had not presented data documenting that MROs were incorrectly reporting specimens, and it was unclear how the reports could be matched to laboratory report information submitted to the National Laboratory Certification Program (NLCP). Another commenter stated that it was unclear what actions would be taken if the Department disagreed with the MRO report. The third commenter was concerned that donors would be identifiable, and that ''a database of legal drug use'' would violate donor privacy. One of the commenters expressed concern over ''unintended consequences'' for DOT and state workplace drug testing programs, without further explanation.

Two commenters disagreed on the basis of added costs and burden to MROs. One claimed that this would result in MROs tracking and reporting all results sent by the laboratory, as they are already required to report positive results to the Federal Motor Carrier Safety Administration (FMCSA) Clearinghouse. The other claimed that this would require documentation and report generation for each non-negative result, and expressed concern that smaller MRO practices could find the process too time-consuming and costly to continue in the program.

One commenter agreed that such reports could be beneficial, but suggested that MROs provide the same information as provided by laboratories to the NLCP. The commenter incorrectly stated that laboratories do not provide specimen identification numbers to the NLCP.

The Department has reviewed the comments and determined that no change is needed to the proposed Guidelines. To clarify, this reporting policy is only for Federal agency specimens, not DOT-regulated specimens. Further, the reports are not for all positive specimens, only for those specimens that were reported as positive by the laboratory and verified as negative by the MRO. The requested MRO information is sufficient to enable matching to HHS-certified laboratory information provided to the NLCP without identifying the donor. At this time, there is no system-wide mechanism for identifying MRO verification practices for Federal agency specimens that are inconsistent with the Guidelines, so data on incorrect reporting is not available. The Department is not planning to share MRO-specific information, but may share statistical information and deidentified examples by various means (*e.g.,* DTAB meeting presentations, revisions to the MRO Guidance Manual and/or Case Studies). The Department will also provide this information to HHS-approved MRO certification organizations to share with their certified MROs and to update training materials and examinations as needed.

Marijuana Testing

The Department did not propose any changes to the OFMG in regard to marijuana testing, but received comments from 21 commenters: 20 disagreed and one agreed with the current requirements. Seventeen commenters supported medical use of marijuana. Some of these noted that many doctors and medical professionals support the use of medical marijuana and that many States have legalized marijuana for medical use. Commenters expressed concern that Federal employees using marijuana for health reasons could lose their jobs or benefits or that Federal employees without access to medical marijuana may use other drugs such as opioids. Three commenters supported legalization of marijuana in general. One commenter stated that marijuana testing should be removed from the Guidelines until research can establish reliable levels to distinguish marijuana use from use of a legal hemp product (*i.e.,* as defined by the 2018 Farm Bill).

One commenter agreed with continuing to recognize marijuana as a Schedule I drug, with zero tolerance for safety-sensitive positions. The commenter stated that the liability and risk are not worth allowing employees in safety-sensitive positions to use medical marijuana.

Current Federal law requires Federal agencies to test for marijuana under E.O. 12564 in their workplace drug testing

programs. The Department also edited Section 13.5(c) to clarify that only prescription medications can be offered as a legitimate medical explanation for a positive drug test (as described under Section 13.5 below). No further edits are required at this time.

General Comments

Five commenters submitted general comments concerning the OFMG. Three agreed with the use of oral fluid testing, citing benefits of oral fluid as a testing matrix compared to urine (*e.g.,* less invasive collection is preferable for body/gender issues and the need to respect donor privacy; reduces specimen tampering; eliminates need for same gender observers; saves time). Two commenters disagreed with making any changes to the previous OFMG (published October 25, 2019).

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or for minor wording changes (*e.g.,* edits for clarity, typographical or grammatical corrections).

Subpart A—Applicability

Section 1.5 What do the terms used in these Guidelines mean?

Two commenters agreed and two disagreed with the Department's proposed revision to the Substituted Specimen definition in Section 1.5 to include specimens tested for a biomarker.

Of the two commenters who disagreed, one stated that there are situations in which a legitimate specimen may be reported as outside the standards for human specimens, and these should be reported as invalid. The other commenter stated that there should be clear notice and the opportunity to comment on specific biomarkers and criteria for substitution and that HHS should continue to require laboratories to report specimens as invalid based on normally occurring endogenous substances that appear unusual but do not violate standards for identified validity tests. The Department has reviewed the comments and determined that no change is needed to the proposed Guidelines. The Department will follow the procedures summarized under *Authorized drug testing panel* above to enable public comment and review, and will ensure that a biomarker test is scientifically supported and forensically sound to identify specimens as substituted before allowing its use with federally regulated drug testing. Specimens that do not meet established criteria for the biomarker test will not be reported as substituted.

Section 1.7 What is a refusal to take a federally regulated drug test?

In Section 1.7(a), the Department proposed to remove two exceptions for reporting a refusal to test for a pre-employment test: a donor who fails to appear in a reasonable time and a donor who leaves the collection site before the collection process begins. Nine commenters submitted a total of 16 comments on this proposal. Many of the commenters referenced DOT drug testing requirements and/or transportation industry issues that are not relevant to these Guidelines.

Eight commenters disagreed with the changes, noting that an applicant may fail to appear because they have taken a different job offer. The commenters noted that a refusal to test in the individual's record could prevent individuals from taking other job offers and/or require them to undergo unnecessary return-to-duty testing. The Department has reviewed the comments and determined that no change is needed. As stated in this section, the Federal agency determines a reasonable time for the donor to take the test, specifies the time consistent with agency regulations, and directs the individual accordingly. At the time an applicant is scheduled for a pre-employment drug test, or before, Federal agencies should provide the applicant with instructions on how to notify the agency in the event that they decide to withdraw their application or to not accept a job offer. Such instructions will allow the agency to cancel the drug test and help applicants avoid a refusal to test result.

Three commenters noted that the Guidelines should state that the designated employer representative (DER) makes the determination of a refusal to test. A fourth commenter noted that the employer, not the collector, should determine whether a failure to appear for a pre-employment test should be considered a refusal, as the collection site may not know that a donor is coming or how much time the employer allows the donor to complete a test. The Department has reviewed the comments and determined that no change is needed. As stated in this section, the Federal agency takes action consistent with applicable agency regulations. Corresponding wording in Section 8.3 specifies that the collector follows the Federal agency policy or contacts the Federal agency representative to obtain guidance on action to be taken before reporting a refusal to test because a donor does not arrive at an assigned time.

One commenter suggested that the Department add procedures to follow when the collection site cannot collect a specimen (*e.g.,* collection site closed early, collection site ran out of supplies). The Department disagrees with this suggestion. The applicant and/or the collector should contact the Federal agency representative when a situation beyond the applicant's control prevents completing a drug test within the specified time.

Subpart B—Oral Fluid Specimens

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

In Section 2.2, the Department allows oral fluid to be used for any type of testing conducted in Federal agency drug testing programs, and had not proposed any changes. Six commenters submitted comments in response to DOT's February 28, 2022 NPRM, regarding whether oral fluid should be allowed for all or only some testing reasons.

Section 2.5 How is the split oral fluid specimen collected?

The Department did not propose any changes to the requirements for split oral fluid collections in Sections 2.5 and 8.8 (*How does the collector prepare the oral fluid specimens?*). In its February 28, 2022 NPRM, DOT prohibits serial or simultaneous collections of A and B oral fluid specimens using two separate devices, which are allowed under the OFMG. Four commenters requested that HHS and DOT harmonize their requirements.

Three of the commenters requested a clear definition of ''single device'' and the fourth commenter recommended that both HHS and DOT specifically allow a device that collects a specimen that is then split or divided into the primary (A) and split (B) specimens. HHS and DOT have discussed oral fluid collection requirements. The Department will retain the split specimen collection requirements in the current OFMG which are based on current devices used in non-regulated drug testing and also allow for development of additional device types validated to meet program requirements. HHS-certified laboratories must ensure compliance with DOT regulations for specimens collected and tested under their regulations.

Subpart C—Oral Fluid Specimen Tests

Section 3.4 What are the drug and biomarker test analytes and cutoffs for undiluted (neat) oral fluid?

The Department revised Section 3.4 to describe the annual publication of the drug testing and biomarker testing panels and the nomenclature required for laboratory and MRO reports. Seven commenters submitted 10 comments on the required nomenclature required for laboratory and MRO reports, which are addressed below. Comments on the testing panels are addressed under *Authorized drug testing panel* and *Authorized biomarker testing panel* above.

In regard to the required nomenclature specified in the annual **Federal Register** Notice, four commenters noted it is difficult and requires substantial effort for stakeholders to make such changes to their information technology (IT) systems. Three of these commenters suggested that HHS convene a working group for review and input on nomenclature changes, to include employers, third party administrators, providers of electronic Federal Custody and Control Forms (ECCF providers), laboratories, and MROs. The other commenter stated that ''industry consensus'' should determine how analytes are identified. This commenter also stated that standardizing nomenclature for urine and oral fluid testing is not practical. One commenter agreed with publishing the required nomenclature for each change to the testing panel, but suggested that nomenclature not be changed after publication to avoid increased costs and confusion. Two commenters recommended a minimum of one-year implementation period after nomenclature changes are published. Another commenter agreed with specifying nomenclature, but noted that clear instructions will be needed for training and updating databases. The Department will establish required terminology based on correct scientific nomenclature for added analytes. As described under *Authorized drug testing panel* above, the Department has developed procedures to allow public notice and comment on proposed drug analyte changes through DTAB meetings and procedures. The Department will publish separate nomenclature lists for urine and oral fluid analytes.

One commenter disagreed with requiring both cocaine and benzoylecgonine as confirmatory test analytes, and recommended testing oral fluid specimens for benzoylecgonine only. The commentor cited their experience in testing for cocaine and metabolites in oral fluid; however, the commentor did not provide a scientific literature citation for their recommendation. SAMHSA has reviewed the literature and disagrees that testing for benzoylecgonine alone yields the same results as testing for both analytes. A 2010 dosing study showed that testing for both cocaine and benzoylecgonine increases detection rates in the periods 0.08–0.25 hours and 24–48 hours post-dosing as compared to testing for cocaine or benzoylecgonine alone.[1]

The annual **Federal Register** Notification will be posted on the SAMHSA website, *https://www.samhsa.gov/workplace.* The table in Section 3.4 of these final Guidelines will remain in effect until the effective date of the new panels published in the separate FRN.

Section 4.1 Who may collect a specimen?

One commenter submitted suggested rewording Section 4.1(a) to require the collector to be trained on ''each manufacturer's procedures for the collection device.'' The Department disagrees with the suggested edit, which may be misconstrued as requiring a collector to be trained on all devices. The current OFMG wording (*i.e.,* ''the manufacturer's procedures for the collection device'') is clear and consistent with the Oral Fluid Specimen Collection Handbook.

Five commenters submitted comments in response to DOT's February 28, 2022 NPRM, regarding who may collect an oral fluid specimen.

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What Federal form is used to document custody and control?

The Department did not propose any changes to this section. One commenter submitted a comment in response to DOT's February 28, 2022 NPRM, regarding maintaining a fax number on the Federal Custody and Control Form (CCF).

Section 6.2 What happens if the correct Office of Management and Budget (OMB)-approved Federal CCF is not available or is not used?

One commenter stated that the Department should specify what constitutes an incorrect form, how a collector's signed memorandum must be submitted to correct submission of an incorrect CCF, and what actions an HHS-certified laboratory must take in response to an incorrect CCF. The Department has determined that no changes to the Guidelines are needed. The Department issues Guidance for Using the Federal CCF as part of the OMB-approved package and provides information and guidance specific to the current and expired versions of the Federal CCF, rather than including them in these Guidelines.

Subpart G—Oral Fluid Specimen Collection Devices

Section 7.2 What are the requirements for an oral fluid collection device?

In Section 7.2(b)(2), the Department added a requirement for oral fluid specimen tubes to be sufficiently transparent to enable a visual assessment of the contents without opening the tube. See also Section 8.5(a)(3). Two commenters disagreed with the term ''sufficiently transparent,'' noting that opaque tubes would enable visual assessment. The Department did not intend that all tubes must be entirely clear (thus, the term ''sufficiently transparent''). An opaque tube would not allow visual assessment of the contents. For clarity, the Department has added ''(*e.g.,* translucent)''.

In Section 7.2(b)(3), the Department added a requirement for the collection device manufacturer to include the device lot expiration date on each specimen tube, to enable the collector to verify that each tube is within its expiration date prior to use. This is consistent with the current Federal CCF and associated documents (*i.e.,* Instructions for Completing the Federal CCF for Oral Fluid Specimen Collection, Guidance for Using the Federal CCF) which require the collector to verify the expiration date and mark the checkbox in Step 2 of the Federal CCF. The collector may, but is not required to, document the expiration date on each tube in Step 4 of the CCF. Four commenters disagreed with current requirements, stating that it is sufficient for the collector and not the laboratory to document the expiration date of each device on the Federal CCF. These commenters suggested that failure of the collector to record the date could be recovered with a signed memorandum for the record (MFR). Three of the four commenters also stated that the expiration date would likely be covered by the label/seal applied by the collector and noted changing to a transparent label would incur additional costs, while the fourth noted that even a partially transparent label would take time to develop and would not eliminate concerns about label/seal placement. The Department has

reviewed the comments and determined that no change is needed to the proposed OFMG. The expiration date is critical information supporting the scientific and forensic defensibility of the test result, and the laboratory must not test the specimen if it is unable to verify that the device was within its expiration date at the time of collection. A trained collector should avoid covering this information when placing the label on the tube. If the collector records an incorrect expiration date on the CCF, the laboratory corrects the information and is not required to obtain an MFR from the collector to recover the error.

One commenter agreed that the manufacturer should include the lot number and expiration date on each collection tube. The Department has provided additional guidance to laboratories noting that if the expiration date is not visible on the tube upon receipt and the device lot number is visible, the laboratory may use that information to recover the expiration date.

One of the commenters noted that the expiration date could be a required field on an ECCF, preventing the collector from continuing the collection without entering an expiration date. The Department agrees that ECCF system providers could implement this safeguard, but this does not obviate the need for the laboratory to verify the expiration date on each tube, just as the laboratory must verify the specimen identification number on each tube and the CCF.

Subpart H—Oral Fluid Specimen Collection Procedure

Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

The Department proposed revisions to Section 8.3 consistent with removal of refusal to test exceptions for pre-employment collections (see Section 1.7), reordered collection steps (*e.g.,* item d, item h.4), and reworded items for clarity (*e.g.,* items g and h). The Department also added steps similar to those for urine collections to deter donor attempts to adulterate or substitute the specimen. Eight commenters submitted comments concerning this section.

In regard to determining a refusal to test, one commenter suggested that the Department establish the beginning of the collection by specifying that the collection begins when the collector has checked the donor's identification. Another commenter who suggested the Department retain exceptions for pre-employment drug test collections (see Section 1.7) also suggested that this step be specified as the beginning of a pre-employment collection. The Department has determined that no revision is needed. The Guidelines clearly describe the preliminary collection steps and specify that the collector reports a refusal to test when a donor leaves the collection site before the collection is complete.

To deter donor attempts to adulterate or substitute the specimen, the Department proposed that the collector inspect the contents of the donor's pockets only when the collector does not keep the donor under direct observation until the end of the collection, including the 10-minute wait period described in Section 8.3(h). If the donor refuses to display the contents of their pockets, the collector will continue with the oral fluid collection, but will keep the donor under their direct observation and will not report this as a refusal to test. Five commenters disagreed, stating that a donor's refusal to empty their pockets should be reported as a refusal to test, for consistency with requirements for a urine collection. The Department has considered these comments and decided that no change is needed. The proposed procedures facilitate the collection process and prevent specimen tampering while maintaining donor privacy. There were no comments on this topic; however, the Department added a sentence in item e stating that a donor is not required to remove any items worn for faith-based reasons. This requirement will be specified for all authorized specimen types.

One commenter expressed concern over the requirement in Section 8.3(h)(4) for the collector to direct the donor to remain at the collection site until the end of the collection, stating that the refusal to test could be cancelled if the donor claimed that the collector did not mention this. The Department has determined that no revision is needed. It is incumbent upon the collector to instruct the donor throughout the collection process, including the instruction to remain through the end of the collection, and to inform the donor of the consequences for leaving early.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

The Department added steps in Section 8.4 to deter donor attempts to tamper with the specimen. Added item a requires the donor to wash their hands under the collector's observation and to keep their hands within view and avoid touching items or surfaces after handwashing. Added Section 8.4(b)(1) specifies that the collector opens the package containing the collection device in the presence of the donor. Five commenters submitted comments on this section.

Two commenters stated that requiring the donor to wash their hands was unnecessary and could cause a problem when the oral fluid collection site has no sink or water. The commenters suggested allowing the donor to wear gloves or use hand wipes as an alternative. The Department has reviewed these comments and determined that no changes are needed to the Guidelines. The instruction does not preclude the use of other means of handwashing. The Department has included examples of alternate means (*e.g.,* alcohol-free hand wipes, moist towelette, or hand sanitizer) in the Oral Fluid Specimen Collection Handbook.

The same two commenters suggested that the donor be instructed not to touch the collection pad. The Department does not agree that this added instruction is needed. The OFMG require the collector to be present and maintain visual contact with the donor throughout the collection, and specifically require the collector to go over the manufacturer's instructions for use of the device with the donor, observe the donor washing their hands before handling the device, and observe the donor positioning the device in their mouth. If the collector detects any conduct that clearly indicates an attempt to tamper with the specimen, the collector reports a refusal to test.

One commenter stated that requiring the donor to avoid touching items or surfaces was unnecessary and unreasonable. Two others agreed that the donor should not touch items that they brought with them after washing their hands, but stated that it may be difficult for the donor to avoid touching surfaces at the collection site. The Department has reviewed the comments and determined that no changes are needed to the Guidelines. The instruction to not touch items or surfaces at the collection site is a reasonable precaution, and compliance should not be difficult for the donor.

Another commenter specifically agreed with added Section 8.4(a)(1), noting this would eliminate errors and attempts to subvert the test.

In regard to added Section 8.4(b)(1), three commenters disagreed with the collector opening the package containing the collection device. Two recommended that the donor open the package, because some devices that are

inserted into the donor's mouth may not be separately wrapped. A third commenter disagreed, stating that a donor could argue that the collector contaminated the device when opening the package. This commenter also noted that remote collections would not be possible if the collector was required to open the package. The Department has reviewed the comments and determined that no change is needed to the Guidelines. Collectors must be trained to maintain the integrity of the specimen (per Section 4.4), and remotely viewed collections are not allowed (*i.e.,* the collector must be present).

Another commenter suggested adding the instruction for the collector to verify and record the device expiration date in Section 8.4(b)(1). The Department agrees with the commenter in part, and has edited Section 8.4(b) to state that each device used must be within the manufacturer's expiration date and inserted a new Section 8.4(c) requiring the collector to verify that each device is within its expiration date prior to use and to document the action on the Federal CCF. As discussed under Section 7.2 above, the Department disagrees with requiring the collector and not the laboratory to record the expiration date.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

One commenter suggested that the Department clarify how many collection attempts should be allowed when a donor is unable to provide a sufficient specimen and recommended that only one additional attempt be allowed to limit costs. The Department reviewed the comment and determined that no change is needed to the proposed Guidelines. As noted in the preamble to the current OFMG, the Department set the time limit but did not set a limit for the number of attempts because there may be different reasons for failing to collect the specimen from the donor.

Section 8.8 How does the collector prepare the oral fluid specimens?

Comments relating to Section 8.8 are addressed under Section 2.5 above.

Section 8.9 How does the collector report a donor's refusal to test?

One commenter disagreed with the requirement for the collector to send all copies of the Federal CCF to the Federal agency's designated representative, and stated that the collector should keep the Collector Copy and give the Donor Copy to the donor. The Department has reviewed the comment and determined that no change is needed. The current wording reflects HHS requirements.

Subpart M—Medical Review Officer (MRO)

Section 13.3 What training is required before a physician may serve as an MRO?

Two commenters submitted comments on this section. One commenter stated that the requirements for additional MRO training in the section are unclear and should be revised to clarify requirements (*e.g.,* what must training consist of, must the MRO take another certification exam, would training be required for annual panel changes). This commenter also suggested that MROs register with SAMHSA to get updates/announcements and acknowledge review of that information. A second commenter indicated that new and existing MROs should receive additional training for oral fluid testing (*e.g.,* collection procedures and documentation; differences in drug detection times for oral fluid and urine; urine and oral fluid cutoffs; criteria for substituted, adulterated, and refusal to test results; dry mouth scenarios; and effect of pre-existing conditions on ability to provide oral fluid).

The Department has reviewed these comments and edited item b of this section to clarify that MROs must be trained on any revisions to the drug and biomarker testing panels. In regard to training, SAMHSA relies on the approved MRO certification entities to ensure that MROs certified by their organizations meet Guidelines requirements. Current documents on the SAMHSA website *https://www.samhsa.gov/workplace* include the HHS Medical Review Officer Guidance Manual, MRO Cases Studies for Urine, and MRO Case Studies for Oral Fluid which address most of the suggested topics. The Department does not maintain an email list, but sends a notice through the NLCP to HHS-approved MRO certification organizations for dissemination to their certified MROs. The Department also sends additional guidance to HHS-certified laboratories to share with MROs, clients, and collectors as applicable.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

The Department received three comments on its proposed revisions to Section 13.5.

One commenter agreed with the Department's proposed revision to item 13.5(b)(2) clarifying that the MRO acts on an invalid result only when the MRO has verified the other results for the specimen as negative or when the split specimen was reported as a failure to reconfirm.

The Department revised Section 13.5(c)(2) to clarify that passive exposure to any drug (not just marijuana smoke) and ingestion of food products containing a drug (not just those containing marijuana) are not acceptable medical explanations for a positive drug test. The Department clarified existing item ii regarding ingestion of food products containing a drug and added a new item iii. Although an increased number of States have authorized marijuana use for medical purposes, marijuana remains a Schedule 1 controlled substance and cannot be prescribed under Federal law. For purposes of the Federal drug free workplace program, Federal law pertaining to marijuana control supersedes State marijuana laws, so a physician's recommendation for marijuana use is not a legitimate medical explanation for a positive marijuana test. Also see comments under *Marijuana testing* above.

In addition to the changes described above, the Department reordered OFMG Sections 13.8 and 13.9 to reflect the procedural order (*i.e.,* requirements for an MRO to report a primary specimen test result are now in Section 13.8, and requests for a test of the split specimen are addressed in Section 13.9).

Subpart O—Criteria for Rejecting a Specimen for Testing

15.1 What discrepancies require an HHS-certified laboratory to report an oral fluid specimen as rejected for testing?

As noted in Section 7.2(b), an oral fluid collection device must have an indicator that demonstrates the adequacy of the volume of oral fluid specimen collected. Because the oral fluid specimen volume is critical for determining the specimen concentration, the collector must document that they observed the volume indicator(s) at the time of collection. The Department has revised Section 15.1 (*i.e.,* new paragraph (e)) specifying that the laboratory must reject the specimen when the collector failed to document observation of the volume indicator at the time of collection. This is consistent with current program documents (*e.g.,* Oral Fluid Specimen Collection Handbook for Federal Agency Workplace Drug

Testing Programs, Collection Site Manual, and Medical Review Officer Guidance Manual) posted on the SAMSHSA website, as well as the NLCP Manual for Oral Fluid Laboratories.

Regulatory Impact and Notices

The potential impact that these Guidelines have on the Department of Transportation (DOT) and/or Nuclear Regulatory Commission (NRC) regulated industries depend on the extent to which these agencies incorporate the OFMG revisions into their regulatory programs. Therefore, analysis of the potential impact of these Guidelines on such programs falls under the regulatory purview of DOT and NRC.

Executive Order 14094, 13563 and 12866

Executive Order 14094 of April 6, 2023 (Modernizing Regulatory Review) reaffirms the statement set forth in 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) that ''Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.'' Consistent with this mandate, Executive Order 13563 requires agencies to tailor ''regulations to impose the least burden on society, consistent with obtaining regulatory objectives.'' Executive Order 13563 also requires agencies to ''identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice'' while selecting ''those approaches that maximize net benefits.'' The regulatory approach in this document will reduce burdens to providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the Guidelines under Executive Order 12866, as amended by Executive Order 14094, which directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

According to Executive Order 12866, as amended by Executive Order 14094, a ''significant regulatory action'' is one that is likely to result in a rule that may meet any one of a number of specified conditions, including: (1) have an annual effect on the economy of $200 million or more in any one year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern Federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

Costs and Benefits

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the April 7, 2022 **Federal Register** Notification for the proposed OFMG (87 FR 20522), and requested public comment on all estimates and assumptions. Three commenters submitted comments concerning the Department's costs and benefits analysis.

One commenter noted that the Department did not consider the application of the Guidelines to DOT testing, and recommended reanalysis of the costs and burden of the proposed changes with consideration of the impact on testing by the transportation industry. Please see the first paragraph of the Regulatory Impact and Notices section above.

One commenter stated that the Department did not consider costs to MROs for training and education to bring MROs and MRO staff up to date on new drug panels and reporting methods. This commenter requested that the MRO community be allowed input to testing panel and nomenclature changes to enable adequate staffing and preparation. Another commenter disagreed with the Department's statement in the preamble to the proposed OFMG that ''implementation costs would be lower for laboratories that already offer the drug test'' compared to those laboratories that do not test for the added drug. The commenter indicated that the list of cost impacts for any change should include the laboratory's assay validation, materials management, and updates to IT systems (*e.g.,* laboratory information management system [LIMS], recipient systems, and electronic ordering systems). This commenter indicated that these additional costs should be considered, and that they will be dependent on the complexity and adaptability of these systems. The Department agrees that costs will depend on the change and noted that in the preamble to the proposed OFMG. The Department will continue to proactively solicit cost information from stakeholders when conducting a cost analysis. As described under *Authorized drug testing panel* above, the Department will include a discussion of related costs and benefits when presenting a proposed panel change during a DTAB meeting.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in oral fluid drug testing for Federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form (Federal CCF) used to document the collection and chain of custody of urine and oral fluid specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination; the National Laboratory Certification Program (NLCP) application; the NLCP Laboratory Information Checklist; and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect.

In support of the Government Paperwork Reduction Act (PRA), the

Department revised the Federal CCF to enable its use as an electronic form (78 FR 42091, July 15, 2013) and developed requirements and oversight procedures to ensure that HHS-certified test facilities and other service providers (*e.g.,* collection sites, MROs) using an ECCF maintain the accuracy, security, and confidentiality of electronic drug test information. Before a Federal ECCF can be used for Federal agency specimens, HHS-certified test facilities must submit detailed information and proposed standard operating procedures (SOPs) to the NLCP for SAMHSA review and approval, and undergo an NLCP inspection focused on the proposed ECCF.

Since 2013, SAMHSA has encouraged the use of Federal ECCFs and other electronic processes in HHS-certified test facilities, when practicable, for federally regulated testing operations. In accordance with section 8108(a) of the SUPPORT for Patients and Communities Act, SAMHSA originally set a deadline of August 31, 2023 for all HHS-certified laboratories to submit a request for approval of a digital (paperless) electronic Federal CCF. The Department subsequently extended the deadline to August 31, 2026, to enable sufficient time for all HHS-certified laboratories to identify and contract with an ECCF supplier or to develop an ECCF.

The title and description of the information collected and respondent description are shown in the following paragraphs with an estimate of the annual reporting, disclosure, and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid

Description: The Mandatory Guidelines establish the scientific and technical guidelines for Federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions.

Description of Respondents: Individuals or households, businesses, or other-for-profit and not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 10,500 donors who apply for employment or are employed in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory or IITF required to submit application for certification.	10	1	3	30
9.10(a)(3)	Materials to submit to become an HHS inspector	10	1	2	20
11.3	Laboratory submits qualifications of responsible person (RP) to HHS.	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.20	Specifications for laboratory semiannual statistical report of test results to each Federal agency.	10	5	0.5	25
13.8 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the Federal agency.	100	14	0.05 (3 min)	70
13.11	Specifications for MRO semiannual report to the Secretary or designated representative for Federal agency specimen results that were laboratory-positive and MRO-verified negative.	100	2	0.5	100
16.1(b) & 16.5(a).	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total	.....	256	.....	.....	392

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF (Sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (Section 10.3(a)); MRO notifies the Federal agency and HHS when an error occurs on a blind sample (Section 10.4(d)); and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide an oral fluid specimen. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(a), 8.6(b)(2)	Collector must contact Federal agency point of contact	100	1	0.05 (3 min)	5
11.21, 11.22	Information on drug test that laboratory must provide to Federal agency upon request or to donor through MRO.	25	10	3	750
13.9(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	14	3	4,200
Total		225			4,955

The following disclosure requirements are also included in the Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the basic collection procedure to the donor and answer any questions (Section 8.3(h)). SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.4, 8.5, 8.8	Collector completes Federal CCF for specimen collected	100	380	0.07 (4 min)	2,660
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	38,000	1	0.08 (5 min)	3,040
11.8(a) & 11.17	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	25	1,520	0.05 (3 min)	1,900
13.4(d)(4), 13.8(c), 14.7(c).	MRO completes Federal CCF before reporting the primary or split specimen result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested	100	2	0.05 (3 min)	10
Total		38,325			9,510

The Guidelines contain several recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector (Section 4.3(a)(3)) and the documentation must be maintained in the collector's training file (Section 4.3(c)). SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a Federal agency specimen, the collector is required to provide a statement (Section 6.2(b)) explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H (Section 8.4(e)) requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subpart K describes a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* Sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.10(a); 11.13(a); 11.16; 11.19(a), (b), and (c); 11.20; 11.21(a) and 11.22). These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. These practices are integrated in the current processes and, therefore, SAMHSA does not consider these standard business practices to be an additional burden for disclosure.

Thus, the total annual response burden associated with the testing of oral fluid specimens by the laboratories is estimated to be 13,221 hours (that is, the sum of the total hours from the above tables). Because of the expected transition from urine to oral fluid testing, this number will replace some of the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of the proposed Guidelines to OMB for its review. Comments on the information collection requirements were specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

References

1. Scheidweiler K.B., Spargo E.A., Kelly T.L., Cone E.J., Barnes A.J., Huestis M.A., 2010. Pharmacokinetics of cocaine and metabolites in human oral fluid and correlation with plasma concentrations after controlled administration. *Ther Drug Monit.,* 32(5), 628–37.

Dated: September 27, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid Specimens

Subpart A—Applicability

1.1 To whom do these Guidelines apply?

Subpart A—Applicability

Section 1.1 To whom do these Guidelines apply?

(a) These Guidelines apply to:

(1) Executive agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3), but excluding the Armed Forces as defined in 5 U.S.C. 2101(2);

(3) Any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the Federal agencies;

(6) Collectors who provide specimen collection services to the Federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the Federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

Section 1.2 Who is responsible for developing and implementing these Guidelines?

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for Federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How does a Federal agency request a change from these Guidelines?

(a) Each Federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a Federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How are these Guidelines revised?

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) Revisions to these Guidelines will be published in final as a notification in the **Federal Register**.

Section 1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Accessioner. The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of a normal constituent (*e.g.,* nitrite in urine).

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Biomarker Testing Panel. The panel published in the **Federal Register** that includes the biomarkers authorized for testing, with analytes and cutoffs for initial and confirmatory biomarker tests, as described under Section 3.4.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the Federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or the specimen has been rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Device. A product that is used to collect an oral fluid specimen and may include a buffer or diluent.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support an initial specimen validity test result.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The analytical value (*e.g.,* drug, drug metabolite, or biomarker concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

Donor. The individual from whom a specimen is collected.

Drug Testing Panel. The panel published in the **Federal Register** that includes the drugs authorized for testing, with analytes and cutoffs for initial and confirmatory drug tests, as described under Section 3.4.

External Service Provider. An independent entity that performs services related to Federal workplace drug testing on behalf of a Federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or (for urine) an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB)

approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic(digital), or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is adulterated, invalid, substituted, or (for urine) dilute.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.8 when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection (LOD). The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material, oral fluid collection device) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the Federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmatory test cutoff.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2).

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Oral Fluid). A collection in which two specimens (primary [A] and split [B]) are collected, concurrently or serially, and independently sealed in the presence of the donor; or a collection in which a single specimen is collected using a single collection device and is subdivided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.

Substituted Specimen. A specimen that has been submitted in place of the donor's specimen, as evidenced by the absence of a biomarker or a biomarker concentration inconsistent with that established for a human specimen, as indicated in the biomarker testing panel, or (for urine) creatinine and specific gravity values that are outside the physiologically producible ranges of human urine, in accordance with the criteria to report a urine specimen as substituted in the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), Section 3.7.

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: a collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101 through 24.104, all agency contracts with laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of section 503 of Public Law 100–71. Each Federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, subparts A and E, may be applicable to certain health care providers with whom a Federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *https://www.hhs.gov/hipaa/index.html.*

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test within a reasonable time, as determined by the Federal agency, consistent with applicable agency regulations, after being directed to do so by the Federal agency;

(2) Fail to remain at the collection site until the collection process is complete;

(3) Fail to provide a specimen (*e.g.,* oral fluid or another authorized specimen type) for any drug test required by these Guidelines or Federal agency regulations;

(4) Fail to provide a sufficient amount of oral fluid when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(5) Fail or decline to participate in an alternate specimen collection (*e.g.,* urine) as directed by the Federal agency or collector (*i.e.,* as described in Section 8.6);

(6) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the Federal agency. In the case of a Federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the Federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(7) Fail to cooperate with any part of the testing process (*e.g.,* disrupt the collection process, fail to rinse the mouth or wash hands after being directed to do so by the collector, refuse to provide a split specimen);

(8) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(9) Attempt to adulterate, substitute, or dilute the specimen; or

(10) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) A refusal to take a test may result in the initiation of disciplinary or adverse action for a Federal employee, up to and including removal from Federal employment. An applicant's refusal to take a pre-employment test may result in non-selection for Federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test, the collector must terminate the collection process and take action as described in Section 8.9. Required action includes immediately notifying the Federal agency's designated representative by any means (*e.g.,* telephone, email, or secure facsimile [fax] machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the Federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Oral Fluid Specimens

Section 2.1 What type of specimen may be collected?

A Federal agency may collect oral fluid and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using oral fluid must follow these Guidelines.

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

A Federal agency may collect an oral fluid specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each oral fluid specimen collected?

Each oral fluid specimen is collected as a split specimen (*i.e.,* collected either simultaneously or serially) as described in Sections 2.5 and 8.8.

Section 2.4 What volume of oral fluid is collected?

A volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated ''Tube A'' and ''Tube B'') is collected using a collection device. If the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen), the A and B tubes must have a volume marking clearly noting a level of 1 mL.

Section 2.5 How is the split oral fluid specimen collected?

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''A'' (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''B'' (split) either simultaneously or serially (*i.e.,* using two devices or using one device and subdividing the specimen), as described in Section 8.8.

Section 2.6 When may an entity or individual release an oral fluid specimen?

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable Federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.9.

Subpart C—Oral Fluid Specimen Tests

Section 3.1 Which tests are conducted on an oral fluid specimen?

A Federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine as provided in the drug testing panel described under Section 3.4;

(b) Is authorized to test each specimen for other Schedule I or II drugs as provided in the drug testing panel;

(c) Is authorized upon a Medical Review Officer's request to test an oral fluid specimen to determine specimen validity using, for example, a test for a specific adulterant;

(d) Is authorized to test each specimen for one or more biomarkers as provided in the biomarker testing panel; and

(e) May perform additional testing if a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis.

Section 3.2 May a specimen be tested for drugs other than those in the drug testing panel?

(a) On a case-by-case basis, a specimen may be tested for additional

drugs, if a Federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a Federal agency employee may be tested by the Federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The Federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the Federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in the drug testing panel described under Section 3.4. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under Section 3.2(a).

Section 3.3 May any of the specimens be used for other purposes?

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with subpart C of these Guidelines. Use of specimens by donors, their designees, or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable Federal law.

(b) These Guidelines are not intended to prohibit Federal agencies specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the drug and biomarker test analytes and cutoffs for undiluted (neat) oral fluid?

The Secretary will publish the drug and biomarker test analytes and cutoffs (*i.e.,* the ''drug testing panel'' and ''biomarker testing panel'') for initial and confirmatory drug and biomarker tests in the **Federal Register** each year. The drug and biomarker testing panels will also be available on the internet at *https://www.samhsa.gov/workplace.*

This drug testing panel will remain in effect until the effective date of a new drug testing panel published in the **Federal Register**:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff
Marijuana (THC) [2]	4 ng/mL [3]	THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine	8 ng/mL.
		Benzoylecgonine	8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL [3]	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.
MDMA [4]/MDA [5]	50 ng/mL.	MDMA	25 ng/mL.
		MDA	25 ng/mL.

[1] *For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):*
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol (THC).
[3] *Alternate technology (THC and 6–AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 2 ng/mL for THC, 2 ng/mL for 6–AM).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

(a) The drug testing panel will include drugs authorized for testing in Federal workplace drug testing programs, with the required test analytes and cutoffs;

(b) The biomarker testing panel will include biomarkers authorized for testing in Federal workplace drug testing programs, with the required test analytes and cutoffs; and

(c) HHS-certified laboratories and Medical Review Officers must use the nomenclature (*i.e.,* analyte names and abbreviations) published in the **Federal Register** with the drug and biomarker testing panels to report Federal workplace drug test results.

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* specimen validity tests). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of d,l stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?

An HHS-certified laboratory reports a primary (A) specimen as adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report an oral fluid specimen as substituted?

An HHS-certified laboratory reports a primary (A) specimen as substituted when a biomarker is not detected or is present at a concentration inconsistent with that established for human oral fluid for both the initial (first) test and the confirmatory (second) test on two separate aliquots (*i.e.,* using the test analytes and cutoffs listed in the biomarker testing panel).

Section 3.8 What criteria are used to report an invalid result for an oral fluid specimen?

An HHS-certified laboratory reports a primary (A) oral fluid specimen as an invalid result when:

(a) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(b) Interference with the confirmatory drug test occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(c) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments;

(d) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(e) A specimen validity test on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a Federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a Federal agency applicant may only collect that Federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A Federal agency employee who is in a testing designated position and subject to the Federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work with that employee on a daily basis.

(b) A Federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a personal friend of the employee (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the Federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to the collection procedure described in these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen tube tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in *Section 4.3*(a).

(c) The collector must maintain the documentation of their training and provide that documentation to a Federal agency when requested.

(d) An individual may not collect specimens for a Federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, Federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that documentation to a Federal agency when requested.

Section 4.5 What must a Federal agency do before a collector is permitted to collect a specimen?

A Federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, Federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the Federal agency representative.

Subpart E—Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, providing the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies; and

(f) A restricted access area for the secure storage of records.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory.

Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What Federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-Federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a Federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory must handle and test the specimen as a Federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that the collector used an incorrect form, the laboratory or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Oral Fluid Specimen Collection Devices

Section 7.1 What is used to collect an oral fluid specimen?

A single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

(a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;

(b) One or two sealable, non-leaking tubes [depending on the device type, as described in Section 8.8(a)] that:

(1) maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites,

(2) are sufficiently transparent (*e.g.,* translucent) to enable a visual assessment of the contents (*i.e.,* oral fluid, buffer/diluent, collection pad) for identification of abnormal physical characteristics without opening the tube, and

(3) include the device lot expiration date on each specimen tube (*i.e.,* the expiration date of the buffer/diluent or, for devices without a buffer/diluent, the earliest expiration date of any device component);

(c) Components that ensure pre-analytical drug and drug metabolite stability; and

(d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be at least 1.0 mL ±10 percent, and

(2) The volume of diluent in the device should be within ±2.5 percent of the diluent target volume;

(c) Stability (recoverable concentrations ≥80 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for five days at room temperature (64–77 °F/18–25 °C) and under the manufacturer's intended shipping and storage conditions; and

(d) Recover ≥80 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff listed in the drug testing panel.

Subpart H—Oral Fluid Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?

The following privacy requirements apply when a donor is providing an oral fluid specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor.

Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

The collector must take all reasonable steps to prevent the adulteration or substitution of an oral fluid specimen at the collection site.

Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

The collector must take the following steps before beginning an oral fluid specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the Federal agency policy or contact the Federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a Federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the Federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(e) The collector asks the donor to remove any unnecessary outer garments (*e.g.,* coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the oral fluid specimen. The collector must ensure that all personal belongings (*e.g.,* purse or briefcase) remain with the outer garments. The donor may retain the donor's wallet. The donor is not required to remove any items worn for faith-based reasons.

(f) If the donor will remain under the collector's direct observation until the end of the collection, including the 10-minute wait period described in Section 8.3(h), the collector proceeds to Section 8.3(g). If the collector will not keep the donor under direct observation from this point until the end of the collection, the collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(1) If no items are present that can be used to adulterate or substitute the specimen, the collector instructs the donor to return the items to their pockets and continues the collection procedure.

(2) If an item is present whose purpose is to adulterate or substitute the specimen (*e.g.,* a commercial drug culture product or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(3) If an item that could be used to adulterate or substitute the specimen (*e.g.,* common personal care products such as mouthwash, lozenges, capsules) appears to have been inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) If the donor refuses to show the collector the items in their pockets, the collector must keep the donor under direct observation until the end of the oral fluid collection.

(g) The collector requests that the donor open the donor's mouth, and the collector inspects the oral cavity to ensure that it is free of any items (*e.g.,* candy, gum, food, tobacco) that could impede or interfere with the collection of an oral fluid specimen or items that could be used to adulterate, substitute, or dilute the specimen.

(1) If an item is present that whose purpose is to adulterate or substitute the specimen (*e.g.,* a commercial drug culture product or other item for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(2) If an item is present that could impede or interfere with the collection of an oral fluid specimen (including abnormally colored saliva), or the donor claims to have ''dry mouth,'' the collector gives the donor water (*e.g.,* up to 4 oz.) to rinse their mouth. The donor may drink the water. If the donor refuses to remove the item or refuses to rinse, this is a refusal to test.

(3) If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector follows the procedure in Section 8.6(b)(2).

(h) The collector must initiate a 10-minute wait period prior to collecting the specimen. During these 10 minutes, the collector must:

(1) Explain the basic collection procedure to the donor;

(2) Provide the instructions for completing the Federal CCF for the donor's review, and informs the donor that these instructions and the collection device-specific instructions are available upon request.

(3) Answer any reasonable and appropriate questions the donor may have regarding the collection procedure; and

(4) Inform the donor that they must remain at the collection site (*i.e.,* in the area designated by the collector) during the wait period, and that failure to follow these instructions will be reported as a refusal to test.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector shall instruct the donor to wash and dry the donor's hands under the collector's observation, and to keep their hands within view and avoid touching items or surfaces after handwashing. If the donor refuses to wash their hands when instructed by the collector, this is a refusal to test.

(b) The collector will provide or the donor may select the specimen collection device(s) to be used for the collection. The device(s) must be clean, unused, and wrapped/sealed in original packaging and must be within the manufacturer's expiration date printed on the specimen tube. See Section 8.8(a) for types of specimen collection devices used for oral fluid split specimen collections.

(1) The collector will open the package in view of the donor.

(2) Both the collector and the donor must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(c) The collector verifies that each device is within the manufacturer's expiration date, and documents this action on the Federal CCF.

(d) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(e) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to prevent the device from collecting sufficient oral fluid; an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must report a refusal to test in accordance with Section 8.9.

Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for positioning the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working properly. If there is a failure to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states that they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedure in Section 8.6.

(2) The donor and the collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(3) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid oral fluid specimen (*e.g.,* unusual color, presence of foreign objects or material), documents any unusual findings on the Federal CCF, and takes action (*e.g.,* recollection) to obtain an acceptable specimen.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as required in Section 8.5(a)(1), refuses to provide a split specimen as instructed by the collector, or refuses to provide an alternate specimen when directed to do so, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

(a) If the donor states that they are unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor may choose not to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (*i.e.,* in an area designated by the collector) during the wait period.

(2) If the donor states that they are unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the Federal agency's designated representative for authorization to collect an alternate specimen, and sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency's designated representative. The Federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the Federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

(a) All Federal agency collections are to be split specimen collections. An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. The donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF;

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or

(4) A single specimen collected using a single collection device, that is subsequently subdivided into two specimens.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube

A'' and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube B''.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all required information is included on the Federal CCF.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

(a) Notifying the Federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test including the reason on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the Federal agency's designated representative.

Section 8.10 What are a Federal agency's responsibilities for a collection site?

(a) A Federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H of these Guidelines.

(b) A Federal agency (or only one Federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A Federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories

Section 9.1 Who has the authority to certify laboratories to test oral fluid specimens for Federal agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory, including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory is prohibited from stating or implying that it is certified by HHS under these Guidelines to test oral fluid specimens for Federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory to become HHS-certified?

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for Federal agencies.

Section 9.3 What is the process for a laboratory to maintain HHS certification?

(a) To maintain HHS certification, a laboratory must:

(1) Successfully participate in both the maintenance PT and inspection programs (*i.e.,* successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory does not maintain its HHS certification?

(a) A laboratory that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and subpart P of these Guidelines; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS

procedures in subpart P of these Guidelines that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in the drug testing panel and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from Section 9.5(a)(1)(i) and (ii) for a special purpose.

(2) A PT sample may contain an interfering substance, an adulterant, or other substances for special purposes, or may satisfy the criteria for a substituted specimen or invalid result.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) The laboratory must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What are the PT requirements for an applicant laboratory that seeks to perform oral fluid testing?

(a) An applicant laboratory that seeks certification under these Guidelines to perform oral fluid testing must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the specified criteria; and

(10) Do not report any PT sample as adulterated with a compound that is not present in the sample or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to satisfy these requirements will result in the denial of the laboratory's application for HHS certification to perform oral fluid testing.

Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

(a) A laboratory certified under these Guidelines to perform oral fluid testing must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group means;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the specified criteria; and

(10) Do not report any PT sample as adulterated with a compound that is not present in the sample or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the inspection requirements for an applicant laboratory?

(a) An applicant laboratory is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's testing procedures and facilities using an inspection checklist.

Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

(a) An HHS-certified laboratory must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory is inspected by two or more inspectors. The number of inspectors is determined according to the number of specimens to be reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in subpart K of these Guidelines;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.

(b) The Secretary or a Federal agency may conduct an inspection at any time.

Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory fails to satisfy the minimum requirements for certification, the laboratory is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's certification is revoked or suspended in accordance with the process described in subpart P of these Guidelines, the laboratory is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory has successfully completed the certification requirements as a new applicant laboratory.

Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for Federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory with written notice of the suspension or proposed revocation by fax, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart P of these Guidelines contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or 9.14, respectively, and the name of any HHS-certified laboratory that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart P of these Guidelines.

Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test Federal agency specimens?

Following revocation, a laboratory may apply for recertification. Unless

otherwise provided by the Secretary in the notice of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

Section 9.17 Where is the list of HHS-certified laboratories published?

(a) The list of HHS-certified laboratories is published monthly in the **Federal Register**. This notice is also available on the internet at *https://www.samhsa.gov/workplace.*

(b) An applicant laboratory is not included on the list.

Subpart J—Blind Samples Submitted by an Agency

Section 10.1 What are the requirements for Federal agencies to submit blind samples to HHS-certified laboratories?

(a) Each Federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each Federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must contain one or more of the drugs or metabolites listed in the drug testing panel.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the Federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (e.g., a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the Federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the Federal agency. The Secretary shall ensure notification of the finding as appropriate to other Federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified

laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of Federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.,* for the Department, a Federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff, using samples at several concentrations between 0 and 150 percent of the cutoff;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.12 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification (*e.g.,* gas chromatography-mass spectrometry [GC–MS], liquid chromatography-mass spectrometry [LC–MS], GC–MS/MS, LC–MS/MS) or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff;

(5) The accuracy (bias) and precision at 40 percent of the cutoff;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff;

(2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

An HHS-certified laboratory may perform specimen validity tests in accordance with Sections 3.1 and 3.5.

(a) Each invalid, adulterated, or substituted specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report, as described in items o and p below.

Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in Section 11.17(g)(1) through (5).

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with the cutoffs listed in the drug testing panel.

(d) A primary (A) oral fluid specimen is reported adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (A) oral fluid specimen is reported substituted when a biomarker is not present or is present at a concentration inconsistent with that established for human oral fluid.

(f) For a specimen that has an invalid result for one of the reasons stated in Section 11/17(g)(1) through (5), the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive, adulterated, or substituted result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(g) A primary (A) oral fluid specimen is reported as an invalid result when:

(1) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(3) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(4) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(5) A specimen validity test on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

(h) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(i) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a drug and adulterated.

(j) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(k) An HHS-certified laboratory must report numerical values of the specimen validity test results that support an adulterated, substituted, or invalid result (as appropriate).

(l) An HHS-certified laboratory must report results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

(m) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(n) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* fax, computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(o) HHS-certified laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(p) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.18 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) Retained oral fluid specimens must be kept in secured storage in accordance with the collection device manufacturer's specifications (*i.e.,* frozen at −20 °C or less, or refrigerated), to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period following the laboratory's reporting of the specimen.

Section 11.19 How long must an HHS-certified laboratory retain records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A Federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The Federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

(a) HHS-certified laboratories must provide to each Federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personally identifiable information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;
(4) Number of specimen results reported;
(5) Number of specimens collected by reason for test;
(6) Number of specimens reported negative;
(7) Number of specimens rejected for testing because of a fatal flaw;
(8) Number of specimens rejected for testing because of an uncorrected flaw;
(9) Number of specimens tested positive by each initial drug test;
(10) Number of specimens reported positive;
(11) Number of specimens reported positive for each drug and drug metabolite;
(12) Number of specimens reported adulterated;
(13) Number of specimens reported substituted; and
(14) Number of specimens reported as invalid result.
(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the Federal agency for which the laboratory is performing drug-testing services.
(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a Federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.21 What HHS-certified laboratory information is available to a Federal agency?

(a) Following a Federal agency's receipt of a positive, adulterated, or substituted drug test report, the Federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.
(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:
(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;
(2) A table of contents that lists all documents and materials in the package by page number;
(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;
(4) A brief description of the HHS-certified laboratory's initial drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;
(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;
(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;
(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and
(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.22 What HHS-certified laboratory information is available to a Federal employee?

Federal applicants or employees who are subject to a workplace drug test may submit a written request through the MRO and/or the Federal agency requesting copies of any records relating to their drug test results or a documentation package as described in Section 11.21(b) and any relevant certification, review, or revocation of certification records. Federal applicants or employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a Federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a Federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 May an IITF test oral fluid specimens for a Federal agency's workplace drug testing program?

No, only HHS-certified laboratories are authorized to test oral fluid specimens for Federal agency workplace drug testing programs in accordance with these Guidelines.

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:
(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;
(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;
(3) The training necessary to serve as an MRO as set out in Section 13.3;
(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and
(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for Federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notification in the **Federal Register** listing those

entities and subspecialty boards that have been approved. This notification is also available on the internet at *https://www.samhsa.gov/workplace.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect Federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for Federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any Federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines including any changes to the drug and biomarker testing panels prior to their effective date, to continue serving as an MRO for Federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.17(f) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the Federal agency.

(e) The MRO must maintain records for a minimum of two years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen and an alternate specimen was not collected, as addressed in Sections 8.6 and 13.6.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

(a) When the HHS-certified laboratory reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) specimen, the MRO must follow the verification procedures described in Section 13.5(c) through (f) and:

(1) The MRO reports all verified positive and/or refusal to test results to the Federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, the MRO does not report the verified invalid result to the Federal agency at this time. The MRO takes action for the verified invalid result(s) for the primary (A) specimen as described in Section 13.5(e) only when:

(i) The MRO verifies the positive, adulterated, or substituted result as negative based on a legitimate medical explanation as described in Section 13.5(c)(2) and (d)(1), or based on codeine and/or morphine concentrations less than 150 ng/mL as described in Section 13.5(c)(3)(i); or

(ii) The split (B) specimen is tested and reported as a failure to reconfirm the positive, adulterated or substituted result reported for the primary (A) specimen as described in Section 14.6(m).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor admits unauthorized use of the drug(s) that caused the positive result, the MRO reports the test result as positive to the agency. The MRO must document the donor's admission of unauthorized drug use in the MRO records and in the MRO's report to the Federal agency.

(2) If the donor provides documentation (*e.g.,* a valid prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(i) Passive exposure to a drug (*e.g.,* exposure to marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing a drug (*e.g.,* products containing marijuana) is not a legitimate medical explanation for a positive drug test result. See exceptions for positive codeine and morphine results in Section 13.5(c)(3).

(iii) A physician's authorization or medical recommendation for a Schedule 1 controlled substance is not a legitimate medical explanation for a positive drug test result.

(3) If the donor is unable to provide a legitimate medical explanation for the positive result, the MRO reports the positive result to the agency, for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL, the MRO must report the result as negative to the agency, unless the donor admits unauthorized use of the drug(s) that caused the positive result as described in Section 13.5(c)(1).

(ii) For codeine and/or morphine equal to or greater than 150 ng/mL and no legitimate medical explanation, the MRO shall report a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(d) When the HHS-certified laboratory reports an adulterated or substituted result for the primary (A) oral fluid specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the Federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the Federal agency because the oral fluid specimen was adulterated or substituted.

(e) When the HHS-certified laboratory reports an invalid result for the primary (A) oral fluid specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result.

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medicine), the MRO reports a test cancelled result with the reason for the invalid result and informs the Federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result with the reason for the invalid result and directs the Federal agency to immediately collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in Section 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* urine). If the Federal agency does not authorize collection of another specimen type, the MRO consults with the agency to arrange a clinical evaluation as described in Section 13.7, to determine whether there is a legitimate medical reason for the invalid result.

(f) When the HHS-certified laboratory reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

(a) When another specimen type (*e.g.,* urine) was collected in accordance with Section 8.6, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

(b) When the Federal agency did not authorize the collection of an alternate specimen, the MRO consults with the Federal agency. The Federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate Federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in Section 13.6(b)(3) and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the Federal agency in writing:

(i) A medical condition as defined in Section 13.6(b)(1) has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the Federal agency.

(ii) A permanent or long-term medical condition as defined in Section 13.6(b)(1) has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the Federal agency and recommend that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the Federal agency.

(4) When a Federal agency receives a report from the MRO indicating that a test is cancelled as provided in Section 13.6(b)(3)(i), the agency takes no further action with respect to the donor. When a test is canceled as provided in Section 13.6(b)(3)(ii), the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the Federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the Federal agency does not authorize collection of an alternate specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the Federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen

impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the Federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the Federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

Section 13.8 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* fax, computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 13.9 Who may request a test of a split (B) specimen?

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the Federal agency on the primary (A) specimen.

Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory, or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

Section 13.11 What reports must an MRO provide to the Secretary for oral fluid testing?

(a) An MRO must send to the Secretary or designated HHS representative a semiannual report of Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. The report must not include any personally identifiable information for the donor and must be submitted by mail, fax, or other secure electronic transmission method within 14 working days after the end of the semiannual period (*i.e.,* in January and July). The semiannual report must contain the following information:

(1) Reporting period (inclusive dates);

(2) MRO name, company name, and address;

(3) Federal agency name; and

(4) For each laboratory-reported positive drug test result that was verified as negative by the MRO:

(i) Specimen identification number;

(ii) Laboratory name and address;

(iii) Positive drug(s) or drug metabolite(s) verified as negative;

(iv) MRO reason for verifying the positive drug(s) or drug metabolite(s) as negative (*e.g.,* a donor prescription [the MRO must specify the prescribed drug]);

(v) All results reported to the Federal agency by the MRO for the specimen; and

(vi) Date of the MRO report to the Federal agency.

(b) An MRO must provide copies of the drug test reports that the MRO has sent to a Federal agency when requested to do so by the Secretary.

(c) If an MRO did not verify any positive laboratory results as negative during the reporting period, the MRO should file a report that states that the MRO has no reportable results during the applicable reporting period.

Section 13.12 What are a Federal agency's responsibilities for designating an MRO?

(a) Before allowing an individual to serve as an MRO for the agency, a Federal agency must verify and document the following:

(1) that the individual satisfies all requirements in Section 13.1, including certification by an MRO certification organization that has been approved by the Secretary, as described in Section 13.2; and

(2) that the individual is not an employee, agent of, or have any financial interest in an HHS-certified laboratory that tests the agency's specimens, as described in Section 13.10.

(b) The Federal agency must verify and document that each MRO reviewing and reporting results for the agency:

(1) completes training on any revisions to these Guidelines, including any changes to the drug and biomarker testing panels, prior to their effective date;

(2) at least every five years, maintains their certification by completing requalification training and passing a requalification examination; and

(3) provides biannual reports to the Secretary or designated HHS representative as required in Section 13.11;

(c) The Federal agency must ensure that each MRO reports drug test results to the agency in accordance with Sections 13.8 and 14.7.

(1) Before allowing an MRO to report results electronically, the agency must obtain documentation from the MRO to confirm that the MRO and any external service providers ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

Subpart N—Split Specimen Tests

Section 14.1 When may a split (B) oral fluid specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) oral fluid specimen be tested at a different (*i.e.,* second) HHS-certified oral fluid laboratory when the primary

(A) specimen was determined by the MRO to be positive, adulterated, or substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory to perform the test), the MRO reports a cancelled test to the Federal agency and the reason for the cancellation. The MRO directs the Federal agency to ensure immediate recollection of another oral fluid specimen from the donor, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified oral fluid laboratory, a Federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoffs established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

Section 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established LOQ to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported substituted?

The second HHS-certified laboratory may only conduct the confirmatory biomarker test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

Section 14.5 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.6 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) oral fluid specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and the specimen was adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and the specimen was substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request that Laboratory A test the primary (A) specimen using its confirmatory test for the biomarker.

(1) If the primary (A) specimen's test results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency.

(2) If the primary (A) specimen's results fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and the specimen was not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s]), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was adulterated.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was not adulterated or substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action

based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen had an invalid result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (not adulterated: specifying the adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm substitution or adulteration and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: specifying the adulterant or not substituted, and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure and notifies the HHS office responsible for coordination of the drug-free workplace program.

(l) Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result. The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(m) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and not adulterated: specifying the adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(n) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s] and adulterated) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(o) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s and not adulterated: specifying the adulterant). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(p) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: specifying the adulterant, and not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(q) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (not adulterated: specifying the adulterant). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(r) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

Section 14.7 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* fax, computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.8 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions, in accordance with Section 11.18. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O—Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory to report an oral fluid specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken, or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The primary (A) specimen was collected using an expired device (*i.e.,* the device expiration date precedes the collection date) and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(d) The collector's printed name and signature are omitted on the Federal CCF;

(e) The collector failed to document observation of the volume indicator(s) at the time of collection for a collection device containing a diluent.

(f) There is an insufficient amount of specimen for analysis in the primary (A) specimen and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(g) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(h) The specimen was received at the HHS-certified laboratory without a CCF;

(i) The CCF was received at the HHS-certified laboratory without a specimen;

(j) The collector performed two separate collections using one CCF; or

(k) The HHS-certified laboratory identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory must hold the specimen and attempt to obtain a memorandum for record to recover the collector's signature. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the HHS-certified laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-Federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the report for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's Social Security Number or employee identification number;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) The specimen type box (Oral Fluid) is not marked (*i.e.,* by the collector or laboratory);

(11) A ''collection'' box is not marked;

(12) The ''each device within expiration date'' box is not marked;

(13) The collection site address is missing;

(14) The collector's printed name is missing but the collector's signature is properly recorded;

(15) The time of collection is not indicated;

(16) The date of collection is not indicated;

(17) Incorrect name of delivery service;

(18) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(19) The donor's name inadvertently appears on the HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory should not cause an MRO to cancel a test:

(1) The testing laboratory fails to indicate the correct name and address in the results section when a different laboratory name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 What discrepancies may require an MRO to cancel a test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or substituted; or

(3) The electronic report provided by the HHS-certified laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or substituted.

(b) If the error in Section 15.4(a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If the error in Section 15.4(a)(2) occurs, the MRO must obtain a statement from the certifying scientist that they forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If the error in Section 15.4(a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P—Laboratory Suspension/Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory in writing that its certification to perform drug testing

under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of the official's employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period, advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedures are used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the

hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at their discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of the official's employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At their discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Section 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by fax, secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by fax, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and Federal holidays. However, if a due date falls on

a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue their decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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Part VI

Commodity Futures Trading Commission

17 CFR Part 4
Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools: Updating the 'Qualified Eligible Person' Definition; Adding Minimum Disclosure Requirements for Pools and Trading Programs; Permitting Monthly Account Statements for Funds of Funds; Technical Amendments; Proposed Rule

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 4

RIN 3038–AF25

Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools: Updating the 'Qualified Eligible Person' Definition; Adding Minimum Disclosure Requirements for Pools and Trading Programs; Permitting Monthly Account Statements for Funds of Funds; Technical Amendments

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is proposing amendments to certain provisions of its regulations that would: update the Portfolio Requirement thresholds within the ''Qualified Eligible Person'' definition; require commodity pool operators (CPOs) and commodity trading advisors (CTAs) operating pools and trading programs under the applicable Commission regulations to provide certain minimum disclosures to their prospective pool participants and advisory clients; include revisions that are consistent with long-standing Commission exemptive letters addressing the timing of certain pools' periodic financial reporting; and several technical amendments related to the structure of the regulations that are the subject of this proposal.

DATES: Comments must be received by December 11, 2023.

ADDRESSES: You may submit comments, which must be in writing and identified by RIN 3038–AF25, by any of the following methods:

- *CFTC Comments Portal: https://comments.cftc.gov.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instruction as for Mail, above. Please submit your comments using only one of these methods. Submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://comments.cftc.gov.* You should only submit information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act (FOIA), a petition for confidential treatment of the exempt information may be submitted according to the procedures in § 145.9 of the Commission's regulations. The Commission reserves the right, but shall have no obligation, to review, prescreen, filter, redact, refuse, or remove any or all of your submission from *https://comments.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act (APA) and other applicable laws and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Amanda L. Olear, Director, 202–418–5283 or *aolear@cftc.gov;* Pamela M. Geraghty, Acting Deputy Director, 202–418–5634 or *pgeraghty@cftc.gov;* Elizabeth Groover, Special Counsel, 202–418–5985 or *egroover@cftc.gov;* or Andrew Ruggiero, Special Counsel, 202–418–5712 or *aruggiero@cftc.gov;* each in the Market Participants Division at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

As amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act),[1] section 1a(11) of the Commodity Exchange Act (CEA or Act) defines the term ''commodity pool operator'' as any person engaged in a business that is of the nature of a commodity pool, investment trust, syndicate, or similar form of enterprise, and who, with respect to that commodity pool, solicits, accepts, or receives from others, funds, securities, or property, either directly or through capital contributions, the sale of stock or other forms of securities, or otherwise, for the purpose of trading in commodity interests.[2] CEA section 1a(10) defines a ''commodity pool'' as any investment trust, syndicate, or similar form of enterprise operated for the purpose of trading in commodity interests.[3] CEA section 1a(12) defines the term ''commodity trading advisor'' as any person who, for compensation or profit, engages in the business of advising others, either directly or through publications, writing, or electronic media, as to the value of or the advisability of trading in commodity interests.[4]

Generally, CEA section 4m(1) requires each person whose intermediary activities satisfy either the CPO or CTA definition to register as such with the CFTC.[5] With respect to both CPOs and CTAs, the CEA also authorizes the Commission to include persons within, or exclude them from, such definitions, by rule, regulation, or order, if the Commission determines that such action will effectuate the purposes of the CEA.[6] In addition to the general registration authority set forth in CEA section 4m(1), CEA section 4n specifically empowers the Commission to impose compliance obligations related to the registration process, recordkeeping, disclosure, and reporting.[7] Finally, the CEA also gives the Commission authority to make and promulgate such rules and regulations, as in the judgment of the Commission, are reasonably necessary to effectuate the provisions or to accomplish any purposes of the CEA.[8]

Part 4 of the Commission's regulations specifically governs the operations and activities of CPOs and CTAs.[9] These regulations implement the statutory authority provided to the Commission by the CEA and also establish registration exemptions and definitional

[1] Public Law 111–203, 124 Stat. 1376 (2010).

[2] 7 U.S.C. 1a(11).

[3] 7 U.S.C. 1a(10).

[4] 7 U.S.C. 1a(12).

[5] 7 U.S.C. 6m(1) (noting that it is unlawful for any CTA or CPO, unless registered under the provisions of that chapter, to make use of the mails or any means or instrumentality of interstate commerce with his business as such CTA or CPO). *See also* 17 CFR 3.10.

[6] 7 U.S.C. 1a(11)(B); 7 U.S.C. 1a(12)(B)–(C).

[7] 7 U.S.C. 6n.

[8] 7 U.S.C. 8a(5).

[9] 17 CFR part 4.

exclusions for CPOs and CTAs.[10] Part 4 also contains detailed regulations that establish the ongoing compliance requirements applicable to registered CPOs and CTAs. These compliance requirements pertain to the commodity pools and separate accounts that CPOs and CTAs operate and advise, and provide customer protection, disclosures, and regular reporting to a registrant's pool participants or advisory clients.

Regulation 4.7 provides exemptions from certain part 4 compliance requirements regarding disclosure, periodic reporting, and recordkeeping for registered CPOs and CTAs, whose prospective and actual pool participants and/or advisory services are restricted to individuals and entities considered ''Qualified Eligible Persons,'' and who claim the desired exemptions, pursuant to paragraph (d) of that section.[11] As of the end of FY 2022, 837 registered CPOs operated approximately 4,304 commodity pools pursuant to claimed Regulation 4.7 exemptions (4.7 pools, and together with CTA programs operated under Regulation 4.7, the 4.7 pools and trading programs).[12] Relatedly, approximately 865 CTAs claim an exemption under Regulation 4.7 for their trading programs, which the Commission estimates to number in the thousands. During discussions with CFTC staff, the National Futures Association (NFA), the registered futures association to whom the Commission has delegated many of its regulatory oversight functions with respect to CPOs and CTAs, has predicted that this population of CPOs, CTAs, commodity pools, and trading programs operating pursuant to Regulation 4.7 will only continue to grow in the future.[13] Since its adoption over thirty years ago, the Commission has occasionally amended Regulation 4.7 to enhance its usability and ensure that it remains fit for purpose.[14] For the reasons discussed below, however, it is the Commission's preliminary view that certain aspects of Regulation 4.7 no longer align with the Commission's intentions and thus require amendment.

After a careful review of the existing language and structure of Regulation 4.7, and considering the clear public and regulatory interest of maintaining and modernizing older, but still widely utilized provisions, the Commission is issuing this Notice of Proposed Rulemaking (NPRM or Proposal) comprised of targeted amendments to update the regulation in several ways. In particular, the Commission is proposing amendments that would: (1) increase the financial thresholds in the Portfolio Requirement of the ''Qualified Eligible Person'' (QEP) definition in Regulation 4.7(a) to reflect inflation; (2) require certain minimum disclosures for 4.7 pools and trading programs operated and offered by CPOs and CTAs; (3) add a process under Regulation 4.7(b)(3) permitting CPOs to elect an alternative account statement schedule for certain 4.7 pools consistent with long-standing exemptive letters issued by the Commission; [15] and (4) improve the structure and utility of Regulation 4.7 through several technical adjustments (for example, reorganizing the QEP definition, updating cross-references, etc.).

II. The Proposal

a. Updating Financial Thresholds in the Portfolio Requirement of the ''Qualified Eligible Person'' Definition

As discussed above, Regulation 4.7 provides exemptions to CPOs and CTAs for their 4.7 pools and trading programs from various compliance, disclosure, and recordkeeping requirements within part 4 of the Commission's regulations, provided that their prospective and actual pool participants and advisory clients are restricted to QEPs. Regulation 4.7(a) bifurcates the definition of QEP into paragraphs (a)(2) and (a)(3) representing two different QEP categories: (1) those persons [16] who do not need to satisfy an additional ''Portfolio Requirement,'' as defined in Regulation 4.7(a)(1)(v), to be considered a QEP,[17] and (2) those persons who do.[18] Notably, natural persons are among those listed under Regulation 4.7(a)(3) and are thus required to satisfy the Portfolio Requirement to be considered QEPs. Pursuant to Regulation 4.7(a)(3), to be considered QEPs, such natural persons must meet the ''accredited investor'' definition adopted by the Securities and Exchange Commission (SEC) under Regulation D applicable to private securities offerings exempt from registration under the Securities Act, as well as the Portfolio Requirement adopted by the Commission.[19]

Currently, the Portfolio Requirement contains two thresholds; if either (or some combination of the two) is satisfied by a person listed under Regulation 4.7(a)(3), then a CPO or CTA may consider them a QEP eligible to invest in the offered 4.7 pool or trading program. More specifically, a person can satisfy the Portfolio Requirement by: (1) owning securities (including pool participations) of issuers not affiliated with such person and other investments

[10] *See* 7 U.S.C. 6n; 17 CFR 4.5, 4.6, 4.13, 4.14.

[11] 17 CFR 4.7.

[12] These numbers are drawn from data in National Futures Association Form PQR filings for Q4 2022.

[13] In fact, as of March 31, 2023, there were approximately 1,128 CPOs registered with the Commission, and on average, approximately 5,257 pools were reported via CFTC Form CPO–PQR on a quarterly basis in FY 2022. Assuming there is no material difference in the number of registered CPOs and pools reported between the closings of Q4 2022 and of Q1 2023, NFA and CFTC data show that approximately 69% of registered CPOs operate 4.7 pools, and approximately 81% of all pools reported on CFTC Form CPO–PQR are 4.7 pools. After amendments to Form CPO–PQR and Regulation 4.27 adopted in 2020, the Commission accepts NFA Form PQR as substituted compliance for the required completion of its own Form CPO–PQR. *See* 17 CFR 4.27. Therefore, the data sources for both NFA and CFTC are fundamentally the same, if not identical.

[14] *See, e.g.,* 84 FR 67355 (Dec. 10, 2019).

[15] Such exemptive letters are routinely drafted by Commission staff in the Market Participants Division (MPD) and constitute an exercise of the authority in Regulation 4.12(a), which is delegated by the Commission to MPD's predecessor division, the Division of Swap Dealer and Intermediary Oversight, through Regulation 140.93. *See* 17 CFR 4.12(a) and 140.93.

[16] 17 CFR 1.3 (defining ''person'' as ''includ[ing] individuals, associations, partnerships, corporations, and trusts'').

[17] 17 CFR 4.7(a)(2). Generally, this list includes, but is not limited to: (1) registered futures commission merchants (FCMs), registered retail foreign exchange dealers (RFEDs), registered swap dealers, and principals thereof; (2) a registered broker or dealer, or principal thereof; (3) certain registered CPOs, and principals thereof; (4) certain registered CTAs, and principals thereof; (5) certain investment advisers registered under the Investment Advisers Act of 1940 (IAA), and principals thereof; (6) ''qualified purchasers'' as defined in section 2(a)(51)(A) of the Investment Company Act of 1940 (ICA); (7) ''knowledgeable employees'' as defined in 17 CFR 270.3c–5 pursuant to the ICA; (8) certain persons associated with an exempt pool or account, outlined in Regulation 4.7(a)(2)(viii)(A) and (B), respectively; (9) certain trusts; (10) organizations described in section 501(c)(3) of the Internal Revenue Code (IRC), subject to some conditions; (11) non-United States persons; and (12) exempt pools. *Id.*

[18] 17 CFR 4.7(a)(3). Generally, this list includes, but is not limited to: (1) certain investment companies registered under the ICA or a business development company as defined in section 2(a)(48) of the ICA; (2) banks as defined in section 3(a)(2) of the Securities Act of 1933 (Securities Act), or any savings and loan association or other institution as defined in section 3(a)(5)(A) of the Securities Act acting for its own account or for the account of a QEP; (3) certain insurance companies acting for their own account or that of a QEP; (4) certain state employee benefit plans; (5) certain employee benefit plans within the meaning of the Employee Retirement Income Security Act of 1974 (ERISA); (6) private business development companies; (7) certain corporations, Massachusetts or similar business trusts, or partnerships, limited liability companies or similar business ventures; (8) natural persons meeting the individual net worth or joint net worth tests within the ''accredited investor'' definition; (9) natural persons who would otherwise be considered accredited investors; (10) certain pools, trusts, insurance company separate accounts, or bank collective trusts; and (11) certain government entities.

[19] 17 CFR 4.7(a)(3)(ix) and (x). For the SEC's ''accredited investor'' definition, see 17 CFR 230.501.

with an aggregate market value of at least $2,000,000 [20] (Securities Portfolio Test); (2) having on deposit with a futures commission merchant, for its own account at any time during the six months preceding either the date of sale to that person of a pool participation in the exempt pool or the date the person opens an exempt account with the CTA, at least $200,000 in exchange-specified initial margin and option premiums, together with required minimum security deposit for retail forex transactions for commodity interest transactions [21] (Initial Margin and Premium Test); or (3) owning a portfolio comprised of a combination of the funds or property specified in the Securities Portfolio Test and the Initial Margin and Premium Test, which, when expressed as percentages of the required amounts, meet or exceed 100%.[22]

The Portfolio Requirement has remained unchanged since its original adoption by the Commission in 1992.[23] When it developed the QEP definition and the associated Portfolio Requirement, the Commission sought to create ''objective criteria'' by which one could assess a person's commodity interest experience, believing that appropriate experience would involve an investment portfolio of a size sufficient to indicate that the participant has substantial investment experience and thus a high degree of sophistication with regard to investments as well as financial resources to withstand the risk of their investments.[24] The Commission sought in the 1992 Final Rule to harmonize Regulation 4.7 with existing securities laws and regulations for sophisticated investors by incorporating the SEC's ''accredited investor'' definition into the QEP definition, which was intended to capture similarly experienced and sophisticated persons participating in the commodity interest markets.[25] However, the Commission determined that an additional, higher standard of experience was necessary for certain natural and other persons, citing the differences between futures and securities investments.[26]

The 1992 Proposed and Final Rules provide insight into the level of sophistication the Commission then considered necessary for natural persons (and other persons listed within Regulation 4.7(a)(3)) to qualify as QEPs. For example, in response to comments suggesting that the Commission not adopt any Portfolio Requirement, and instead rely solely on the parameters of the SEC's ''accredited investor'' definition, the Commission explicitly declined to do so.[27] The Commission continues to believe that a Portfolio Requirement provides a reasonable proxy for the experience, acumen, and resources necessary for certain persons, including natural persons, to be considered QEPs eligible to invest in complex commodity interest products without receiving the full panoply of information otherwise required under part 4.[28] These dollar thresholds have not been modified since their adoption over 30 years ago, and the Commission preliminarily believes it is long overdue to update these measures.

In determining an appropriate increase for each threshold, the Commission preliminarily believes two inflation indexes published by the United States Bureau of Labor Statistics (BLS) are appropriate to consider. Specifically, the Commission consulted the Consumer Price Index for All Urban Consumers (CPI–U) and the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W).[29] The CPI–U and CPI–W indexes indicate that inflation has had a considerable impact on the monetary thresholds established in the 1992 Final Rule. The CPI–U and CPI–W data reveal that the current monetary thresholds in Regulation 4.7(a)(1)(v) may no longer reasonably indicate the high level of investor sophistication, acumen, and resources that the Commission intended when the Portfolio Requirement was adopted. For example, based on analysis using CPI–U data, as of February 2023, the $2,000,000 threshold in the Securities Portfolio Test has the same buying power as approximately $4,270,000, and the $200,000 threshold in the Initial Margin and Premiums Test has the same buying power as approximately $427,000.[30]

Given these results, the Commission is proposing to update the Portfolio Requirement's thresholds by doubling the Securities Portfolio Test in Regulation 4.7(a)(1)(v)(A) to $4,000,000, and the Initial Margin and Premium Test in Regulation 4.7(a)(1)(v)(B) to $400,000. Although these figures do not match the results provided by the CPI–U and CPI–W indexes exactly, being slightly lower than the February 2023 buying power stated above, the Commission preliminarily believes that Portfolio Requirement thresholds rounded down to the nearest million and hundred thousand would be simpler for CPOs and CTAs relying on Regulation 4.7 to apply in determining if a prospective pool participant or advisory client is a QEP. Additionally, the Commission would continue to permit persons to meet the Portfolio Requirement through a combination of the two Portfolio Requirement thresholds as currently allowed under Regulation 4.7(a)(1)(v)(C), which would largely remain unchanged by this NPRM, except to update the example provided therein of how the two tests could be combined to reflect the higher proposed thresholds.

The Commission recognizes that these increases to the Portfolio Requirement will likely result in a certain portion of currently-qualifying QEPs no longer

[20] 17 CFR 4.7(a)(1)(v)(A).

[21] 17 CFR 4.7(a)(1)(v)(B).

[22] 17 CFR 4.7(a)(1)(v)(C).

[23] 57 FR 34853 (Aug. 7, 1992) (1992 Final Rule).

[24] 57 FR 3148, 3152 (Jan. 28, 1992) (1992 Proposed Rule).

[25] *See* the persons listed within 17 CFR 4.7(a)(2) and (3); *cf.* 17 CFR 230.501.

[26] 1992 Proposed Rule, 57 FR at 3151.

[27] *Id.*

[28] Although in the 1992 Final Rule the Commission cited the lack of disclosure requirements as one of the reasons for adopting a Portfolio Requirement, it was not the only policy justification; the inherent differences between futures and securities investments, as discussed above, were also cited. *See* 1992 Final Rule, 57 FR at 34855. Despite the Commission's original rationale in adopting the QEP definition including the policy decision of not requiring disclosures, the Commission has preliminarily concluded that retaining and increasing the Portfolio Requirement, while also proposing new disclosure requirements, is necessary given the increased variety and general evolution of the commodity interest markets since 1992. *See infra* Proposal, pt. II.b.

[29] *See* the U.S. BLS Handbook of Methods, for more information on the CPI, CPI–U, and CPI–W, *available at https://www.bls.gov/opub/hom/cpi/presentation.htm.* As described by the BLS Handbook of Methods, ''CPI–U represents the buying habits of the residents of urban and metropolitan areas in the United States and covers over 90 percent of the U.S. population.'' *Id.* Comparatively, ''the CPI–W is computed using the same prices as the CPI–U, but the weights of the CPI–W are based on a subset of the CPI–U population, covering approximately 30 percent of the U.S. population.'' *Id.* The CPI–W also includes ''households where more than one-half of the household's earners must have been employed for at least 37 weeks during the previous 12 months.'' *Id.* Given the relevance of these indexes to the population of natural persons that may qualify as QEPs via the Portfolio Requirement, the Commission believes these indexes are the most appropriate to use in determining today's buying power of the Portfolio Requirement's monetary thresholds established in 1992.

[30] The actual calculator for CPI–U can be found at *https://www.bls.gov/data/inflation_calculator.htm.* The Commission is preliminarily choosing to include the February 2023 CPI–U data above because it provides a clear example of today's buying power of the Portfolio Requirement, as it was established in 1992, and because the data can be easily accessed and verified via the BLS inflation calculator link provided herein. In comparing the results of each index, as applied to the Portfolio Requirement thresholds, the Commission found no material difference between the CPI–W and CPI–U. Analysis using the CPI–W provided similar buying power figures to those produced by the CPI–U analysis. Given that the Commission is proposing updated thresholds rounded down to the nearest million and hundred thousand, the Commission believes that providing the CPI–U analysis is sufficient for purposes of this Proposal.

meeting the thresholds. Regulation 4.7(a)(3) provides that CPOs must assess a person's QEP status, including satisfaction of the Portfolio Requirement, at the time of sale of any pool participation units, and that CTAs must make a similar assessment at the time that a person opens an exempt account.[31] The Commission believes that continuing this requirement, as opposed to requiring mandatory redemptions or terminations of advisory relationships for those current QEPs who may not meet the proposed heightened thresholds, minimizes the potential for disruption to the 4.7 pool or trading program, as well as possible negative consequences for the current QEPs. Therefore, the Commission is proposing to retain the requirements of current Regulation 4.7(a)(3) in Proposed Regulation 4.7(a)(6)(ii), and requests comment on this aspect of the proposal.

The Commission solicits comment on these proposed increases to the Portfolio Requirement in the QEP definition. In addition, the Commission also seeks comment on the following:

1. Are the CPI–U and the CPI–W indexes the most appropriate for considering the impact of inflation on the thresholds within the Portfolio Requirement, and if they are not, what other suggested indexes or methods should the Commission consider using to assess inflationary effects?

2. The Commission is also seeking any data or information, from CPOs and CTAs that utilize Regulation 4.7, on the estimated number of advisory clients and pool participants that currently qualify as QEPs via the existing Portfolio Requirement, but would not so qualify if the increased monetary thresholds in the Portfolio Requirement described above are adopted.

3. How much time would CPOs and CTAs need to determine that their existing QEP pool participants and clients would continue to satisfy the increased Securities Portfolio or Initial Margin and Premium Tests, if adopted as proposed?

b. Establishing Minimum Disclosure Requirements Under Regulation 4.7

As stated above, Regulation 4.7 provides exemptions from the broader part 4 compliance requirements, including those regulations requiring disclosures of general and performance information about a pool or trading program, for CPOs with respect to pools offered solely to QEPs, and for CTAs advising or managing the accounts of QEPs. More specifically, Regulation 4.7(b)(2) provides an exemption for CPOs with respect to their pools offered solely to QEPs regarding: (1) the requirement to deliver a disclosure document in Regulation 4.21; (2) the general disclosures required by Regulation 4.24; (3) the performance disclosures required by Regulation 4.25; and (4) the use and amendment requirements in Regulation 4.26; so long as the CPO provides a form statement on the cover page of any offering memorandum it chooses to distribute to its prospective pool participants (or near the signature line of the pool's subscription agreement, if its CPO chooses not to distribute an offering memorandum).[32] Similarly, Regulation 4.7(c)(1) provides an exemption for CTAs with respect to their trading programs offered to QEPs regarding: (1) the requirement to deliver a disclosure document in Regulation 4.31; (2) the general disclosures required by Regulation 4.34; (3) the performance disclosures required by Regulation 4.35; and (4) the use and amendment requirements in Regulation 4.36; provided that the CTA includes a form statement on the cover page of any brochure or disclosure statement it chooses to distribute to its prospective advisory clients (or near the signature line of the advisory agreement, if the CTA chooses not to distribute a brochure or disclosure statement).[33] Currently, because of Regulations 4.7(b)(2) and (c)(1), CPOs and CTAs claiming these exemptions [34] are not required to deliver or disseminate any offering memoranda, brochures, or disclosure statements to their prospective QEP pool participants or advisory clients (QEP Disclosures). Rather, these CPOs and CTAs are only required to ensure that any QEP Disclosures they elect to provide, ''include all disclosures necessary to make the information contained therein, in the context in which it is furnished, not misleading.'' [35]

At the time of Regulation 4.7's adoption in 1992, the Commission's rationale for providing these broad disclosure exemptions was, in part, based on the belief that QEPs are able to identify and obtain the information they deem necessary to evaluate the investment offered and thus that prescriptive rules imposing specific disclosure requirements are not essential.[36] The 1992 Final Rule further stated that the QEP definition is designed to assure that 4.7 offerings are made only to investors with sufficient sophistication and expertise to assess the appropriateness of the investment for their purposes and to obtain all the information they need to evaluate and monitor the contemplated investment, and placed the responsibility for obtaining such information about 4.7 pools and trading programs squarely on the prospective QEP pool participant or advisory client.[37] The Commission also noted that requirements under other regulatory structures may apply to investor pools or their principals and require the CPO of an investor pool to make disclosure[s] to such participants.[38] The Commission explained then that, despite the relief provided by Regulation 4.7, CPOs and CTAs relying on those exemptions with respect to the disclosure requirements in part 4 remain subject to the generally applicable statutory provisions in the CEA that prohibit defrauding or misleading investors, as well as those that specifically prohibit CPOs, CTAs, and their associated persons from defrauding or deceiving their participants and clients.[39] In sum, the Commission sought in 1992 to create a simplified regulatory and compliance framework for CPO and CTA offerings to QEPs, leveraging the applicability of other Federal regulations to require disclosures to investors, and relying upon its broader enforcement powers to safeguard against fraud at inception, and throughout the lifecycle of the 4.7 offering, as well as the ability of QEPs to demand and receive such disclosures on their own.

In proposing Regulation 4.7, the Commission explained that, with respect to its oversight of CPOs and CTAs, it had endeavored to construct a regulatory framework that avoids unnecessary burdens without reducing investor protection and refined that framework as appropriate to respond to changing market conditions and to simplify and streamline the regulatory structure without creating regulatory

[31] 17 CFR 4.7(a)(3).

[32] 17 CFR 4.7(b)(2) (providing an exemption from the specific requirements of §§ 4.21, 4.24, 4.25, and 4.26 with respect to each exempt pool). The prescribed ''form statement'' indicates that the CPO's offering memorandum has not been, nor is it required to be, filed with the Commission, and that the CFTC has not reviewed or approved such offerings or any related offering memoranda for the 4.7 pool. *Id.*

[33] 17 CFR 4.7(c)(1) (providing an exemption ''from the specific requirements of §§ 4.31, 4.34, 4.35, and 4.36''). The prescribed ''form statement'' indicates that the CTA's brochure has not been, nor is it required to be, filed with the Commission, and that the CFTC has not reviewed or approved such trading program or brochure. *Id.*

[34] *See* 17 CFR 4.7(d).

[35] 17 CFR 4.7(b)(2); 17 CFR 4.7(c)(1).

[36] 1992 Final Rule, 57 FR at 34857.

[37] *Id.* at 34858.

[38] *Id.* (citing pension plan regulations as an example).

[39] *Id.*

gaps.[40] Although the Commission expects QEPs meeting a properly calibrated Portfolio Requirement to generally possess the level of financial sophistication, as described by the Commission in 1992, the Commission preliminarily concludes in this proposalthat current market conditions and industry practices support proposing an evolved disclosure regime in Regulation 4.7. The Commission is concerned that the absence of minimal disclosure obligations and an ongoing requirement to keep them accurate fails to ensure that all QEPs have the leverage and resources to demand the information necessary for QEPs to make informed investment decisions, or to engage in ongoing close monitoring to confirm that the information provided remains accurate and complete to facilitate their continued understanding of their investments. The definition of QEP in Regulation 4.7 encompasses a broad spectrum of market participants from large fund complexes and other institutional investors with significant assets under management to individuals with varying backgrounds and experience, each of which has vastly different resources available to insist upon the disclosure of information regarding the offered 4.7 pool or trading program and then to analyze whatever information is provided.

In 2014, staff in the Commission's Division of Swap Dealer and Intermediary Oversight (DSIO) convened a roundtable on the risk management practices of CPOs.[41] As part of that discussion, participants addressed the manner in which CPOs of pools that are ''Funds of Funds,'' [42] or that allocate some or all of their assets under management to unaffiliated asset managers, engage with their underlying funds and asset managers. Specifically, several large CPOs discussed the ongoing oversight that they engage in regarding their investee funds, from analyzing past performance and understanding liquidity limitations, both of which require a deep understanding of the investment activities of the underlying funds, to addressing issues of governance, organization, and staffing; these CPOs explained that all of these efforts are undertaken to ensure that underlying investments remain the right fit for their investor fund's strategy and their participants.[43] Such large asset managers have the market power necessary to demand detailed investment information across all aspects of their underlying funds and managers, due to their role as gatekeepers for enormous pools of investor capital.[44] Moreover, they also possess the resources necessary to develop sophisticated internal systems and technology to digest that information and engage in real-time monitoring of whether the underlying fund or manager's actual trading and conduct is consistent with the information being provided.[45] Conversely, individual natural persons, who meet the QEP definition through the Portfolio Requirement, but nonetheless do not command the assets of large financial institutions, likely lack the ability to demand the same level of transparency afforded through the prospect of additional significant asset allocations, and thus are more likely to be reliant upon whatever information the CPO or CTA is providing as its baseline disclosure with limited ability to demand more, or analyze its accuracy and completeness.[46] This perceived disparity may increase the likelihood of CPOs and CTAs with less rigorous risk management and controls to seek capital from such individuals who are generally less able to engage in the same rigorous monitoring.[47]

Moreover, particularly once their relationship with a CPO or CTA is established, QEPs of all types may have diminished power over time to demand the same level of information about their investments as they had received at the outset, due to the presence of lock-up periods or infrequently permitted redemptions that may require extended notice periods following initial investment.[48] The Commission understands that, with respect to CPOs and CTAs who claim and operate under Regulation 4.7 exemptions, NFA staff has observed situations where the quality and provision of the information presented to the customer may be inconsistent.[49] The Commission preliminarily believes that these factors warrant reconsideration of the disclosure exemptions. Furthermore,

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[40] 1992 Proposed Rule, 57 FR at 3149.

[41] Public Roundtable to Discuss Risk Management Practices by Commodity Pool Operators (Mar. 18, 2014), *available at www.cftc.gov/idc/groups/public/@newsroom/documents/file/transcript031814.pdf* (Roundtable Transcript).

[42] ''Funds of funds'' as used in this document means pools that invest in unrelated funds, pools, or other collective investment vehicles.

[43] *See, e.g., id.* at 31–35 (comments from representative of UBS Alternative and Quantitative Investments); *id.* at 39–41 (comments from representative of Mesirow Advanced Strategies, Inc.).

[44] *See, e.g.,* Blackstone Alternative Asset Management, a registered CPO, manages approximately $81bn in client assets and uses the services of other asset managers, *available at https://www.blackstone.com/our-businesses/hedge-fund-solutions-baam/* (noting, ''Our size also gives us the ability to negotiate customized mandates and improved terms with managers,'' and touting their ''rigorous process for evaluating managers and opportunities''); Lighthouse Investment Partners, LLC, another registered CPO that similarly allocates assets to other managers, manages approximately $15bn, *available at https://www.linkedin.com/company/lighthouse-investment-partners-llc* and *http://lighthousepar.wpengine.com/our-funds/* (noting that their portfolio of hedge funds uses a ''proprietary managed account framework'' that enables them to ''negotiate better terms'' and ensures that Lighthouse retains the ''ability to revoke manager trading authority at any time'').

[45] Roundtable Transcript, at 40–41 (comments from representative of Mesirow Advanced Strategies, Inc., describing how the firm had their ''tracking index running next to their performance at all times and if at any time their performance deviates from that basic tracking index, [they] are on the phone with that manager trying to understand why that happens'').

[46] *See, e.g., Herbert Moskowitz and Ari Moskowitz* v. *Accredited Investment Management Corp.,* Peter G. Catranis, and Russell E. Tanner, CFTC Docket Nos. 13–R15 and 13–R20, Default Judgment, Apr. 20, 2018, available at *https://www.cftc.gov/idc/groups/public%40lrdispositions/documents/legalpleading/idmoskowitz05122016.pdf* (finding in favor of the plaintiffs regarding a 4.7 CTA's failure to provide ''fair and balanced'' disclosures regarding the risks and rewards of the offered trading program); Susan Taylor Martin, How Tampa's James Cordier went from high roller to YouTube apology after losing $150 million, Tampa Bay Times, Feb. 11, 2019, available at *https://www.tampabay.com/business/how-tampas-james-cordier-went-from-high-roller-to-youtube-apology-after-losing-150-million-20190206/* (describing how Mr. Cordier, according to deposition testimony from a former client, failed to provide an accurate statement regarding the treatment of customer funds held at a futures commission merchant and characterized the only risk to the client's funds as ''market risk''); Leanna Orr, Remember Wall Street's Viral Laughingstock, OptionSeller.com?, Institutional Investor, May 13, 2020, available at *https://www.institutionalinvestor.com/article/b1lm2xg8g69vbc/Remember-Wall-Street-s-Viral-Laughingstock-OptionSeller-com* (quoting counsel to the failed 4.7 CTA's clients, many of whom were retirees, ''These people work their whole lives to make a nice middle class life, and then the bottom drops out and they drop out of the middle class. They don't even understand why it happened . . . They rely on these [expletives] who said they knew what they were doing.'').

[47] Susan Taylor Martin, How Tampa's James Cordier went from high roller to YouTube apology after losing $150 million, Tampa Bay Times, Feb. 11, 2019, *available at https://www.tampabay.com/business/how-tampas-james-cordier-went-from-high-roller-to-youtube-apology-after-losing-150-million-20190206/* (reciting allegations from a complaint against a 4.7 CTA stating that the CTA promised ''fastidious'' risk management, but failed to hedge its naked options appropriately for the risk profile of its clients).

[48] *See, e.g.,* In the Matter of: Highland Quantitative Driven Investments LLC and Michael Todd Zatorski, NFA Case No. 20–BCC–004 (alleging that the named CPO and its principal failed to update their private placement memoranda, and thereby inform their current and prospective 4.7 pool participants, with respect to significantly increased fees, while simultaneously imposing a one- to two-year lock up period, which foreclosed the possibility of threatening to withdraw their capital contributions absent updated disclosures).

[49] *See id.; see also* U.S. CFTC v. Mankad, 2022 WL 17752224 (D.C. Ariz. Oct. 19, 2022) (finding that the defendant and his CPO failed to update the private placement memorandum for its 4.7 pool following changes to their trading strategy).

these circumstances, acting together, could foster an environment in which QEPs seeking to participate in a pool or advisory program must choose between a very limited number of offerings subject to the full panoply of compliance requirements under part 4 that provide them with more complete and regular information about their holdings, or a more varied and growing collection of QEP offerings, with substantially lower compliance obligations and no formal regulatory requirements with respect to disclosure that would ensure QEPs receive consistent, accurate, and current information about these products.

In addition to the aforementioned concerns about the unequal bargaining power of QEPs, in the 30 years since that provision was adopted, the Commission has, as described above, witnessed a significant expansion and growth in the complexity and diversity of commodity interest products offered to QEPs via 4.7 pools and trading programs, as well as an expansion in the asset classes subject to the Commission's jurisdiction and oversight. Broadly speaking, since the CFTC's authority over swaps and the swap markets was expanded under the Dodd-Frank Act, there has been a considerable change in the way that swaps trade. For example, when Regulation 4.7 was adopted in 1992, swaps trading occurred over-the-counter and the total estimated size of the market was approximately $9T in today's dollars;[50] whereas, after the Dodd-Frank Act's implementation, many swaps products are exchange-traded and the total size of the swaps market has increased exponentially,[51] and many CPOs and CTAs today incorporate swaps into the portfolios of their pools and trading programs. Regarding the products themselves, there has also been considerable development of new and complex commodity interest products.[52]

Although the Commission in 1992 considered the commodity interest products then available in developing existing customer protections for QEPs in Regulation 4.7, product innovation in the commodity interest markets has continued at a rapid and unrelenting pace[53] raising concern that certain QEP participants and clients may not have the level of information necessary to fully appreciate the nature of the risk associated with their trading. For example, futures are now available on digital assets, which, although subject to the same regulatory regime as other futures products, often experience higher levels of volatility than more traditional commodity reference assets.[54] Moreover, the technology underlying these assets is highly complex, subject to rapid innovation, and can pose substantially different principal risks as compared to traditional commodities, including unique cybersecurity risks and the potential for hacks and vulnerabilities in the storage and transmission of these assets. Given the relatively recent development of digital assets, it remains unclear as to whether the underlying markets, to which the futures and other derivatives are tied, are subject to market fundamentals similar to those of the traditional commodities markets. The Commission preliminarily believes that this can result in unpredictable movements in both the spot and commodity interest markets. As the financial system continues to experience a period of rapid evolution in the era of artificial intelligence and other technological advancements, the Commission expects to see continued development of novel investment products that, although structured like the traditional asset classes enumerated under the CEA, may in fact deviate from the typical operations of markets now subject to the Commission's oversight. In view of these developments, the Commission believes that minimum disclosure requirements are essential to ensure that pool participants and advisory clients fully understand the risks associated with their investments.

In addition to developments regarding products, market structure has also evolved in the years following the initial adoption of Regulation 4.7. Commodity pools and CTA advisory clients can access the futures markets either directly[55] or through an FCM, which present different risks and benefits to pool participants and advisory clients. Where FCMs are not part of the market structure, there may be fewer independent sources of information available to pool participants and advisory clients, making it even more important that QEPs receive full and accurate information regarding the risks related to their investments.

Thus, given these developments in the commodity interest markets, among others, and similar to the circumstances underlying the 1992 Final Rule, with respect to Regulation 4.7, the Commission continues seeking to construct a regulatory framework that avoids unnecessary burdens without reducing investor protection and to respond to changing market conditions without creating regulatory gaps.[56] The Commission preliminarily believes that requiring the provision of specific minimum disclosures for CPOs and CTAs operating 4.7 pools and trading programs will assist in mitigating the customer protection gaps that have developed since 1992 by ensuring that QEPs receive the information necessary to make informed investment decisions,

[50] *See* Adam R. Waldman, *OTC Derivatives and Systemic Risk: Innovative Finance or the Dance into the Abyss?,* 43 a.m. U. L. Rev. 1023, 1025 n.5 (1994) (citing Andrew Barry, BARRON'S, Sept. 13, 1993, at 49, reporting a swaps market size of $3.8T, as compiled by the International Swaps and Derivatives Association, Inc. (ISDA), which equates to roughly $8.8T based on CPI–U).

[51] *See* the ISDA SwapsInfo First Quarter 2023 Review, May 2023, *available at https://www.isda.org/2023/05/02/swapsinfo-first-quarter-of-2023-review-summary/* (stating that the interest rate derivatives market alone was valued at $106.1T notional in the first quarter of 2023); Bank for International Settlements, ''OTC derivatives statistics at end-June 2022,'' *available at https://www.bis.org/publ/otc_hy2211.pdf* (stating that ''the notional value of outstanding over-the-counter (OTC) derivatives rose to $632 trillion at end-June 2022, up from $598 trillion at end-2021'').

[52] Most notable, and as widely covered in the press, is the recent development and availability of commodity interest products linked to digital assets, such as bitcoin, discussed *infra.*

[53] *See* Katherine Ross, CME Group to add ether/bitcoin ratio futures in July pending regulatory approval, Blockworks, June 29, 2023, *available at https://blockworks.co/news/cme-adds-ether-bitcoin-ratio-futures.*

[54] The risks of these products to investors are of such concern that the CFTC and SEC have both acknowledged their volatility in various publications. In fact, and most relevant to this discussion, the SEC and CFTC released a joint investor alert to investors thinking about investing in a fund with exposure to bitcoin futures. The alert emphasized that investors should understand the unique characteristics and heightened risks compared to other funds. *See* CFTC/SEC Investor Alert: Funds Trading in Bitcoin Futures, *available at https://www.cftc.gov/LearnAndProtect/AdvisoriesAndArticles/fraudadv_funds_trading_in_bitcoin_futures.html.* Although these are not the only new products that have launched over the last 30 years, the Commission believes they are examples that highlight a need for updating the customer protections provided under Regulation 4.7. *See* Hannah Smith, Bitcoin crash: what was behind the crypto collapse?, The Times (May 22, 2023), *available at https://www.thetimes.co.uk/money-mentor/article/is-bitcoin-crash-coming/#Why-is-bitcoin-so-volatile?* (noting that bitcoin ''has no underlying asset'' and that ''means that the movements in its price are solely based on speculation among investors about whether it will rise or fall in the future''); Nicole Lapin, Explaining Crypto's Volatility, Forbes (Dec. 23, 2021), *available at https://www.forbes.com/sites/nicolelapin/2021/12/23/explaining-cryptos-volatility/?sh=1640938f7b54* (noting that ''it isn't intrinsically valuable,'' which ''means the investment's value isn't very grounded, which makes its price incredibly sensitive to even slight changes in investors' expectations or perceptions'').

[55] *See, e.g.,* In the Matter of the Application of LedgerX, LLC For Registration as a Derivatives Clearing Organization, Amended Order of Registration, *available at https://www.cftc.gov/media/4556/ledgerxllcamededdcoorder9-2-2020/download.*

[56] 1992 Proposed Rule, 57 FR at 3149.

and that such disclosures are subject to Commission and NFA oversight.

Importantly, the Commission does not intend this NPRM to dissuade registered CPOs and CTAs from structuring their pools and trading programs to qualify for and utilize the exemptions in Regulation 4.7. Rather, the Commission preliminarily believes that, as a result of the changing market conditions described above, an evolved approach to QEP Disclosures under Regulation 4.7 is necessary to ensure that QEPs consistently receive specific, baseline information with respect to their investments in the commodity interest markets, and further, that such proposed regulatory adjustments would not greatly reduce the benefits intermediaries currently derive from relying upon the relief in Regulation 4.7.

With this Proposal, the Commission is not proposing to rescind the disclosure exemptions in Regulations 4.7(b)(2) and (c)(1) in their entirety. Rather, the Commission aims to make targeted updates to these provisions that are designed to enhance customer protection, transparency, and fairness within the market of 4.7 pools and trading programs. The proposed amendments are intended to: (1) recognize the increasingly complex and diverse commodity interest investment products offered to QEPs today, and reflect the resulting evolution in view by the Commission that requiring basic disclosures to encourage informed investment decisions is the necessary and preferred approach for 4.7 pools and trading programs; (2) create a formalized Commission regulatory regime for promotional, advertising, and disclosure practices for CPOs and CTAs relying on Regulation 4.7 with respect to their QEP offerings, allowing for prospective and current participants and clients to better compare strategies, fees, and other characteristics of 4.7 pools and trading programs through consistent QEP Disclosures; and (3) strengthen intermediary oversight by incorporating the review of QEP Disclosures into existing examination processes used by the Commission and NFA, which, in turn, would increase their accuracy and quality over time.

By creating a formalized regulatory regime in part 4 for the promotional, advertising, and disclosure practices of CPOs and CTAs with respect to their 4.7 pools and trading programs, the Commission preliminarily believes that this would strengthen its oversight of CPOs and CTAs relying on Regulation 4.7 and that QEPs and the commodity interest markets overall would benefit as a result. The promotional, advertising, and disclosure practices of CPOs and CTAs utilizing Regulation 4.7 have changed a great deal since the original adoption of these exemptions. The Commission has observed that, despite there being no such requirements in Regulation 4.7, many CPOs and CTAs currently provide and distribute some disclosures and information regarding their 4.7 pools and trading programs to prospective QEP pool participants and advisory clients. These QEP Disclosures are commonly delivered in the form of private placement memoranda or trading program brochures, and typically include much of the information the Commission is proposing to require in this rule proposal. This practice results both from investor demand seeking to understand the 4.7 pools and trading programs offered in the current marketplace, as described above, as well as the requirements of other applicable regulatory regimes, like the Federal securities laws.[57] The Commission notes, however, that some CTAs, which are not also regulated as registered investment advisers by the SEC, may not be otherwise required to provide any disclosures and may, in fact, only provide cursory promotional material.

The Commission preliminarily believes that establishing minimum content requirements would ensure that existing QEP Disclosures are consistent in structure, accurate, kept up-to-date, and contain materially complete information regarding 4.7 pools and trading programs. As a result, current and prospective QEP participants and clients would be able to better compare investment programs, trading strategies, fees, and other characteristics of 4.7 pools and trading programs. Additionally, even if the QEP Disclosures provided by CPOs and CTAs relying upon Regulation 4.7 differ in form and detail, the minimum required disclosures proposed in this NPRM would result in all QEPs receiving the same level of basic information prior to making an investment decision. The Commission preliminarily concludes that replacing the existing broad exemptions with a targeted minimum disclosure regime under Regulation 4.7 will ultimately bring discipline to the current *ad hoc* QEP Disclosure process, resulting in more uniform and consistent disclosures for prospective and current QEP advisory clients and pool participants.

Finally, the Commission believes that amending Regulation 4.7 to require CPOs and CTAs to disclose certain information about their 4.7 pools and trading programs, as well as to keep such QEP Disclosures as business records, would facilitate more effective oversight of registered CPOs and CTAs and their offerings by the Commission and NFA. The Commission expects that creating a formalized, affirmative regulatory requirement that materially accurate QEP Disclosures be delivered and kept current, would likely enhance investor confidence in commodity interest products generally by providing an increased level of transparency for the Commission and NFA into these registrants' activities for examination and enforcement purposes, thereby improving oversight.[58] Moreover, by facilitating Commission and NFA access to QEP Disclosures kept amongst CPO and CTA business records, the Commission believes that the proposed affirmative recordkeeping requirements in Regulations 4.7(b)(5) and (c)(2) would serve as an additional deterrent to CPOs or CTAs engaging in fraud or providing misleading representations in QEP Disclosures.

The amendments proposed in this NPRM strike an appropriate balance, in the Commission's opinion, by establishing minimum content requirements for QEP Disclosures regarding 4.7 pools and trading programs, and mandating that they be kept as business records of the intermediary, while still retaining exemptions from the provisions of part 4 that require filing and pre-approval of non-4.7 Disclosure Documents by the Commission and NFA.[59] These proposed amendments would elevate the disclosure provided for 4.7 pools and trading programs to a higher

[57] *See, e.g.,* Rule 502(b)(2) of Regulation D, 17 CFR 230.502(b)(2) (requiring certain disclosures for offerings under Rule 506(b) of Regulation D, 17 CFR 230.506(b)). Additionally, many CPOs and CTAs operating under Regulation 4.7 are also registered with the SEC as investment advisers. All investment advisers registered with the SEC under the IAA, 15 U.S.C. 80b–1, *et seq.,* are required to comply with the applicable disclosure requirements under the IAA and the SEC's regulations promulgated thereunder, regardless of the financial sophistication of any or all of their clients. Conversely, ''Exempt Reporting Advisers'' have limited reporting requirements with the SEC under the IAA, but otherwise are not required to register, and therefore, are not required to comply with the disclosure requirements imposed on registered investment advisers. *See* 15 U.S.C. 80b–3(*l*) and (m) (providing registration exemptions for advisers to venture capital funds and certain advisers to private funds).

[58] The Commission notes here its belief and understanding that the current applicable requirement that any information in QEP Disclosures a CPO or CTA decides to provide is, ''in the context in which it is furnished, not misleading'' is fundamentally different and a much lower standard than the proposed requirement that QEP Disclosures be generally required and regularly updated so that they remain ''materially accurate and complete.''

[59] *See, e.g.,* 17 CFR 4.26(d).

standard than that imposed on non-required promotional material under Regulation 4.41.[60] In particular, the Commission believes that, if adopted, these amendments would permit it and NFA to monitor and assess the accuracy of distributed QEP Disclosures, as compared to a CPO's or CTA's actual trading activities, via existing examination processes, as well as through comparison to information these intermediaries regularly provide in other filings, like Forms CPO–PQR and/or CTA–PR. Having the ability to review QEP Disclosures during routine examinations, combined with an affirmative requirement that CPOs and CTAs provide information that is materially complete, accurate and up-to-date, would, in the Commission's preliminary opinion, provide the CFTC and NFA with an additional level of oversight that simply does not exist under the current regulatory framework. Moreover, the Commission further preliminarily believes that QEP Disclosures would likely qualitatively improve over time, should these proposed amendments be adopted, by virtue of the QEP Disclosures being regularly examined and/or reviewed by Commission and NFA staff possessing the unique, deep subject matter expertise with respect to commodity interests that other Federal agencies simply do not and are not reasonably expected to possess.

Among the existing disclosures outlined in part 4 for registered CPOs and CTAs not claiming Regulation 4.7, the Commission believes that both the general disclosures, as described in Regulations 4.24 and 4.34, and performance disclosures, as described in Regulations 4.25 and 4.35, form the foundational level of information about a pool's or advisory program's trading strategies, material risks, fees, and conflicts associated therewith; furthermore, the Commission preliminarily believes that disclosure by a CPO or CTA is the primary source of information a prospective or actual participant or client would rely upon to make an appropriately informed investment decision, even for those financially sophisticated persons who are QEPs. Specifically, the subset of general disclosures listed in Regulations 4.24 and 4.34 that the Commission is proposing to now be required for 4.7 pools and trading programs would provide prospective QEP pool participants and clients with important information on principal risk factors, investment programs, use of proceeds, custodians, fees and expenses, and conflicts of interest. The subset of performance disclosures from Regulations 4.25 and 4.35 that the Commission is proposing to require would further involve the presentation of vital current and past performance metrics in a format consistent with that already developed for non-QEP pool participants and advisory clients. Combined, the Commission intends the proposed addition of these disclosures to Regulation 4.7 to both provide appropriate customer protection safeguards and to support its intermediary oversight through methods that have been assessed and further developed since their adoption, nearly thirty years ago.[61]

The Commission requests comment on all aspects of the proposed amendments outlined below that would require certain information be disclosed to prospective QEP pool participants and advisory clients under Regulation 4.7, that QEP Disclosures are regularly updated and materially complete, and that they be included in the business records of CPOs and CTAs claiming Regulation 4.7 exemptions. In addition, the Commission seeks comment on the following questions:

1. Should the Commission increase or decrease the types of information included in Proposed Regulations 4.7(b)(2) and (c)(1)? In particular, should additional disclosure requirements listed in Regulations 4.24 and 4.34 be included for CPOs and CTAs, respectively? If so, what disclosures?

2. The Commission is seeking specific data or information regarding: (i) the current number of CPOs and CTAs utilizing Regulation 4.7 that provide the proposed minimum disclosures to their QEP participants and clients; (ii) the level of disclosure currently provided by CPOs and CTAs to their QEP participants and clients; (iii) if disclosures are provided, the general format, tenor, and manner used in both structuring and delivering the disclosures; and (iv) the context and timing of when any such disclosures are provided (*e.g.,* whether during solicitation or otherwise during the course of the investment relationship).

3. What specific challenges would CPOs and CTAs face in complying with the disclosure requirements in Proposed Regulations 4.7(b)(2) and (c)(1)? Should the Commission consider an implementation period for the proposed amendments, and if so, how much time should the Commission allow for CPOs and CTAs to develop and prepare QEP Disclosures that would comply with the proposed amendments?

The following sections explain the proposed amendments in more detail.

i. Proposed Amendments to Regulations 4.7(b)(2) and (b)(5)

The Commission is proposing to amend the disclosure relief outlined in Regulations 4.7(b)(2)(i) and (ii) to require CPOs to deliver to their 4.7 pools' prospective participants QEP Disclosures that enumerate certain specific disclosures, including descriptions of the 4.7 pool's principal risk factors, its investment program, use of proceeds, custodians, fees and expenses, conflicts of interest, and certain performance disclosures, including basic past performance information. As a consequence of requiring these minimum disclosures for 4.7 pools, the Commission is also proposing a corresponding amendment to remove the exemption from disclosing the past performance of 4.7 pools in the Disclosure Documents of non-4.7 pools. That provision had been proposed and adopted ''in connection with'' the previous policy position that 4.7 pools had no minimum or mandatory disclosure requirements,[62] which the Commission, as just discussed, now seeks to change through the amendments in this NPRM; the Commission further preliminarily believes such information would be valuable to commodity pool participants of all types. Finally, the Commission proposes to amend Regulation 4.7(b)(5) to additionally require that CPOs maintain such QEP Disclosures among the other books and records of their 4.7 pools, and made available upon request to the Commission, NFA, and the U.S. Department of Justice, in accordance with Regulation 1.31.[63]

As proposed, Regulation 4.7(b)(2)(i) would no longer provide an exemption from Regulation 4.21, and instead of requiring compliance with Regulations

[60] 17 CFR 4.41.

[61] The Commission notes that it developed these part 4 required disclosures originally in response to changing market conditions and to implement its statutory mandates in regulating and overseeing CPO and CTA activities. In fact, in the final rule establishing the initial requirements under Regulations 4.24, 4.25, 4.34, and 4.35, the Commission explicitly highlighted that, since the adoption of the part 4 framework, the number of registered CPOs had more than doubled and the number of CTAs had increased threefold; assets under the management of CPOs had grown dramatically; and the range of available futures and option contracts had increased substantially. 60 FR 38147 (July 25, 1995) (1995 Final Rule). This justification, cited in 1995, is arguably even more relevant to today's CPO and CTA population using Regulation 4.7 because the growth of that specific category of intermediaries and that sector of the commodity interest markets has continued significantly since the 1995 Final Rule.

[62] 1992 Proposed Rule, 57 FR at 3151; 1992 Final Rule, 57 FR at 34858.

[63] 17 CFR 1.31.

4.24 and 4.25 in their entirety, the proposed amendments include new Regulations 4.7(b)(2)(i)(A) through (E) that enumerate the specific disclosures the Commission preliminarily believes prospective QEP pool participants should receive, and that incorporate certain subparagraphs of those part 4 disclosure regulations by reference. As mentioned above, the specific disclosures proposed to be required for 4.7 pools include: descriptions of the 4.7 pool's principal risk factors, its investment program, use of proceeds, custodians, fees and expenses, conflicts of interest, and certain performance disclosures, including past performance. Importantly, the Commission is not proposing to require that CPOs provide QEP Disclosures identical to the Disclosure Documents subject to the full panoply of requirements under Regulations 4.24 and 4.25. Rather, the Commission has specifically chosen what it believes to be the most meaningful and important information for prospective QEP pool participants, and is proposing to require that CPOs provide this information in QEP Disclosures, subject to the substance and formatting requirements of Regulations 4.24 and 4.25. The Commission is also proposing to retain, but reformat, the existing language in Regulation 4.7(b)(2)(i) into Proposed Regulations 4.7(b)(2)(i)(F) and (G). Proposed Regulation 4.7(b)(2)(i)(F) would include the requirement that QEP Disclosures provide all disclosures necessary to make the information contained therein, in the context in which it is furnished, not misleading, and Proposed Regulation 4.7(b)(2)(i)(G) would continue to require a form disclaimer like that currently required by Regulation 4.7(b)(2)(i).

Furthermore, it is crucial that QEP Disclosures used and distributed by CPOs be kept current and that they be maintained as business records to ensure compliance with the proposed general and performance disclosure requirements and to facilitate Commission and NFA oversight of these intermediaries. The Commission is therefore proposing to amend Regulation 4.7(b)(5) to require that QEP Disclosures be maintained among a CPO's other books and records for a 4.7 pool and made available to any representative of the Commission, NFA, or the U.S. Department of Justice in accordance with Regulation 1.31. This amendment would allow the Commission and NFA to review QEP Disclosures as part of routine examinations and civil enforcement actions. Finally, Proposed Regulation 4.7(b)(2)(i) no longer provides an exemption from Regulation 4.26 in its entirety; the Commission is proposing to restrict this exemption to Regulation 4.26(d) only, such that compliance with Regulations 4.26(a) through (c), provisions that generally govern the use and amendment of this information, would otherwise be required. Because the Commission is not proposing to require that QEP Disclosures for 4.7 pools be filed and approved by NFA prior to their first use, Proposed Regulation 4.7(b)(2)(i) retains an exemption from Regulation 4.26(d).

A. Principal Risk Factors

The Commission is proposing to add Proposed Regulation 4.7(b)(2)(i)(A) that would require QEP Disclosures distributed in connection with soliciting prospective participants in a 4.7 pool to include a description of the principal risk factors as required by Regulation 4.24(g). Specifically, Regulation 4.24(g) requires CPOs to describe, in their Disclosure Documents, the principal risk factors of a pool investment including, without limitation, risks relating to volatility, leverage, liquidity, counterparty creditworthiness, as applicable to the types of trading programs to be followed, trading structures to be employed and investment activity (including retail forex and swap transactions) expected to be engaged in by the offered pool.[64] Proposed Regulation 4.7(b)(2)(i)(A) would incorporate Regulation 4.24(g) by reference and would similarly require CPOs to provide a description of their 4.7 pool's principal risk factors in their QEP Disclosures.

B. Investment Program and Use of Proceeds

The Commission is also proposing to require that QEP Disclosures include the information mandated by Regulation 4.24(h), *i.e.,* a 4.7 pool's investment program, custodians, and use of proceeds. Specifically, Regulation 4.24(h) requires CPOs to disclose: (1) the types of commodity interests and other interests which the pool will trade; (2) a description of the trading and investment programs and policies that will be followed by the offered pool; (3) a summary description of the pool's major CTAs, including their respective percentage allocations of the pool assets and a description of the nature and operation of the trading programs such CTAs will follow; (4) a summary description of the pool's major investee pools or funds, including their respective percentage allocations of pool assets and a description of the nature and operation of such investee pools and funds; and (5) certain use of proceeds information, including the manner in which the pool will fulfill its margin requirements, the percentage of the pool's assets held in segregation pursuant to the CEA, and information regarding to whom income from margin or security deposits will be paid.[65] Additionally, Regulation 4.24(h)(1)(iii) requires CPOs to disclose both the types of commodity interests and other interests the pool will be trading, including the custodian or other entity (*e.g.,* bank or broker-dealer) that will hold such interests, and if such interests will be held in jurisdictions outside of the United States, the jurisdiction in which such interests or assets will be held.[66] Proposed Regulation 4.7(b)(2)(i)(B) would require QEP Disclosures to include the information described above by incorporating Regulation 4.24(h) by reference.

C. Fees and Expenses

The Commission is also proposing to require that CPOs disclose information regarding their fees and expenses for their 4.7 pools in a manner consistent with Regulation 4.24(i). Regulation 4.24(i) requires CPOs to provide a complete description of each fee, commission, and other expense, which the CPO knows or should know has been incurred by the pool for its preceding fiscal year and is expected to be incurred by the pool in its current fiscal year, including fees and other expenses incurred in connection with the pool's participation in investee pools and funds.[67] Proposed Regulation 4.7(b)(2)(i)(C) would incorporate Regulation 4.24(i) by reference and require, without limitation, the disclosure of all the fees specifically enumerated in Regulation 4.24(i), subject to the other provisions therein, including the requirement to provide, in a tabular format, an analysis setting forth how the break-even point for a 4.7 pool was calculated, including all fees, commissions, and other expenses of the 4.7 pool.

D. Conflicts of Interest

The Commission is proposing to amend Regulation 4.7(b)(2)(i) to require the disclosure of conflicts of interest in QEP Disclosures for 4.7 pools, as required by Regulation 4.24(j). Regulation 4.24(j) requires CPOs to provide a full description of any actual or potential conflicts of interest

[64] 17 CFR 4.24(g).

[65] 17 CFR 4.24(h).

[66] 17 CFR 4.24(h)(1)(iii).

[67] 17 CFR 4.24(i)(1).

regarding any aspect of the pool on the part of: (1) the CPO; (2) the pool's trading manager, if any; (3) any major CTA; (4) the CPO of any major investee pool; (5) any principal of the foregoing; and (6) any other person providing services to the pool, soliciting participants for the pool, acting as a counterparty to the pool's retail forex or swap transactions, or acting as a swap dealer with respect to the pool.[68] Additionally, Regulation 4.24(j) requires the disclosure of any other material conflict involving the offered pool, as well as a description of any arrangements described in Regulation 4.24(j)(3).[69] Proposed Regulation 4.7(b)(2)(i)(D) would incorporate Regulation 4.24(j) by reference, requiring comparable disclosure of these conflicts of interest by CPOs with respect to their 4.7 pools.

E. Past Performance of 4.7 Pools

The Commission is further proposing to require CPOs to disclose certain performance information as required by Regulation 4.25 in the QEP Disclosures for their 4.7 pools. Specifically, the Commission is proposing to partially remove the existing complete exemption from Regulation 4.25 by requiring CPOs to disclose all performance information listed under Regulation 4.25 with respect to their 4.7 pools, with the exception of performance information for pools other than the 4.7 pool. Regulation 4.25 requires CPOs to include capsule performance information for both pools and accounts, subject to certain presentation and content requirements outlined in paragraph (a) of that section.[70] Regulation 4.25(a) also provides requirements for the time period for required performance, trading programs, the calculation of and recordkeeping concerning performance information, proprietary trading results, as well as a legend for all performance disclosures, whether mandatory or voluntary, that is prominently displayed and states, ''PAST PERFORMANCE IS NOT INDICATIVE OF FUTURE RESULTS.'' [71] Among the additional requirements within Regulation 4.25, paragraph (a)(3) requires CPOs to disclose certain past performance information for pools other than the offered pool. Finally, Regulations 4.25(b) and (c) clarify and establish the required performance disclosures for offered pools that have at least a three-year operating history, and for those with less than a three-year operating history, respectively.[72] For the purposes of targeting this NPRM to requiring performance disclosures the Commission preliminarily believes are most important and valuable to prospective QEP participants, and to lessen the potential burden on CPOs resulting from incorporating minimum QEP Disclosures in Regulation 4.7, the Commission is not proposing to require that CPOs of 4.7 pools provide the disclosures referenced in paragraphs (a)(3) or (c)(2) of Regulation 4.25 regarding past performance information for pools other than the 4.7 pool in their QEP Disclosures, which the Commission preliminarily believes strikes the appropriate balance of these potentially competing interests. Therefore, Proposed Regulation 4.7(b)(2)(i) would no longer provide the specific exemption from Regulation 4.25, and the Commission is proposing to add Regulation 4.7(b)(2)(i)(E), which would require QEP Disclosures to include performance disclosures that comply with Regulation 4.25, except paragraphs (a)(3) and (c)(2) of that section.

ii. Proposed Amendments to Regulations 4.7(c)(1) and (c)(2)

Consistent with the proposed amendments regarding additional disclosures for 4.7 pools discussed above, the Commission is also proposing to specifically enumerate additional disclosure requirements for 4.7 trading programs in Regulation 4.7(c)(1). Specifically, Proposed Regulation 4.7(c)(1)(i) would no longer provide an exemption from Regulation 4.31, and, in lieu of requiring compliance with Regulations 4.34 and 4.35 in their entirety, the Commission is proposing to enumerate specific disclosure requirements it wishes to prioritize for 4.7 trading programs. Proposed Regulation 4.7(c)(1)(i) would also include new paragraphs (c)(1)(i)(A) through (F) that list the specific disclosures the Commission is proposing to require for CTAs and their 4.7 trading programs, including descriptions of certain persons to be identified, the principal risk factors of the investment, the CTA's trading program, fees, conflicts of interest, and performance disclosures. The Commission also proposes to relocate the existing disclosure requirements in current Regulation 4.7(c)(2)(i) into Proposed Regulations 4.7(c)(2)(i)(G) and 4.7(c)(2)(i)(H). Proposed Regulation 4.7(c)(2)(i)(G) continues to require that QEP Disclosures provide all additional disclosures necessary to make the information contained therein, in the context in which it is furnished, not misleading, and Proposed Regulation 4.7(c)(2)(i)(H) continues to require a form statement like that currently required by Regulation 4.7(c)(1)(i).

Additionally, the Commission is proposing to remove the exemption from disclosing past performance of 4.7 trading programs in the Disclosure Documents of non-4.7 trading programs. That provision had been proposed and adopted in connection with the previous policy position that 4.7 trading programs offered by CTAs had no minimum or mandatory disclosure requirements for their prospective QEP advisory clients, which the Commission is proposing to change through this NPRM. Moreover, the Commission preliminarily believes such information would be valuable to all prospective CTA clients, regardless of their sophistication or experience, and therefore, proposes to require more complete disclosure of a CTA's programs, whether 4.7 or not, in Disclosure Documents provided to non-QEP advisory clients.

Further, as discussed in relation to 4.7 pools above, the Commission preliminarily believes that it is crucial that QEP Disclosures used by CTAs be maintained as business records of the CTA to ensure compliance with the general and performance disclosure requirements proposed in this NPRM and to facilitate Commission and NFA oversight of these intermediaries. Therefore, the Commission is also proposing to amend Regulation 4.7(c)(2), such that CTAs would be required to maintain the QEP Disclosures among the other books and records for their 4.7 trading programs, making them available to the Commission, NFA, and the U.S. Department of Justice, in accordance with Regulation 1.31. Finally, Proposed Regulation 4.7(c)(1)(i) would also no longer provide an exemption from Regulation 4.36 in its entirety; the Commission is proposing to restrict this exemption to Regulation 4.36(d) only, such that compliance with Regulations 4.36(a) through (c), provisions that generally govern the use and amendment of this information, would be required. Because the Commission is not proposing to require that QEP

[68] 17 CFR 4.24(j).

[69] 17 CFR 4.24(j)(2) and (3). Regulation 4.24(j)(3) requires a description of the conflicts of interest of any arrangements whereby someone may benefit, directly or indirectly, from the pool's account maintenance with an FCM or RFED; from maintenance of the pool's swap positions with a swap dealer; from the introduction of the pool's account by an introducing broker to an FCM, RFED, or swap dealer; or from the investment of the pool's assets in other investee pools or funds or other investments. 17 CFR 4.24(j)(3).

[70] 17 CFR 4.25.

[71] 17 CFR 4.25(a).

[72] 17 CFR 4.25(b) and (c).

Disclosures used by CTAs for their 4.7 trading programs be filed and approved by the Commission or NFA prior to their first use, Proposed Regulation 4.7(c)(1)(i) purposefully retains an exemption from Regulation 4.36(d).

A. ''Persons To Be Identified''

The Commission is proposing to require that CTAs provide their prospective QEP clients with information on certain persons to be identified, as mandated by Regulation 4.34(e). Specifically, Regulation 4.34(e) requires CTAs to identify by name each principal of the CTA, the FCM and/or RFED with which the CTA will require its client to maintain an account, and the introducing broker through which the CTA will require the client to introduce its account (or, if the client is free to choose which FCM, RFED, or introducing broker it uses, then a statement to that effect).[73] Proposed Regulation 4.7(c)(1)(A) would incorporate Regulation 4.34(e) by reference and require CTAs offering 4.7 trading programs to identify the persons listed therein in their QEP Disclosures in the same manner as required for non-4.7 trading programs under part 4.

B. Principal Risk Factors

The Commission is proposing to require that QEP Disclosures contain a discussion of the 4.7 trading program's principal risk factors, identical to that required by Regulation 4.34(g). Regulation 4.34(g) requires CTAs to discuss in their Disclosure Documents the principal risk factors of their trading programs, including, without limitation, risks due to volatility, leverage, liquidity, and counterparty creditworthiness, as applicable to the offered trading program and the types of transactions and investment activity expected to be engaged in pursuant to such program (including retail forex and swap transactions, if any).[74] Proposed Regulation 4.7(c)(1)(i)(B) would incorporate Regulation 4.34(g) by reference, and thus require CTAs to similarly discuss in QEP Disclosures their 4.7 trading programs' principal risk factors.

C. Description of the 4.7 Trading Program

The Commission is also proposing to require CTAs to provide in their QEP Disclosures a description of the 4.7 trading program as required by Regulation 4.34(h). Regulation 4.34(h) requires CTAs to include a description of their trading programs in their Disclosure Documents; such description must include: (1) the method chosen by the CTA concerning how FCMs and/or RFEDs carrying accounts it manages treat offsetting positions pursuant to Regulation 1.46, if the method is other than to close out all offsetting positions or to close out offsetting positions on other than a first-in, first-out basis; and (2) the types of commodity interests and other interests the CTA intends to trade, with a description of any restrictions or limitations on such trading established by the CTA or otherwise.[75] Proposed Regulation 4.7(c)(1)(i)(C) would incorporate Regulation 4.34(h) by reference, and thus require CTAs to provide the same description of their 4.7 trading programs in QEP Disclosures.

D. Fees

The Commission is further proposing to require CTAs to provide in the QEP Disclosures a description of each fee they will charge QEP advisory clients, as required by Regulation 4.34(i). Regulation 4.34(i) requires CTAs to include within their Disclosure Documents a complete description of fees they will charge their clients. Pursuant to this requirement, the description must specify the dollar amount of each fee, wherever possible, and must provide additional detail and explanation of certain fees, where the fees are dependent on specifically listed base amounts, or on any increase in a client's commodity interest account.[76] Proposed Regulation 4.7(c)(1)(i)(D) would incorporate Regulation 4.34(i) by reference, and thus require CTAs offering 4.7 trading programs to provide the same description of their fees in QEP Disclosures.

E. Conflicts of Interest

With respect to conflicts of interest, the Commission is proposing to require CTAs offering 4.7 trading programs to disclose their conflicts of interest as required by Regulation 4.34(j) in their QEP Disclosures. Regulation 4.34(j) requires CTAs to include a full description of any actual or potential conflicts of interest regarding any aspect of their trading programs on the part of: (1) the CTA; (2) any FCM and/or RFED with which the client will be required to maintain its commodity interest account; (3) any introducing broker through which the client will be required to introduce its account to an FCM and/or RFED; and (4) any principal of the foregoing, within their Disclosure Documents.[77] Under Regulation 4.34(j), such description of the conflicts of interest must also include any other material conflicts involving any aspect of the offered trading programs and any certain specified direct or indirect arrangements where the CTA or any principal thereof may benefit.[78] Proposed Regulation 4.7(c)(1)(i)(E) would incorporate Regulation 4.34(j) by reference, and thus require CTAs to list and fully describe any conflicts of interest in QEP Disclosures for their 4.7 trading programs.

F. Past Performance of 4.7 Trading Programs

Finally, the Commission is also proposing to require CTAs offering 4.7 trading programs to include past performance information in their QEP Disclosures as required by Regulation 4.35. Currently, CTAs are exempt from disclosing performance information for their 4.7 trading programs. Because the Commission preliminarily believes such performance information regarding 4.7 trading programs would be valuable and provide necessary detail to prospective QEP advisory clients, the Commission is proposing to require CTAs include all performance information required under Regulation 4.35 with respect to the offered 4.7 trading program in their QEP Disclosures.

Regulation 4.35 requires CTAs to include in their Disclosure Documents capsule performance information for past performance of an account or trading program, subject to certain presentation and content requirements as outlined paragraph (a) of that section.[79] Regulation 4.35(a) also provides detailed requirements for composite presentation, how current the disclosed information must be, the time period that must be covered in the performance disclosures, the calculation of and recordkeeping concerning the disclosed performance information, disclosing the performance of partially-funded accounts, the presentation of proprietary trading results, and a mandatory legend for all performance disclosures, stating, ''PAST PERFORMANCE IS NOT NECESSARILY INDICATIVE OF FUTURE RESULTS.'' [80] Additionally, Regulation 4.35(b) provides that a CTA

[73] 17 CFR 4.34(e).

[74] 17 CFR 4.34(g).

[75] 17 CFR 4.34(h).

[76] 17 CFR 4.34(i).

[77] 17 CFR 4.34(j).

[78] Regulation 4.34(j)(3) requires a description of the conflicts of interest of any arrangements whereby the CTA or any of its principals may benefit, directly or indirectly, from the client's account maintenance with an FCM or RFED, and/or from the maintenance of the client's swap positions with a swap dealer or from the introduction of such an account through an introducing broker (such as payment for order flow or soft dollar arrangements). 17 CFR 4.34(j)(3).

[79] 17 CFR 4.35.

[80] 17 CFR 4.35(a)(3) through (9).

must disclose the actual performance of all accounts directed by the CTA and by each of its trading principals, unless the CTA or its trading principals previously have not directed any accounts; in that case, the CTA must disclose this using one of three form disclosures listed thereunder.[81] Proposed Regulation 4.7(c)(1)(i) would remove the existing exemption from Regulation 4.35, and Proposed Regulation 4.7(c)(2)(i)(F) would require QEP Disclosures to include performance information as required by Regulation 4.35 with respect to 4.7 trading programs.

c. Permitting Monthly Account Statements for Certain 4.7 Pools Consistent With Commission Exemptive Letters

Regulation 4.7(b)(3) currently provides an exemption from the requirement in Regulations 4.22(a) and (b) that CPOs provide monthly account statements containing specific information to participants in their commodity pools.[82] For 4.7 pools, CPOs are permitted to distribute account statements ''no less frequently than quarterly within 30 days after the end of the reporting period.'' [83] CPOs of 4.7 pools that are Funds of Funds [84] have reported to Commission staff that they often have difficulty complying with this quarterly account statement schedule in Regulation 4.7(b)(3). Such CPOs regularly request exemptive letters from the Commission to permit them to follow an alternate account statement schedule, explaining that they cannot control the timing of when they receive financial information from the underlying investee collective investment vehicles, which often results in the investor Fund of Funds CPO not receiving the requisite information for its own 4.7 pool reporting until the 30-day period for distribution is nearly expired. The Commission has routinely granted these exemptive letter requests, thereby permitting the requesting CPOs to distribute monthly, rather than quarterly, account statements for their 4.7 Fund of Funds pools within 45 days of the month-end.[85] This approach of providing exemptive letter relief from Regulation 4.7(b)(3) has allowed these CPOs additional time to receive and gather the information required for their account statements required by Regulation 4.7, while also ensuring that their QEP participants receive both more accurate and more frequent reporting.

Consistent with past Commission efforts to memorialize routinely granted Commission letter relief via regulatory amendments that streamline availability, provide consistency, and eliminate the need to process and respond to requests individually, the Commission proposes to amend Regulation 4.7 in a manner that would allow the CPOs of 4.7 pools that are Funds of Funds to distribute monthly account statements within 45 days of the month-end, provided that a CPO notifies its QEP pool participants, so they are aware of the schedule for the distribution of account statements. The Commission solicits comment generally on Proposed Regulation 4.7(b)(3)(iv); in particular, the Commission requests comment on whether the proposed amendment effectively creates a mechanism in Regulation 4.7(b)(3) that is equivalent to the exemptive letters currently issued by the Commission, and whether the alternate account statement distribution schedule and notice requirements are clear.

d. Other Technical Amendments

Finally, the Proposal also includes a number of technical amendments to Regulation 4.7 that are designed to improve its efficiency and usefulness for intermediaries and their prospective and actual QEP pool participants and advisory clients, as well as the general public. For example, the Commission is proposing to delete the introductory paragraph to Regulation 4.7 and to generally restructure the definitions section in Regulation 4.7(a), eliminating what it preliminarily views as unnecessary subparagraph levels in the QEP definition and alphabetizing the definitions. The Commission has also proposed amendments to ensure that cross-references within Regulation 4.7 and other part 4 regulations are accurate. The Commission is seeking comment on these and any other technical amendments that it should consider for ease of use, as well as whether there are any other cross-references within Regulation 4.7 not addressed by the Proposal that should also be corrected. The Commission intends to include additional conforming amendments correcting cross-references to Regulation 4.7 provisions found in other parts of the Commission's regulations as technical amendments in a future final rule. The Commission requests comment and public input on this approach as well.

III. Related Matters

a. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that Federal agencies, in promulgating regulations, consider whether the regulations they propose will have a significant economic impact on a substantial number of small entities, and if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities.[86] The regulatory amendments proposed by the Commission hereinwould affect only persons registered or required to be registered as CPOs and CTAs and those commodity pools and trading programs operated under Regulation 4.7 and offered solely to QEPs.

i. CPOs

The Commission has previously established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its rules on such entities in accordance with the requirements of the RFA.[87] With respect to CPOs, the Commission previously has determined that a CPO is a small entity for purposes of the RFA, only if it meets the criteria for an exemption from registration under Regulation 4.13(a)(2).[88] The regulations proposed herein apply to persons registered or required to be registered as CPOs with the Commission (specifically, those registered CPOs whose prospective and actual pool participants are restricted to QEPs) and/or provide relief to qualifying registrants from certain periodic reporting burdens. Accordingly, the Chairman, on behalf of the Commission, certifies pursuant to 5 U.S.C. 605(b) that this NPRM will not have a significant economic impact on a substantial number of small entities, with respect to CPOs.

ii. CTAs

Regarding CTAs, the Commission has previously considered whether such registrants would be deemed small entities for purposes of the RFA on a case-by-case basis, in the context of the particular Commission regulation at

[81] 17 CFR 4.35(b).

[82] 17 CFR 4.7(b)(3), 4.22(a) and (b).

[83] 17 CFR 4.7(b)(3)(i); cf. 17 CFR 4.22(a) and (b).

[84] *See supra* n. 42 (defining ''Funds of Funds'').

[85] *See, e.g.,* CFTC Letters 18–29, 19–01, 19–03, 20–11, 21–16, 23–04.

[86] 5 U.S.C. 601, *et seq.*

[87] *See, e.g.,* Policy Statement and Establishment of Definitions of ''Small Entities'' for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18620 (Apr. 30, 1982).

[88] *Id.* at 18619–20. Regulation 4.13(a)(2) exempts a person from registration as a CPO when: (1) none of the pools operated by that person has more than 15 participants at any time, and (2) when excluding certain sources of funding, the total gross capital contributions the person receives for units of participation in all of the pools it operates or intends to operate do not, in the aggregate, exceed $400,000. *See* 17 CFR 4.13(a)(2).

issue.[89] Because certain of these registered CTAs may besmall entities for the purposes of the RFA, the Commission is considering whether this Proposal would have a significant economic impact on such registrants.

The portions of this NPRM directly impacting CTAs would affect only CTAs registered or required to register with the Commission that offer and operate trading programs designed for QEPs. These proposed amendments would, in particular: (1) require CTAs claiming the Regulation 4.7 exemption to provide certain general and performance disclosures enumerated in other part 4 regulations regarding their 4.7 trading programs to their prospective and current QEP advisory clients; (2) require such CTAs to include past performance information for their 4.7 trading programs in any Disclosure Documents they use and distribute for their non-4.7 trading programs' advisory clients; and (3) require such registered CTAs to retain the proposed limited QEP Disclosures regarding their 4.7 trading programs as business records of the intermediary. As stated above, these proposed requirements primarily impact registered CTAs offering 4.7 trading programs to QEP advisory clients and claiming the compliance exemptions currently offered by Regulation 4.7. Although data on the specific size of registered CTAs offering 4.7 trading programs is limited, it is the Commission's anecdotal experience that such CTAs claiming compliance exemptions in Regulation 4.7 for the purposes of soliciting and serving QEP advisory clients are frequently large financial institutions with substantial financial assets and advisory experience, or affiliates thereof. Given that registered CTAs do not have a capital requirement applicable to them, it is not possible for the Commission to readily determine the typical or average size of registered CTAs, or even of registered CTAs who solely offer 4.7 trading programs; moreover, registered CTAs frequently offer a mix of 4.7 trading programs and trading programs or strategies subject to the full application of the Commission's part 4 regulations. Therefore, although the Commission has previously determined whether CTAs are small entities for RFA purposes on a case-by-case basis, the Commission is not currently in a position to determine whether registered CTAs affected by this NPRM would include a substantial number of small entities, on which the NPRM would have a significant economic impact. Therefore, pursuant to 5 U.S.C. 603, the Commission offers for public comment this initial regulatory flexibility analysis addressing the impact of the Proposal on small entities:

A. A description of the reasons why action by the agency is being considered.

As discussed in detail above in this Preamble, since the 1992 Final Rule adopting Regulation 4.7, the Commission has witnessed substantial increases in the intermediary population utilizing those exemptions for 4.7 pools and trading programs offered and available to QEPs. This development also coincides with current commodity interest market conditions, in which the Commission has also seen significant expansion and growth in the complexity and diversity of commodity interest products offered via 4.7 pools and trading programs, which may be more challenging to fully understand. Given further that QEPs, for a variety of reasons, may have varying levels of resources and leverage to demand and monitor the information necessary for them to make informed investment decisions, the Commission believes it is no longer appropriate to rely solely on QEPs' individual ability to obtain such information, absent formal regulatory requirements that such information be provided.

B. A succinct statement of the objectives of, and legal basis for, the Proposal.

The objective of these proposed amendments is to establish minimum disclosure requirements applicable to all CTAs offering 4.7 trading programs, replacing the current *ad hoc* methods of informing QEPs that have developed over time, and leveling the playing field amongst QEP advisory clients who may currently receive varying levels of investment information dependent upon their size and available resources. The proposed amendments are also intended to raise the quality and consistency of QEP Disclosures provided by registered CTAs by requiring them to be materially complete, accurate, and subject to regular updates by the CTA, and to enable the consistent review of such QEP Disclosures by the Commission or NFA through regular examinations of registered CTAs' business records. As stated above, the CEA grants the Commission the authority to regulate and register CTAs, as well as to require the maintenance of books and records and filing of reports that the Commission believes is necessary to accomplish its regulatory mission and the goals of the CEA.[90]

C. A description of and, where feasible, an estimate of the number of small entities to which the Proposal would apply.

As mentioned above, CTAs are generally not subject to any minimum capital requirements, nor does the Commission collect data on the ''size'' of registered CTAs via Commission registration applications or other required Commission filings or reports. Therefore, the Commission has no data to analyze that would enable it to estimate how many registered CTAs[91] may be considered small entities for RFA purposes. It is the Commission's experience that registered CTAs claiming Regulation 4.7 exemptions and offering 4.7 trading programs to QEP advisory clients are frequently large financial institutions offering a variety of trading programs and strategies. Nonetheless, the Commission acknowledges that a certain percentage or portion of the population of CTAs affected by this Proposal, *i.e.,* those registered or required to register with the Commission and utilizing the exemptions in Regulation 4.7, may, in fact, be considered small entities as defined by the RFA, though the Commission lacks the information or data necessary to determine or estimate how many.

D. A description of the projected reporting, recordkeeping, and other compliance requirements of the Proposal, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

The proposed amendments would require CTAs registered and claiming the exemption in Regulation 4.7(c)(1) to provide certain general and performance disclosures regarding their 4.7 trading programs to prospective and current QEP advisory clients, to ensure that the information provided is materially complete and accurate, and to periodically update such information as needed. As noted above, the proposed amendments would, in particular: (1) require CTAs relying on the Regulation 4.7 exemption to provide certain general and performance disclosures enumerated in other part 4 regulations regarding their 4.7 trading programs to their prospective and current QEP advisory clients; (2) require such CTAs to include past performance information for their 4.7 trading programs in the Disclosure Documents they use and distribute for their non-4.7 trading programs; and (3) require such

[89] *Id.* at 18620.

[90] 7 U.S.C. 6m, 6n.

[91] As of June 2023, there were approximately 1,280 CTAs registered with the Commission.

registered CTAs to retain the proposed QEP Disclosures regarding their 4.7 trading programs as business records of the intermediary. The Commission expects that some CTAs may already be disclosing some of this information, via the existing *ad hoc* industry practices that have developed for QEP Disclosures like private placement memoranda and trading program brochures, as discussed above. Additionally, the proposed amendments would require registered CTAs to provide past performance information regarding their 4.7 trading programs in the Disclosure Documents of other trading programs they operate that are subject to broader part 4 compliance. Finally, CTAs offering 4.7 trading programs would be required to keep their QEP Disclosures containing the information the Commission proposes to require as business records, subject to routine examination and inspection by the Commission and/or NFA.

The Commission anticipates that the proposed amendments would affect registered CTAs claiming Regulation 4.7 and offering 4.7 trading programs, which, as stated above, may include some small entities for RFA purposes. Nonetheless, regardless of whether a CTA is considered a small entity, the Commission believes that all registered CTAs offering and managing 4.7 trading programs generally possess the professional skills necessary to generate and distribute the subset of disclosures proposed to be required and to appropriately retain such QEP Disclosures as business records of their registered intermediary, *i.e.,* the CTA, as such skills are not significantly different from those already necessary to establish, register, and operate a CTA subject to the broader part 4 compliance requirements beyond Regulation 4.7.

E. An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the Proposal.

The Commission is generally unaware of any Federal rules or regulations which may conflict with the proposed amendments. Federal securities laws and regulations do govern investment disclosures by registered investment advisers, which may result in those entities that are dually registered with the SEC and CFTC being subject to more than one regulatory regime. The Commission does not expect the proposed amendments to conflict with those laws and regulations, based on its understanding of those disclosure requirements. Moreover, some 4.7 CTAs are registered only with the Commission and thus, are not currently subject to any other regulations mandating disclosures to their QEP advisory clients.

F. A description of any significant alternatives to the Proposal which accomplish the stated objectives of applicable statutes and which minimize significant economic impact of the Proposal on small entities.

Potential alternatives to the proposed amendments would be: (1) to not amend Regulation 4.7 to add disclosure requirements for 4.7 trading programs; or (2) to amend Regulation 4.7(c)(1) to require compliance with the entirety of the disclosure regulations generally applicable to registered CTAs offering trading programs to non-QEP advisory clients. Additionally, the Commission could also consider limiting the application of the proposed amendments to registered CTAs claiming Regulation 4.7 and offering 4.7 trading programs to those CTAs who are not small entities for RFA purposes.

The Commission believes that there have been significant developments in the commodity interest markets since Regulation 4.7 was adopted in 1992. Based on current market conditions and the increasing complexity of commodity interest products, among other factors, the Commission preliminarily believes it necessary to establish minimum disclosures for CTAs offering 4.7 trading programs at this time. Although declining to require any disclosures would certainly minimize the economic impact on registered CTAs that are also small entities, the Commission believes that, due to the circumstances explained above, including the varying resources available to QEPs to independently demand and assess the accuracy of such disclosures, certain information should be required to be disclosed to all QEP advisory clients, in furtherance of the Commission's regulatory goals and the purposes of the CEA. Additionally, the Commission believes it would be overly burdensome if registered CTAs offering 4.7 trading programs were required to comply with the entirety of Regulations 4.34 and 4.35, and to comply with the review and filing requirements in Regulation 4.36, given the characteristics of their advisory clients. Through these proposed amendments, the Commission is seeking to balance its customer protection and regulatory concerns for QEP advisory clients and 4.7 trading programs with the existing compliance burdens of registered CTAs. Thus, the proposed amendments prioritize and require certain disclosures, while providing relief from others, and permit CTAs to use and distribute QEP Disclosures containing that information without filing or advance review by the Commission or NFA, provided that they are complete, accurate, and kept as business records of the CTA. In the Commission's opinion, the proposed amendments offer a more tailored approach to QEP Disclosure requirements applicable to CTAs' 4.7 trading programs and would have less of an economic impact on CTAs claiming Regulation 4.7 than requiring compliance with the entirety of the part 4 disclosure requirements.

Finally, as stated above, CTAs are generally not subject to capital requirements under the Commission's regulatory regime, and CTAs manage the assets of their advisory clients, whether QEPs or not, without receiving or taking custody of those assets, due to the statutory and regulatory provisions defining the permitted activities of CTAs. The Commission also does not collect data on the size of CTAs registered or required to register with it, beyond their assets under management, and it would be difficult to determine or estimate the number of registered CTAs that may be considered small entities for RFA purposes. Therefore, the Commission is unable to limit the application of the proposed amendments to CTAs offering 4.7 trading programs who are not small entities for RFA purposes, though anecdotally the Commission believes that the majority of CTAs utilizing Regulation 4.7 would not be considered small entities. As noted earlier, regardless of whether a CTA is considered a small entity, the Commission believes that all registered CTAs offering and managing 4.7 trading programs generally possess the resources and know-how necessary to generate and distribute the subset of disclosures proposed to be required and to appropriately retain such QEP Disclosures as business records of their registered intermediary.

To the extent the proposed amendments may apply to an unknown number of small entities who are registered CTAs offering 4.7 trading programs, the Commission believes that its customer protection and oversight concerns under the CEA in ensuring that QEP advisory clients are adequately and consistently informed regarding 4.7 trading programs, and that the Commission can effectively oversee the activities of all CTAs claiming exemptions under Regulation 4.7, nevertheless outweigh that concern. The Commission understands that the direct effect of these proposed amendments would be an increase in the operating costs of CTAs utilizing Regulation 4.7, due to the addition of minimum content, dissemination, and recordkeeping requirements for QEP

Disclosures. The Commission also understands, however, that some of the information proposed to be required is similar in content to information many CTAs are already providing based on the demands of their QEP advisory clients, or because they are required to provide them by other applicable regulatory regimes. Notwithstanding these additional operating costs, the Commission preliminarily believes that mandating the provision of certain foundational information to all QEPs, which the proposed amendments would require to be kept up-to-date and accurate, is expected to result in more consistent disclosures to all persons gaining exposure to the commodity interest markets through registered CTAs, which may include small entities for RFA purposes. The Commission preliminarily concludes that the proposed amendments would result in better informed QEP advisory clients, who may, as a result of consistent, detailed disclosures, possess enhanced confidence in their intermediaries and the commodity interest markets overall, by virtue of their increased understanding of the nature of the advisory services they are procuring. The Commission therefore believes that the QEP Disclosures proposed in this NPRM would benefit both the CTAs and their QEP advisory clients by requiring certain general and performance disclosures, thereby promoting transparency and consistency, as well as increasing confidence in the CTAs and the commodity interest markets overall.

Therefore, in comparing the aforementioned alternatives of (1) not amending Regulation 4.7 to impose disclosure requirements for 4.7 trading programs, and (2) amending Regulation 4.7(c)(1) to require compliance with the entirety of the disclosure regulations generally applicable to registered CTAs offering trading programs to non-QEP advisory clients, the Commission believes that the proposed minimum disclosure requirements strike an appropriate balance that achieves the Commission's regulatory objectives without burdening the small entity population of CTAs offering 4.7 trading programs with the compliance costs and burdens that would be associated with the full disclosure regime required under part 4.

b. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) [92] imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any ''collection of information,'' as defined by the PRA. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number from the Office of Management and Budget (OMB).[93] The PRA is intended, in part, to minimize the paperwork burden created for individuals, businesses, and other persons as a result of the collection of information by Federal agencies, and to ensure the greatest possible benefit and utility of information created, collected, maintained, used, shared, and disseminated by or for the Federal Government.[94] The PRA applies to all information, regardless of form or format, whenever the Federal Government is obtaining, causing to be obtained, or soliciting information, and includes required disclosure to third parties or the public, of facts or opinions, when the information collection calls for answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons.[95]

This NPRM, if adopted, would result in a collection of information within the meaning of the PRA, as discussed below. The Proposal affects a collection of information for which the Commission has previously received a control number from OMB. The title for this collection is, ''Rules Relating to the Operations and Activities of Commodity Pool Operators and Commodity Trading Advisors and to Monthly Reporting by Futures Commission Merchants'' (Collection 3038–0005).[96] Collection 3038–0005 primarily accounts for the burden associated with the Commission's part 4 regulations that concern compliance generally applicable to CPOs and CTAs, as well as certain exemptions from registration as such and exclusions from those definitions, and available relief from compliance with certain regulatory requirements, *e.g.,* Regulation 4.7.

The Commission is therefore submitting this NPRM to OMB for review.[97] Responses to this collection of information would be mandatory. The Commission will protect any proprietary information according to FOIA and part 145 of the Commission's regulations.[98] In addition, CEA section 8(a)(1) strictly prohibits the Commission, unless specifically authorized by the CEA, from making public any ''data and information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers.'' [99] Finally, the Commission is also required to protect certain information contained in a government system of records according to the Privacy Act of 1974.[100]

i. Collection 3038–0005: Revisions to the Collection of Information

Collection 3038–0005 governs responses made pursuant to part 4 of the Commission's regulations, pertaining to the operations of CPOs and CTAs, including the itemization of compliance burdens remaining after CPOs and CTAs elect certain exemptions from broader compliance obligations in the part 4 regulations. The Commission is proposing to amend Collection 3038–0005 to account for the amendments proposed in this NPRM, as follows: (a) adding reporting burdens for the proposed required general and performance disclosures to prospective or actual QEP pool participants and advisory clients by CPOs and CTAs, pursuant to the proposed amendments to Regulations 4.7(b)(2) and (c)(1); (b) increasing the existing recordkeeping requirements of Regulations 4.7(b)(5) and (c)(2) to include the proposed maintenance of QEP Disclosures as business records by CPOs and CTAs utilizing Regulation 4.7; and (c) adding monthly account statements as a permissible reporting schedule by CPOs of 4.7 pools that are Funds of Funds through Proposed Regulation 4.7(b)(3)(iv). In addition, and more generally, the Commission is proposing to update its estimates of the number of respondents subject to the information collection requirements under Regulation 4.7, such that they are better aligned with more recent NFA data provided to the Commission on the number of CPOs (and pools) and CTAs subject to those requirements. Accordingly, the Commission proposes to revise Collection 3038–0005 to address the reporting and recordkeeping burdens associated with these proposed amendments as described in further detail below.

[92] 5 U.S.C. 601, *et seq.*

[93] *See* 44 U.S.C. 3507(a)(3); 5 CFR 1320.5(a)(3).

[94] *See* 44 U.S.C. 3501.

[95] *See* 44 U.S.C. 3502(3).

[96] *See* Notice of Office of Management and Budget Action, OMB Control No. 3038–0005, *available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202011-3038-006* (last visited Sept. 27, 2023).

[97] *See* 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[98] *See* 5 U.S.C. 552; *see also* 17 CFR part 145 (Commission Records and Information).

[99] 7 U.S.C. 12(a)(1).

[100] 5 U.S.C. 552a.

A. Proposed Amendments Affecting CPOs

As stated above, Regulation 4.7 currently provides exemptions from the broader part 4 compliance requirements, and Regulation 4.7(b)(2), in particular, provides exemptions for CPOs with respect to 4.7 pools offered solely to QEPs from the requirements of Regulations 4.21, 4.24, 4.25, and 4.26, under certain additional conditions further specified in the regulation.[101] As a result, Collection 3038–0005 does not currently include any reporting burden with respect to Regulation 4.7(b)(2). Proposed Regulation 4.7(b)(2), if adopted, however, would result in additional reporting burdens for CPOs offering and operating 4.7 pools because certain general and performance disclosures would become required for their prospective and actual QEP pool participants. Therefore, the Commission is proposing to amend Collection 3038–0005 in a manner that accounts for the additional reporting burden associated with Proposed Regulation 4.7(b)(2). To that end, the Commission has endeavored to add reporting burden for this proposed amendment that is based upon the burden already itemized in Collection 3038–0005 for compliance with Regulations 4.21/4.26, but that is proportionate to the more limited scope of disclosures the Commission is proposing to require from CPOs with respect to their 4.7 pools. Accordingly, the aggregate annual estimate for the reporting burden associated with Proposed Regulation 4.7(b)(2) would be as follows:

Estimated number of respondents: 1,000.

Estimated frequency/timing of responses: At least annually, or as-needed.

Estimated number of annual responses per respondent: 5.

Estimated number of annual responses for all respondents: 5,000.

Estimated annual burden hours per response: 1.5.

Estimated total annual burden hours per respondent: 7.5.

Estimated total annual burden hours for all respondents: 7,500.

Additionally, this NPRM proposes to amend Regulation 4.7(b)(5) to require that CPOs retain the QEP Disclosures they use and distribute to their prospective and actual QEP pool participants as business records of the CPO. Collection 3038–0005 currently contains a recordkeeping burden associated with Regulation 4.7(b)(5) which estimates that each CPO expends approximately 2 hours maintaining business records related to its 4.7 pool(s), as that provision requires. The Commission recommends an increase of 0.5 hours to this existing burden, to account for the additional burden of retaining the QEP Disclosures as CPO business records, and estimates that the respondents include 1,000 CPOs each operating up to five 4.7 pools. Accordingly, the aggregate annual estimate for the recordkeeping burden associated with Proposed Regulation 4.7(b)(5) would be as follows:

Estimated number of respondents: 1,000.

Estimated frequency/timing of responses: Annual.

Estimated number of annual responses per respondent: 5.

Estimated number of annual responses for all respondents: 5,000.

Estimated annual burden hours per response: 2.5.

Estimated total annual burden hours per respondent: 12.5.

Estimated total annual burden hours for all respondents: 12,500.

Finally, the Commission is also proposing amendments to Regulation 4.7(b)(3) that would, consistent with routinely issued Commission exemptive letters, permit CPOs of 4.7 pools that are Funds of Funds to distribute monthly account statements within 45 days of the month-end.[102] Collection 3038–0005 currently lists a reporting burden associated with Regulation 4.7(b)(3) that accounts for the quarterly account statements currently required to be distributed by such CPOs to their 4.7 pools' QEP participants. The Commission is proposing to add an additional reporting burden associated with Proposed Regulation 4.7(b)(3)(iv), the provision that, if adopted, would add this monthly reporting as an option for 4.7 pools that are Funds of Funds. The Commission believes that a smaller subset of CPOs and 4.7 pools would rely on this reporting schedule, and therefore, burden estimates below are based on 100 CPOs utilizing this alternative monthly account statement schedule for up to three 4.7 pools each. Accordingly, the aggregate annual estimate for the reporting burden associated with Proposed Regulation 4.7(b)(3)(iv) would be as follows:

Estimated number of respondents: 100.

Estimated frequency/timing of responses: Monthly.

Estimated number of annual responses per respondent: 36.

Estimated number of annual responses for all respondents: 3,600.

Estimated annual burden hours per response: 1.

Estimated total annual burden hours per respondent: 36.

Estimated total annual burden hours for all respondents: 3,600.

B. Proposed Amendments Affecting CTAs

Similar to Regulation 4.7(b)(2), Regulation 4.7(c)(1) provides exemptions for CTAs with respect to their 4.7 trading programs offered to QEPs from Regulations 4.31, 4.34, 4.35, and 4.36, subject to additional conditions specified in that regulation.[103] Consequently, Collection 3038–0005 does not currently include any reporting burden associated with Regulation 4.7(c)(1). Proposed Regulation 4.7(c)(1), if adopted, would result in CTAs incurring additional burden because certain general and performance disclosures with respect to their 4.7 trading programs would be required to be distributed to their prospective and actual QEP advisory clients. Therefore, the Commission is proposing to amend Collection 3038–0005 in a manner that would account for the additional reporting burden associated with Proposed Regulation 4.7(c)(1). To that end, the Commission has endeavored to add reporting burden for this proposed amendment that is based upon the burden already itemized in this information collection for compliance with Regulations 4.31/4.36, but that is proportionate to the more limited scope of disclosures the Commission is proposing to require from CTAs with respect to their 4.7 trading programs. Accordingly, the aggregate annual estimate for the reporting burden associated with Proposed Regulation 4.7(c)(1) would be as follows:

Estimated number of respondents: 1,000.

Estimated frequency/timing of responses: At least annually, or as-needed.

Estimated number of annual responses per respondent: 12.

Estimated number of annual responses for all respondents: 12,000.

Estimated annual burden hours per response: 1.5.

Estimated total annual burden hours per respondent: 18.

Estimated total annual burden hours for all respondents: 18,000.

Additionally, this NPRM proposes to amend Regulation 4.7(c)(2) to require that CTAs retain the QEP Disclosures they use and distribute to their

[101] *See supra* Section II.b for additional discussion of these regulations.

[102] *See supra* Section II.c for additional discussion of this proposed amendment.

[103] *See supra* Section II.b for additional discussion of these regulations.

prospective and actual QEP advisory clients as business records of the CTA. Collection 3038–0005 currently contains a recordkeeping burden associated with Regulation 4.7(c)(2) which estimates that each CTA expends approximately 2 hours maintaining business records related to its 4.7 trading program(s), as that provision requires. The Commission recommends an increase of 0.5 hours to account for the additional burden of retaining QEP Disclosures as business records of the CTA, and estimates that the respondents include 1,000 CTAs offering and operating up to 12 4.7 trading programs each. Accordingly, the aggregate annual estimate for the recordkeeping burden associated with Proposed Regulation 4.7(c)(2) would be as follows:

Estimated number of respondents: 1,000.

Estimated frequency/timing of responses: Annual.

Estimated number of annual responses per respondent: 12.

Estimated number of annual responses for all respondents: 12,000.

Estimated annual burden hours per response: 2.5.

Estimated total annual burden hours per respondent: 30.

Estimated total annual burden hours for all respondents: 30,000.

e. Request for Comment

The Commission invites the public and other Federal agencies to comment on any aspect of the proposed information collection requirements discussed above. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comment in order to (1) evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the estimated burden of the proposed information collection requirements, including the degree to which the methodology and assumptions the Commission employed were valid; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information proposed to be collected; and (4) minimize the burden of the proposed collections of information on those who are required to respond, *i.e.,* CPOs and CTAs, including through the use of appropriate automated, electronic, mechanical, or other technological information collection techniques.

The public and other Federal agencies may submit comments directly to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Desk Officer of the Commodity Futures Trading Commission, by fax at (202) 395–6566, or by email at *OIRAsubmissions@omb.eop.gov.* Please provide the Commission with a copy of submitted documents, so that all comments can be summarized and addressed in the final rule preamble. Refer to the **ADDRESSES** section of this NPRM for comment submission instructions to the Commission. A copy of the supporting statements for the collections of information discussed above may be obtained by visiting *https://www.RegInfo.gov.* OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of receiving full consideration if OMB (and the Commission) receives it within 30 days of the publication of this document. Nothing in the foregoing affects the deadline enumerated above for public comment to the Commission on the proposed regulations.

c. Cost-Benefit Considerations

i. Statutory and Regulatory Background

Section 15(a) [104] of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders. CEA section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

The Commission recognizes that the proposed amendments to Regulation 4.7 in this NPRM will result in additional costs for CPOs and CTAs operating 4.7 pools and trading programs. However, the Commission lacks the data necessary to reasonably quantify all of the costs and benefits considered below. Additionally, any initial and recurring compliance costs for any particular CPO or CTA will depend on its size, existing infrastructure, practices, and cost structures. The Commission welcomes comments on such costs, particularly from existing CPOs and CTAs utilizing Regulation 4.7 exemptions, who may be better able to provide quantitative cost data or estimates, based on their respective experiences. Commenters may also suggest other alternative(s) to the proposed approach that would be expected to further the Commission's stated policy and regulatory goals as described in this NPRM.

The Commission is also including a number of questions herein for the purpose of eliciting direct cost estimates from public commenters wherever possible. Quantifying other costs and benefits, such as the effects of potential induced changes in the behavior of CPOs, CTAs, and their QEPs resulting from the proposed amendments are inherently harder to measure *ex ante.* Thus, the Commission is similarly requesting comment through questions to help it better quantify these impacts. Due to these quantification difficulties, for this NPRM, the Commission offers the following qualitative discussion of its costs and benefits.

ii. Increasing Financial Thresholds in the Portfolio Requirement of the ''Qualified Eligible Person'' Definition

A. Baseline

As described in more detail above, the QEP definition in Regulation 4.7 outlines two categories, those that do not have to satisfy the Portfolio Requirement, listed in Regulation 4.7(a)(2), and those that do, listed in Regulation 4.7(a)(3). Persons listed in Regulation 4.7(a)(3), including natural persons who must also be considered ''accredited investors,'' must meet the Portfolio Requirement by either: (1) owning securities and other assets worth at least $2,000,000; (2) having on deposit with an FCM for their own account at least $200,000 in initial margin, option premiums, or minimum security deposits; or (3) owning a portfolio of funds and assets that, when expressed as percentages of the first two thresholds, have a combined value of at least 100%.

B. The Proposal

The Commission is proposing in this NPRM to increase the Portfolio Requirement in Regulation 4.7 such that persons listed in Regulation 4.7(a)(3) could satisfy the QEP definition by either: (1) owning securities and other assets worth at least $4,000,000; (2) having on deposit with an FCM for their own account at least $400,000 in initial margin, option premiums, or minimum security deposits; or (3) owning a portfolio of funds and assets that, when expressed as percentages of the prior two thresholds, have a combined value

[104] 7 U.S.C. 19(a).

of at least 100%. As stated previously in this release, the Commission preliminarily believes that increasing such thresholds appropriately accounts for the impacts of inflation on the Portfolio Requirement's ability to adequately address the Commission's concerns regarding the financial sophistication of QEPs required to meet its terms.

C. Benefits

The Portfolio Requirement was adopted to identify those prospective participants in the commodity interest markets that are of a size sufficient to indicate that the participant has substantial investment experience and thus a high degree of sophistication with regard to investments as well as financial resources to withstand the risk of their investments.[105] As discussed in detail above in this NPRM, these Portfolio Requirement thresholds have not been changed since their adoption in 1992. The Commission preliminarily believes that updating these thresholds would have the benefit of bringing the Portfolio Requirement back in line with the Commission's original intent when adopting the QEP definition.

The Commission understands that raising the Portfolio Requirement thresholds may cause some QEPs to no longer be so qualified, turning them into non-QEP participants in the commodity interest markets. The Commission nonetheless believes preliminarily that this proposed amendment would benefit the commodity interest markets and the general public by realigning financial thresholds in its most commonly used regulations to account for the impacts of inflation since its original adoption and to more accurately reflect the current economic reality, such that the scope of Regulation 4.7 would be more closely aligned with the Commission's original intent in the 1992 Final Rule. Additionally, to the extent that former QEPs choose to continue investing in commodity pools or allocate their funds to be managed by CTAs, such persons may then purchase participations in pools or utilize the services of CTAs not operating pursuant to Regulation 4.7. This, in turn, could result in the creation and offering of additional pools and trading programs by registered CPOs and CTAs outside of the Regulation 4.7 regime, given the potential additional demand by non-QEPs. Because more capital may, as a result, likely be deployed to such pools and trading programs subject to the full panoply of the Commission's part 4 compliance requirements, this could indirectly lead to greater transparency in the offerings of registered CPOs and CTAs, as well as improved customer protection for persons engaging with CPOs and CTAs. Moreover, if additional pools and trading programs are created for the non-QEP investing public, this would be expected to enhance the variety and vibrancy of the non-QEP pool and trading program marketplace. As a result, more options for non-QEP individuals and entities to gain access to the commodity interest markets in a manner consistent with their individual risk appetites and exposure needs would become available.

D. Costs

If the proposed amendments are adopted, CPOs that currently offer pools operated under Regulation 4.7 may no longer accept additional investment from pool participants that fall in the gap between the old and new Portfolio Requirement thresholds. Such registered CPOs and CTAs may decide to offer pools and trading programs not exempt under Regulation 4.7 that would necessarily have higher operating and compliance costs, due to the unavailability of Regulation 4.7 compliance exemptions for those investment products.

E. Questions

The Commission poses the following questions to better assess the costs and benefits of the proposed increases to the QEP definition's Portfolio Requirement in Regulation 4.7(a)(1)(v). The Commission requests further that, to the extent possible, commenters please provide quantitative bases for your responses.

1. How many QEPs would intermediaries expect to no longer be considered QEPs, if the Portfolio Requirement threshold increases are adopted?

2. How many CPOs and CTAs that currently offer pools and trading programs exclusively to QEPs have participants and clients that would no longer be QEPs under the new thresholds?

3. If the increased thresholds are adopted, will registered CPOs and CTAs form and begin offering new pools and trading programs designed for non-QEPs?

F. Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of the proposed amendments to Regulation 4.7 with respect to the following factors: protection of market participants and the public; efficiency, competitiveness, and financial integrity of markets; price discovery; sound risk management practices; and other public interest considerations. As discussed above, the proposed revision of Regulation 4.7(a)(1)(v) would increase the financial thresholds for the Portfolio Requirement in the definition of QEPs. These proposed updates to the thresholds would, in the Commission's preliminary opinion, more closely align the QEP definition with the intent of the regulation, which is to assure that offerings operated pursuant to Regulation 4.7 compliance exemptions are only made to persons with sufficient expertise and assets.

a. Protection of Market Participants and the Public

As stated above, the Commission believes preliminarily that this proposed amendment would benefit the commodity interest markets and the general public by realigning financial thresholds in its most commonly used regulations in a manner that accounts for the impacts of inflation since their original adoption and more accurately reflects current economic circumstances; the Commission expects that this would result in persons investing in commodity interest products offered by registered CPOs and CTAs being more accurately categorized as QEPs, and thus, more appropriately limited in their investment choices. Moreover, raising the Portfolio Requirement thresholds, as a practical matter, would likely limit the prospective investor population for 4.7 pools and trading programs to a smaller number of persons. To the extent persons who meet the higher Portfolio Requirement thresholds are (on average) more financially sophisticated or resilient than those who no longer qualify, this proposed amendment should result in individuals and entities, both QEPs and non-QEPs, being offered pools and trading programs that are regulated in a manner commensurate with their respective needs for customer protection. If the increased thresholds further lead to the creation of more commodity pools and trading programs subject to the full part 4 compliance requirements by registered CPOs and CTAs, this too would potentially lead to greater transparency in their activities, which also protects persons investing in commodity interest investment products. Additionally, greater variety in the commodity pools and trading programs available to non-QEPs would provide more options for this population to consider, which may further enable them to make more appropriate investment decisions by choosing the offerings best suited to

[105] 1992 Proposed Rule, 57 FR at 3152.

their individual risk appetite or other portfolio needs.

b. Efficiency, Competitiveness, and Financial Integrity of Markets

The proposed amendments to the Portfolio Requirement may also affect the size, composition, or number of commodity pools and trading programs in the commodity interest markets, especially those offered solely to QEPs. This may, in turn, affect the flow of investing in commodity interests. Financial economics literature suggests that, to the extent changing the QEP definition reduces the flow of non-commercial funds into commodity interest markets, the cost to commercial traders using futures markets to hedge their risks may increase.[106] Via this mechanism, this proposed amendment may have an indirect effect on efficiency of the futures markets with respect to the hedging costs of operating companies, commodity producers, or other commercial traders.

c. Price Discovery

The increased Portfolio Requirement thresholds are likely to result in fewer persons being considered QEPs, which may further result in fewer participants and clients in offered pools and trading programs operated under Regulation 4.7. An additional indirect effect of the proposed rule change could be a change in the flow of investment in commodity interests by non-commercial traders. The financial economics literature has found ambiguous results regarding the relationship between increased investment by non-commercial traders in commodity interest markets and price discovery.[107] As such, it is difficult to *ex ante* predict how changes in the Portfolio Requirement thresholds would impact price discovery.

d. Sound Risk Management Practices

Increasing the Portfolio Requirement thresholds may result in registered CPOs and CTAs that previously only offered pools and trading programs to QEPs creating and offering pools and trading programs designed for persons that are not QEPs. Consequently, these non-QEP pools and trading programs operated by registered CPOs and CTAs would then be subject to the full complement of part 4 compliance requirements, which could result in more diligent risk management practices by the CPOs and CTAs.

e. Other Public Interest Considerations

The original Portfolio Requirement thresholds in the QEP definition were intended to ensure that only persons possessing an appropriate and high level of trading experience, acumen, and financial resources would be eligible to invest in complex commodity interest investments offered and operated under Regulation 4.7. The Commission determined it appropriate to lessen the compliance burdens for registered CPOs and CTAs limiting their prospective participants and clients to financially sophisticated QEPs through the exemptions provided by Regulation 4.7 for their 4.7 pools and trading programs. The 1992 Portfolio Requirement thresholds were adopted to provide a metric by which CPOs and CTAs could approximately assess the experience and financial wherewithal of potential pool participants or advisory clients, ensuring that they truly possessed the sophistication and resilience of other QEPs not subject to such thresholds. Updating these thresholds to account for inflation would realign the Portfolio Requirement with the original intent of the QEP definition and modernize its provisions consistent with today's economic circumstances.

iii. Requiring Minimum Disclosures for 4.7 Pools and Trading Programs

A. Baseline

In general, registered CPOs and CTAs are required by several part 4 regulations (*i.e.,* Regulations 4.24–4.26 for CPOs and 4.34–4.36 for CTAs) to provide Disclosure Documents containing specific types of information about their commodity pools and trading programs to prospective pool participants and advisory clients; such Disclosure Documents must be filed with and reviewed and approved by NFA prior to being used and distributed. Currently, Regulation 4.7 makes available exemptions from these regulatory requirements for the 4.7 pools and trading programs of registered CPOs and CTAs. While registered CPOs and CTAs are not required to disclose any information to prospective QEP pool participants or advisory clients about their 4.7 pools or trading programs, if they do choose to provide any disclosures, Regulation 4.7 requires the CPO or CTA to include a form disclaimer and to ensure that they provide all disclosures necessary to make the information, in the context in which it is being provided, not misleading.[108]

B. The Proposal

The Proposal would narrow the existing exemptions in Regulation 4.7 by proposing to require compliance with portions of the broader disclosure requirements in part 4, thereby establishing minimum content, use, and recordkeeping requirements applicable to QEP Disclosures, and bringing the disclosure requirements for 4.7 pools and trading programs closer to those applicable to pools and trading programs offered to non-QEPs by registered CPOs and CTAs. Specifically, CPOs and CTAs utilizing Regulation 4.7 would be required by the proposed amendments to provide QEP Disclosures containing, at a minimum, the information outlined above through offering memoranda or trading program brochures delivered to their prospective QEP pool participants or advisory clients. Although the extent of information proposed to be required under Regulation 4.7 is less than that required by the part 4 regulations for non-QEP pools and trading programs, these proposed amendments represent a significant policy change from the current status quo, where Regulation 4.7 currently provides broad exemptions from the entirety of the CPO and CTA disclosure regulations. Under the Proposal, CPOs and CTAs offering and operating 4.7 pools and trading programs would be required to provide information to their prospective QEP participants and clients regarding principal risk factors, investment programs, use of proceeds, custodians, fees and expenses, conflicts of interest, and certain performance information. Importantly, the Proposal also includes amendments to Regulation 4.7 that would require that the QEP Disclosures be materially complete and accurate, be kept up-to-date through routine reviews and updated as needed to reflect any changes to a 4.7 pool or trading program, and be maintained among an intermediary's other books and records for the pool or trading program and made available to any representative of the Commission, NFA, or the U.S. Department of Justice, in accordance with Regulation 1.31.

C. Benefits

The direct effects of these proposed amendments would include greater availability and increased accuracy and reliability of the information QEPs receive prior to making their investment decisions. Mandating the provision of certain foundational information to all QEPs, which the proposed amendments would require to be kept up-to-date and accurate, is expected to result in more

[106] Goldstein and Yang, ''Commodity Financialization and Information Transmission,'' 2022, *Journal of Finance,* 77, 2613–2668.

[107] *Id.*

[108] 17 CFR 4.7(b)(2); 17 CFR 4.7(c)(1).

consistent disclosures to all persons gaining exposure to the commodity interest markets through CPOs and CTAs; better informed pool participants and advisory clients are likely to enhance market participant confidence in intermediaries and the commodity interest markets as a whole, as they better understand the nature of the services they are procuring. Moreover, the Commission preliminarily believes that this potential benefit is likely to be further bolstered by the proposed change in the material accuracy required of the QEP Disclosures. Rather than any disclosures being acceptable provided that they are, in totality, not materially misleading—meaning that material information could be permissibly omitted provided that it does not render the information that is disclosed false—the Proposal would further require that the QEP Disclosures be materially complete and accurate, which would mandate that all material information be included and be correct. This change is expected to result in more complete disclosures by CPOs and CTAs operating under Regulation 4.7, which is likely to result in a better-informed universe of market participants served by such intermediaries. Additionally, by requiring that specific topics be addressed by all CPOs and CTAs offering 4.7 pools and trading programs, QEPs could more readily compare and understand the differences between offered pools and trading programs, and as such, the Proposal could lead to better quality investment decisions by QEPs.[109]

Several aspects of the Proposal may also indirectly enhance Commission and NFA oversight of CPOs and CTAs utilizing Regulation 4.7. First, the improved ability of QEPs to more easily compare and understand critical information about 4.7 pools and trading programs offered to them may provide incentives for better governance of those commodity interest investment products by CPOs and CTAs.[110] Second, as discussed above, QEP Disclosures would be required by the Proposal to be materially complete and accurate, kept current by CPOs and CTAs, and maintained by them as business records available to the CFTC and NFA during routine examinations; these proposed amendments would likely also ensure that QEPs receive accurate information in QEP Disclosures, while also incentivizing good management and operational practices by CPOs and CTAs.

Disclosure of information about an offered 4.7 pool or trading program may also result in additional benefits inuring to QEP pool participants and advisory clients. One such benefit would be the expectation that CPOs and CTAs may seek to compete with one another to offer lower or more cost-efficient fees and expenses, or to minimize potential conflicts of interest, for the purposes of presenting more attractive and competitive investment products to prospective QEP participants and clients. This may result in CPOs and CTAs attempting to eliminate any fees and expenses extraneous to their 4.7 pools and trading programs, and/or to mitigate or resolve their conflicts of interest, each of which would benefit QEPs investing in these offerings. Additionally, by requiring the provision of standard disclosures to QEP pool participants and advisory clients, and the maintenance of such disclosures by the CPO or CTA in its books and records (which are subject to routine review by the Commission and NFA as part of their examination functions), the Commission preliminarily believes that these proposed amendments would result in higher quality disclosures on an on-going basis, even after a QEP participant or client receives information initially, due to the consistent and regular review of such QEP Disclosures by subject matter expert regulators, *i.e.,* the Commission and NFA, that this NPRM would facilitate. As previously acknowledged in this Proposal, many, if not most, CPOs and CTAs offering 4.7 pools and trading programs currently provide some level of disclosure, due to other applicable Federal statutory and regulatory requirements and/or investor demand. Given the complexity and unique nature of the commodity interest markets, especially in light of market and product developments in the past 30 years, the Commission preliminarily believes, however, that participants therein would benefit overall from the application of deep market and product expertise regarding the appropriate disclosure of risks, costs, and investing strategies for such products by the Commission and NFA to QEP Disclosures they may already regularly receive. By enabling this review of QEP Disclosures and requiring updates by CPOs and CTAs when necessary, the Commission preliminarily believes that these proposed amendments would thereby improve the quality and accuracy of QEP Disclosures, and as a result, enhance the understanding of market participants accessing the commodity interest markets through 4.7 pools and trading programs.

D. Costs

The direct effect of these proposed amendments would be an increase in the operating costs of CPOs and CTAs utilizing Regulation 4.7, due to the addition of minimum content requirements for QEP Disclosures and requirements that such information be produced, disseminated to prospective pool participants and advisory clients, updated regularly, and kept as business records of the CPO or CTA. Regarding information production, CPOs and CTAs claiming Regulation 4.7 would be required to disclose information on several important features of their 4.7 pools and trading programs relevant to expected future performance and activities of the CPO or CTA, including past performance, fees and expenses, principal risk factors, and potential conflicts of interest.

The Commission understands that some of the information proposed to be required is similar in content to information that many CPOs and CTAs are already providing based on the demands of such QEPs, or because they are otherwise required to produce such information for compliance requirements in other regulatory regimes, like that of the SEC. Additionally, though, the QEP Disclosures would also require the provision of information that CPOs and CTAs already produce to comply with other CFTC regulations. For example, CPOs are already required by Regulations 4.7(b)(3) and 4.22(a) and (b) to calculate the net asset value of 4.7 pool(s), accounting for fees, expenses, commissions, and other financial information, no less frequently than on a quarterly basis, for the purposes of producing account statements for QEP pool participants. The Proposal would also require CPOs and CTAs to provide past performance information prospectively to QEP pool participants. The Commission expects that the information required to produce a 4.7 pool's or trading program's performance

[109] Sirra and Tufano (''Costly Search and Mutual Fund Flows,'' *Journal of Finance,* 1998, 53, 1589–1622) show that investments in mutual funds are highly influenced by both past returns and fees. Although there is some disagreement in the literature regarding the reason for this relationship, Berk and van Binsbergen (''Measuring Skill in the Mutual Fund Industry'' *Journal of Financial Economics,* 2015, 118, 1–20) provide evidence that this reflects investor money flowing to more skillful managers. Although the Commission is not aware of any analogous studies for investments in commodity pools, it seems plausible that the same factors matter in commodity interest markets.

[110] For example, Del Guercio and Reuter (''Mutual Fund Performance and the Incentive to Generate Alpha,'' *Journal of Finance,* 2014, 1673–1704) show that investors who buy directly from mutual funds managers are highly responsive to funds' risk-adjusted returns.

history is already calculated by CPOs and CTAs for the purposes of providing periodic account statements, as required by other part 4 regulations.

In addition to this direct effect, the proposed disclosure requirements may affect how CPOs and CTAs operate more generally. For example, providing descriptions of 4.7 pools' and trading programs' investment program information, principal risk factors and past returns routinely may likely make such information more publicly available,[111] in turn potentially making it easier for new pools and trading programs to replicate or copy such investment plans and activities of previously formed successful ones. Although this could theoretically discourage CPOs and CTAs from developing more innovative or novel investment offerings, the Commission believes that this potential risk, however, is mitigated by the fact that the complexity, variety, and novelty of commodity interest products appear to be increasing constantly and are expected to continue to generate and propel innovation by asset managers in the future.

E. Questions

The Commission poses the following questions to better assess the costs and benefits of the proposed disclosure requirements that would be added to Regulations 4.7(b) and (c). The Commission requests further that, to the extent possible, commenters please provide quantitative bases for your responses.

1. To what extent is the information necessary to provide past performance and fees already gathered in order to provide account information under Regulations 4.7 and 4.22? What additional steps would be required to process and disseminate that information in QEP Disclosures, as required under the Proposal?

2. What are the costs of gathering and disseminating the other types of information required to be included in QEP Disclosures?

3. How will the fees and expenses charged by CPOs and CTAs for pools and trading programs operated under Regulation 4.7 be affected by the proposed disclosure requirements?

4. To what extent would CPOs' and CTAs' trading strategies be revealed in QEP Disclosures? How would such proposed disclosure requirements impact the development of such trading strategies and/or directly affect the behaviors of CPOs and CTAs utilizing Regulation 4.7?

F. Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of the proposed amendments to Regulations 4.7(b)(2), (b)(5), (c)(1), and (c)(2), with respect to the following factors: protection of market participants and the public; efficiency, competitiveness, and financial integrity of markets; price discovery; sound risk management practices; and other public interest considerations.

As discussed above, for CPOs and CTAs operating pools and trading programs under Regulations 4.7, the NPRM would narrow the existing exemptions from the part 4 disclosure regulations available under Regulations 4.7(b)(2) and (c)(1). Under the Proposal, such CPOs and CTAs would be required to provide QEP Disclosures containing information regarding past performance, fees and expenses, principal risk factors, potential conflicts of interest, and other aspects of their investments to prospective QEP pool participants and advisory clients.

a. Protection of Market Participants and the Public

These proposed amendments to Regulation 4.7 would mandate a minimum amount of transparency into pools and trading programs trading commodity interests and restricting their offerings to QEPs. This could help such QEPs protect themselves against excessive fees and self-dealing, and generally help insure that the products offered by such CPOs and CTAs are performing and being operated, as anticipated. In addition, mandating QEP Disclosures and requiring that they be materially accurate and complete, rather than just optional and not materially misleading, will benefit market participants and the public by ensuring that prospective investors would receive QEP Disclosures containing, at a minimum, certain important general and performance information that they can reliably assume is kept current and materially complete with respect to the items proposed to be required. Finally, requiring that such QEP Disclosures be maintained among CPOs' and CTAs' other books and records, and thus made available to the Commission and NFA, would allow for improved oversight of the regulated activities of CPOs and CTAs.

b. Efficiency, Competitiveness, and Financial Integrity of Markets

The proposed amendments regarding QEP Disclosures may also indirectly affect the functioning of commodity interest markets. To the extent that the proposed changes would increase transparency and affect the number or composition of pools and trading programs operated under Regulation 4.7, the NPRM might also affect the flow of investing in commodity interests. Financial economics literature suggests that, to the extent greater transparency into pools and trading programs increases the flow of non-commercial funds into commodity interest markets, that may also tend to reduce the costs to commercial traders using the futures market to hedge.[112] In that sense, the NPRM may have an indirect effect on the efficiency of the futures market in regard to the hedging costs of operating companies, commodity producers, and other commercial traders.

This increase in transparency resulting from the Proposal may also lead to QEPs having better information about fees and expenses, performance, and potential returns on their investments in 4.7 pools and trading programs, which may lead further to enhanced competition amongst CPOs and CTAs relying on Regulation 4.7. There is considerable evidence that eliminating prohibitions on price advertising, or mandating transparency of prices can lead to more ''competitive markets,'' in the sense that service providers and vendors compete to offer lower prices to consumers of their products.[113] This general trend suggests

[111] For example, the JOBS Act of 2012 required the SEC to adopt regulations that would permit the use of ''general solicitation'' and/or general advertising in private placements under its existing Regulation D. Public Law 112–106, 126 Stat. 306 (Apr. 5, 2012). As a result, the SEC adopted Regulation 506(c), which permits the use of general solicitation in Regulation D securities offerings, subject to certain conditions, including that all purchasers in the offering are accredited investors and that the issuer takes reasonable steps to verify their accredited investor status. *See also* Registration and Compliance Requirements for Commodity Pool Operators and Commodity Trading Advisors, 83 FR 52902, 52909–11 (Oct. 18, 2018); ''Eliminating the Prohibition Against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings,'' A Small Entity Compliance Guide, SEC, *available at https://www.sec.gov/info/smallbus/secg/general-solicitation-small-entity-compliance-guide.* When relying on the exemption in Regulation 506(c), offerors today may comfortably use general solicitation and advertising in their Regulation D offerings, which has led to the use of advertisements, press releases, and other broadly available publications discussing the details of this type of investment.

[112] Goldstein and Yang, ''Commodity Financialization and Information Transmission,'' 2022, *Journal of Finance,* 77, 2613–2668.

[113] Milyo and Waldfogel (''The Effect of Price Advertising on Prices: Evidence in the Wake of 44 Liquormart,'' 1999, *American Economic Review,* 89, 1081–1096) show that the removal of a ban on liquor price advertising led to decreases in the prices of advertised products, and an associated increase in quantity of sales by retailers who chose to advertise. More recently, Itern and Rigbi (''Price Transparency, Media, and Informative

that by increasing transparency of information about 4.7 pools and trading programs through requiring minimum QEP Disclosures, CPOs and CTAs may, as a result, compete to offer lower fees and expenses and more efficiently and honestly implement their investment programs, resulting in better returns for QEPs.

c. Price Discovery

As noted above, an indirect effect of the Proposal could be a change in the flow of investment into commodity interests by non-commercial traders. Financial economics literature has found ambiguous results regarding the relationship between increased investment by non-commercial traders in commodity interest markets and price discovery.[114] As such, it is difficult for the Commission to *ex ante* predict how increasing transparency in the returns, fees, etc. of pools and trading programs operating under Regulation 4.7 would impact price discovery.

d. Sound Risk Management Practices

The NPRM may also help some QEPs better manage their business risks. For example, some QEPs are insurance companies and pensions funds that have specific operational risks that may be mitigated through appropriate financial investment. The availability and provision of more accurate and complete information about 4.7 pools and trading programs, including their fees and principal risk factors, may assist such QEPs in making more appropriate and targeted investment decisions that support their operations.

As discussed above, the Proposal may also promote sound risk management by CPOs and CTAs. Specifically, requiring QEP Disclosures be maintained among CPOs' and CTAs' other books and records would allow for greater regulatory oversight of such intermediaries by the Commission and NFA. This requirement would help identify those intermediaries that lack suitable risk management practices, or that are engaging in practices that do not match their QEP Disclosures and other regulatory filings, potentially encouraging the adoption of better risk management practices. Finally, the anticipation of greater regulatory oversight and transparency in their operations might also provide an incentive for CPOs and CTAs to adopt and follow sound risk management practices.

e. Other Public Interest Considerations

The proposed requirement for CPOs and CTAs to include past performance information in their QEP Disclosures may enable regulators and the general public to gain a better understanding of the trading behavior of CPOs and CTAs utilizing Regulation 4.7, and consequently, the impact they have on commodity interest markets through their 4.7 pools and trading programs.

iv. Permitting Monthly Account Statements Consistent With Commission Exemptive Letters for Certain 4.7 Pools

A. Baseline

CPOs operating pools under Regulation 4.7 are required to provide account statements to investors ''no less frequently than quarterly within 30 days after the end of the reporting period.'' [115] Some of these 4.7 pools invest some or all of their assets in other pools or other types of collective investment vehicles, and are colloquially referred to, as discussed above, as ''Funds of Funds.'' It is the Commission's understanding that the requirement that a 4.7 Fund of Funds pool provide account statements within 30 days of the end of each quarter may become difficult to meet when its CPO may not receive an account statement regarding underlying investment returns until nearly the end of the required 30-day period. For example, if a 4.7 Fund of Funds pool regularly receives account statements from its investee pool's CPO 29 days after the end of the quarter, the CPO of the 4.7 Fund of Funds pool will likely find it difficult to provide accurate and complete account statements to its 4.7 Fund of Funds pool participants within 30 days of quarter end, as Regulation 4.7(b)(3) requires. In recognition of this potential difficulty, the Commission has routinely issued exemptive letters providing relief from this requirement, upon individual request, that permit the requesting CPO to distribute account statements for its 4.7 Fund of Funds pool(s) on a monthly basis within 45 days of the month-end. Nevertheless, the regulatory baseline remains the reporting requirements of Regulation 4.7(b)(3).

B. Proposal

Consistent with longstanding exemptive letter relief described herein, the Proposal would add a provision to Regulation 4.7(b)(3) allowing CPOs of 4.7 pools that are Funds of Funds to distribute account statements on a monthly basis, within 45 days of the end of the month-end, provided that such CPOs notify their pool participants, so they know when to expect to receive their account statements.

C. Benefits

Relative to the baseline, the primary benefit of this proposed amendment is to make it more feasible for 4.7 pools to invest in other pools or collective investment vehicles without potentially violating the periodic reporting requirements in Regulation 4.7. This proposed amendment may also allow CPOs of 4.7 pools to seek higher returns and/or better diversification for their participants by investing in other pools or other collective investment vehicles, without having to seek an exemptive letter to ensure they can meet their periodic reporting requirements, or without risking chronic compliance violations. Consequently, this proposed amendment may encourage more CPOs to operate their 4.7 pools as Funds of Funds, and that may further result in higher returns and/or more effective diversification for their QEP pool participants. Additionally, offering this alternative account statement schedule would allow CPOs of 4.7 Fund of Funds pools to provide more accurate and complete account statements to their QEP participants more frequently, rather than generating quarterly account statements containing estimates of such information, if they have not yet received it. The Commission further predicts that an overall benefit of this proposed amendment would be more frequent, accurate, and complete periodic reporting to QEP participants in 4.7 Fund of Funds pools.

Finally, as noted above, exemptive letters providing relief from this reporting requirement have been commonly issued by the Commission for many years. Hence, as a practical matter, a primary benefit from this proposed amendment is CPOs of 4.7 Fund of Funds pools being able to adopt an alternative account statement schedule at their convenience or immediately when necessary, rather than being required to seek an exemptive letter individually from the

Advertising,'' 2023, *American Economic Journal: Microeconomics,* 15, 1–29) show that a law requiring price transparency on grocery prices led to 4–5% lower prices, as well as less price dispersion. Similarly, Brown (''Equilibrium Effects of Health Care Price Information,'' 2019, *The Review of Economics and Statistics,* 101, 699–712) finds that providing online information on health care procedure pricing led to lower prices and less price dispersion. In a paper on hedge fund returns, Aragon, Liang and Park (''Onshore and Offshore Hedge Funds: Are They Twins?'' 2014, *Management Science,* 60, 74–91) show that advertising restrictions on hedge funds reduce the impact of past returns on new investment.

[114] Goldstein and Yang, ''Commodity Financialization and Information Transmission,'' 2022, *Journal of Finance,* 77, 2613–2668.

[115] 17 CFR 4.7(b)(3).

Commission and potentially delaying operational decisions or changes until such letter is received. Moreover, the proposed amendment would also ensure that similarly situated registrants are treated in a consistent manner by making the alternative schedule available to all qualifying CPOs and 4.7 pools without the need for individual requests. Finally, if this proposed amendment were adopted, such CPOs would no longer have to expend legal and other compliance resources for the purpose of seeking such exemptive letters from the Commission for each of their 4.7 Fund of Funds pools needing this account statement schedule.

D. Costs

Relative to the baseline, the primary cost of the proposed amendment would be the offering of a monthly account statement schedule, provided such monthly statements are provided within 45 days of the end of the month, as an alternative to the current at least quarterly statement schedule provided within 30 days of the end of the quarter. Although the addition of 15 days may slightly delay the arrival of account information to QEP pool participants each month, such participants would also be receiving account statements containing more complete and accurate information more often, as a monthly schedule is more frequent than that required by Regulation 4.7(b)(3) currently, and the 15 days is designed to allow CPOs to compile more information about the 4.7 pool's underlying investments in such statements. CPOs of 4.7 Fund of Funds pools may also incur costs to effectively notify QEP participants of their adoption of this alternative account statement schedule. To the extent this alternative account statement schedule encourages CPOs to operate more of their 4.7 pools as Funds of Funds, QEP participants therein may experience slightly higher costs, as the fees and expenses from underlying pools or other collective investment vehicles could possibly be passed along to them by their 4.7 Fund of Funds pool's CPO.

E. Questions

The Commission poses the following questions to better assess the costs and benefits of the proposed amendment permitting an alternative monthly account statement schedule for Fund of Funds pools operated by CPOs utilizing Regulation 4.7. The Commission requests further that, to the extent possible, commenters please provide quantitative bases for your responses.

1. How many CPOs operate their 4.7 pools as Funds of Funds, meaning such pools invest in other 4.7 pools, other commodity pools, or other collective investment vehicles?

2. How many CPOs operating 4.7 pools provide sufficiently timely account statements to their participants that are other 4.7 commodity pools, so as to allow their CPOs to also produce their own account statements within 30 days of the quarter-end?

3. How many 4.7 Fund of Funds pools are currently able to provide quarterly account statements within 30 days of the end of the quarter, without the alternative monthly schedule currently provided exemptive relief?

F. Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of the proposed amendments to Regulation 4.7(b)(3) with respect to the following factors: protection of market participants and the public; efficiency, competitiveness, and financial integrity of markets; price discovery; sound risk management practices; and other public interest considerations. As discussed above, the addition to Regulation 4.7(b)(3) of a permissible monthly account statement schedule would facilitate compliance with periodic reporting deadlines for CPOs of 4.7 Fund of Funds pools. Absent this change (and assuming such 4.7 pool has received no exemptive letter from the Commission), it may otherwise be impractical for such 4.7 pools to operate as Funds of Funds.

a. Protection of Market Participants and the Public

The baseline requirement in Regulation 4.7(b)(3) for at least quarterly account statements distributed within 30 days of the quarter-end helps ensure that QEP pool participants have access to timely information about the 4.7 pool's performance, and serves to protect such participants from malfeasance and other sources of poor pool performance. As discussed above, relative to the baseline, the proposed amendment would permit CPOs of 4.7 Fund of Funds pools to adopt an alternative monthly account statement schedule, provided such statements are provided within 45 days of the end of each month, and provided that they notify their QEP pool participants of such reporting schedule. To the extent the proposed amendment may encourage QEPs to participate in 4.7 Fund of Funds pools, rather than other 4.7 pools, it may require them to adjust to a different account statement schedule, but would likely ultimately provide them with more complete and accurate account statements on a more frequent basis. Additionally, the proposed amendment may facilitate the formation of 4.7 Fund of Funds pools by making it easier for their CPOs to comply with the applicable periodic reporting requirements under Regulation 4.7; this trend may also serve to benefit QEP participants, in that the CPOs of 4.7 Fund of Funds pools may be able to operate them in a manner that achieves exposure to a wider variety of underlying investment strategies through their investee pools, while continuing to remain compliant with their regulatory obligations. Finally, such CPOs would also have greater incentive and may possess more resources to monitor the behavior of their 4.7 Fund of Funds pools' underlying investments in other pools or funds, than QEPs directly investing therein.

b. Efficiency, Competitiveness, and Financial Integrity of Markets

The proposed amendment to Regulation 4.7(b)(3) may indirectly affect the functioning of commodity interest markets. To the extent that the proposed amendment affects the behavior of CPOs or the size and composition of their 4.7 Fund of Funds pools, it might also affect the flow of investing in commodity interests. The financial economics literature suggests that increased investment by non-commercial traders in commodity interest markets will generally reduce the difference between futures prices and expected future spot prices.[116] This effect means that, to the extent that offering an alternative schedule for periodic reporting in 4.7 Fund of Funds pools increases the flow of non-commercial funds into commodity interest markets, it will tend to also reduce the cost to commercial traders of using the futures market to hedge their risks. In that sense, this proposed amendment may have an indirect effect on efficiency of the futures markets in regard to the hedging costs of operating companies, commodity producers, or other commercial market participants.

c. Price Discovery

To the extent that the proposed amendment to Regulation 4.7(b)(3) affects the size or composition of 4.7 pools, it might also affect the flow of investing in commodity interests. The financial economics literature has found ambiguous results regarding the relationship between increased investment by non-commercial traders

[116] Goldstein and Yang, ''Commodity Financialization and Information Transmission,'' 2022, *Journal of Finance,* 77, 2613–2668.

in commodity interest markets and commodity price discovery.[117] As such, it is difficult for the Commission to *ex ante* predict how the addition of an alternative account statement schedule for 4.7 Fund of Funds pools would impact price discovery.

d. Sound Risk Management Practices

Periodic reporting requirements in the form of regular account statements provided to pool participants serve as an effective means for participants as well as CPOs to monitor pools' risk management. Because the amount of funds a CPO manages through its operated pools is likely responsive to its past performance,[118] requiring the provision of complete financial information on pool performance through regular account statements can serve to provide an incentive for sound risk management by such CPOs. As discussed above, relative to the baseline, the proposed amendment to Regulation 4.7(b)(3) may encourage the formation of 4.7 Fund of Funds pools, whose CPOs may be better able to monitor the performance of underlying commodity pools or funds in which they invest, as compared to QEP participants investing directly therein. This also may positively influence CPOs' risk management practices in their pools, to the extent their participants are other 4.7 pools.

e. Other Public Interest Considerations

A key practical consideration is that, absent exemptive letters issued by the Commission, the existing Regulation 4.7(b)(3) appears to make it very difficult for CPOs to operate their 4.7 pools as Funds of Funds, while complying with applicable periodic reporting requirements. To the extent that facilitating the operation of such 4.7 pools as Funds of Funds is a legitimate policy goal of the Commission (as suggested by its routine granting of exemptive letters on this topic), changing the regulations to explicitly permit this alternative account statement schedule would be a more effective and direct means of accomplishing that objective that further ensures more consistent treatment of similarly situated registrants.

d. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of the CEA in issuing any order or adopting any Commission rule or regulation.[119] The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. The Commission requests comment on whether the Proposal implicates any other specific public interest to be protected by the antitrust laws.

The Commission has considered the proposed amendments in this NPRM to determine whether they are anticompetitive and has preliminarily identified no anticompetitive effects. The Commission requests comment on whether the NPRM is anticompetitive and, if it is, what the anticompetitive effects are.

Because the Commission has preliminarily determined that the Proposal is not anticompetitive and has no anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the CEA. The Commission requests comment on whether there are less anticompetitive means of achieving the relevant purposes of the CEA that would otherwise be served by adopting the amendments proposed in this NPRM.

List of Subjects in 17 CFR Part 4

Advertising, Brokers, Commodity futures, Commodity pool operators, Commodity trading advisors, Consumer protection, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 4 as follows:

PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6(c), 6b, 6c, 6l, 6m, 6n, 6o, 12a, and 23.

■ 2. In § 4.7:
■ a. Remove the introductory text;
■ b. Revise paragraphs (a) and (b)(2)(i);
■ c. Add paragraphs (b)(2)(i)(A) through (G);
■ d. Remove and reserve paragraph (b)(2)(ii);
■ e. Add paragraph (b)(3)(iv);
■ f. Revise paragraphs (b)(5) and (c)(1)(i);
■ g. Add paragraphs (c)(1)(i)(A) through (H);
■ h. Remove and reserve paragraph (c)(1)(ii); and
■ i. Revise paragraphs (c)(2) and (d)(4)(i) and (ii).

The revisions and additions read as follows:

§ 4.7 Exemption from certain part 4 requirements for commodity pool operators with respect to offerings to qualified eligible persons and for commodity trading advisors with respect to advising qualified eligible persons.

(a) *Definitions.* (1) *Affiliate* of, or a person *affiliated* with, a specified person means a person that directly or indirectly through one or more persons, controls, is controlled by, or is under common control with the specified person.

(2) *Exempt account* means the account of a qualified eligible person that is directed or guided by a commodity trading advisor pursuant to an effective claim for exemption under this section.

(3) *Exempt pool* means a pool that is operated pursuant to an effective claim for exemption under this section.

(4) *Non-United States person* means:

(i) A natural person who is not a resident of the United States;

(ii) A partnership, corporation or other entity, other than an entity organized principally for passive investment, organized under the laws of a foreign jurisdiction and which has its principal place of business in a foreign jurisdiction;

(iii) An estate or trust, the income of which is not subject to United States income tax regardless of source;

(iv) An entity organized principally for passive investment such as a pool, investment company or other similar entity; *Provided,* that units of participation in the entity held by persons who do not qualify as Non-United States persons or otherwise as qualified eligible persons represent in the aggregate less than 10% of the beneficial interest in the entity, and that such entity was not formed principally for the purpose of facilitating investment by persons who do not qualify as Non-United States persons in a pool with respect to which the operator is exempt from certain requirements of this part by virtue of its participants being Non-United States persons; and

(v) A pension plan for the employees, officers or principals of an entity organized and with its principal place of business outside the United States.

(5) *Portfolio Requirement* means that a person:

(i) Owns securities (including pool participations) of issuers not affiliated

[117] *Id.*

[118] Sirra and Tufano, ''Costly Search and Mutual Fund Flows,'' Journal of Finance, 1998, 53, 1589–1622; Del Guercio and Reuter, ''Mutual Fund Performance and the Incentive to Generate Alpha,'' Journal of Finance, 2014, 1673–1704.

[119] 7 U.S.C. 19(b).

with such person and other investments with an aggregate market value of at least $4,000,000;

(ii) Has had on deposit with a futures commission merchant, for its own account at any time during the six-month period preceding either the date of sale to that person of a pool participation in the exempt pool or the date that the person opens an exempt account with the commodity trading advisor, at least $400,000 in exchange-specified initial margin and option premiums, together with any required minimum security deposits for retail forex transactions (defined in § 5.1(m) of this chapter), for commodity interest transactions; or

(iii) Owns a portfolio comprised of a combination of the funds or property specified in paragraphs (a)(5)(i) and (ii) of this section, in which the sum of the funds or property includable under paragraph (a)(5)(i) of this section, expressed as a percentage of the minimum amount required thereunder, and the amount of initial margin, option premiums, and minimum security deposits includable under paragraph (a)(5)(ii) of this section, expressed as a percentage of the minimum amount required thereunder, equals at least one hundred percent. An example of a composite portfolio acceptable under this paragraph (a)(5)(iii) would consist of $2,000,000 in securities and other property (50% of paragraph (a)(5)(i) of this section) and $200,000 in initial margin, option premiums, and minimum security deposits (50% of paragraph (a)(5)(ii) of this section).

(6) *Qualified eligible person* means any person, acting for its own account or for the account of a qualified eligible person, who the commodity pool operator reasonably believes, at the time of the sale to that person of a pool participation in the exempt pool, or who the commodity trading advisor reasonably believes, at the time that person opens an exempt account, is eligible to invest in the exempt pool or open the exempt account and is included in the following list of persons that is divided into two categories: Persons who are not required to satisfy the Portfolio Requirement defined in paragraph (a)(5) of this section to be qualified eligible persons, and those persons who must satisfy the Portfolio Requirement in paragraph (a)(5) of this section to be qualified eligible persons.

(i) *Persons who need not satisfy the Portfolio Requirement to be qualified eligible persons.* (A) A futures commission merchant registered pursuant to section 4d of the Act, or a principal thereof;

(B) A retail foreign exchange dealer registered pursuant to section 2(c)(2)(B)(i)(II)(gg) of the Act, or a principal thereof;

(C) A swap dealer registered pursuant to section 4s(a)(1) of the Act, or a principal thereof;

(D) A broker or dealer registered pursuant to section 15 of the Securities Exchange Act of 1934, or a principal thereof;

(E) A commodity pool operator registered pursuant to section 4m of the Act, or a principal thereof; *Provided,* that the pool operator:

(*1*) Has been registered and active as such for two years; or

(*2*) Operates pools which, in the aggregate, have total assets in excess of $5,000,000;

(F) A commodity trading advisor registered pursuant to section 4m of the Act, or a principal thereof; *Provided,* that the trading advisor:

(*1*) Has been registered and active as such for two years; or

(*2*) Provides commodity interest trading advice to commodity accounts which, in the aggregate, have total assets in excess of $5,000,000 deposited at one or more futures commission merchants;

(G) An investment adviser registered pursuant to section 203 of the Investment Advisers Act of 1940 (''Investment Advisers Act'') or pursuant to the laws of any state, or a principal thereof; *Provided,* that the investment adviser:

(*1*) Has been registered and active as such for two years; or

(*2*) Provides securities investment advice to securities accounts which, in the aggregate, have total assets in excess of $5,000,000 deposited at one or more registered securities brokers;

(H) A ''qualified purchaser'' as defined in section 2(a)(51)(A) of the Investment Company Act of 1940 (''Investment Company Act'');

(I) A ''knowledgeable employee'' as defined in § 270.3c–5 of this title;

(J) With respect to an exempt pool:

(*1*) The commodity pool operator, commodity trading advisor or investment adviser of the exempt pool offered or sold, or an affiliate of any of the foregoing;

(*2*) A principal of the exempt pool or the commodity pool operator, commodity trading advisor or investment adviser of the exempt pool, or an affiliate of any of the foregoing;

(*3*) An employee of the exempt pool or the commodity pool operator, commodity trading advisor or investment adviser of the exempt pool, or of an affiliate of any of the foregoing (other than an employee performing solely clerical, secretarial or administrative functions with regard to such person or its investments) who, in connection with his or her regular functions or duties, participates in the investment activities of the exempt pool, other commodity pools operated by the pool operator of the exempt pool or other accounts advised by the trading advisor or the investment adviser of the exempt pool, or by the affiliate; *Provided,* that such employee has been performing such functions and duties for or on behalf of the exempt pool, pool operator, trading advisor, investment adviser or affiliate, or substantially similar functions or duties for or on behalf of another person engaged in providing commodity interest, securities or other financial services, for at least 12 months;

(*4*) Any other employee of, or an agent engaged to perform legal, accounting, auditing or other financial services for, the exempt pool or the commodity pool operator, commodity trading advisor or investment adviser of the exempt pool, or any other employee of, or agent so engaged by, an affiliate of any of the foregoing (other than an employee or agent performing solely clerical, secretarial or administrative functions with regard to such person or its investments); *Provided,* that such employee or agent:

(*i*) Is an accredited investor as defined in § 230.501(a)(5) or (a)(6) of this title; and

(*ii*) Has been employed or engaged by the exempt pool, commodity pool operator, commodity trading advisor, investment adviser or affiliate, or by another person engaged in providing commodity interest, securities or other financial services, for at least 24 months;

(*5*) The spouse, child, sibling or parent of a person who satisfies the criteria of paragraph (a)(6)(i)(J)(*1*), (*2*), (*3*) or (*4*) of this section; *Provided,* that:

(*i*) An investment in the exempt pool by any such family member is made with the knowledge and at the direction of the person; and

(*ii*) The family member is not a qualified eligible person for the purposes of paragraph (a)(6)(ii)(K) of this section;

(*6*) Any person who acquires a participation in the exempt pool by gift, bequest or pursuant to an agreement relating to a legal separation or divorce from a person listed in paragraph (a)(6)(i)(J)(*1*), (*2*), (*3*), (*4*) or (*5*) of this section;

(*7*) The estate of any person listed in paragraph (a)(6)(i)(J)(*1*), (*2*), (*3*), (*4*) or (*5*) of this section; or

(*8*) A company established by any person listed in paragraph (a)(6)(i)(J)(*1*),

(*2*), (*3*), (*4*) or (*5*) of this section exclusively for the benefit of (or owned exclusively by) that person and any person listed in paragraph (a)(6)(i)(J)(*6*) or (*7*) of this section;

(K) With respect to an exempt account:

(*1*) An affiliate of the commodity trading advisor of the exempt account;

(*2*) A principal of the commodity trading advisor of the exempt account or of an affiliate of the commodity trading advisor;

(*3*) An employee of the commodity trading advisor of the exempt account or of an affiliate of the trading advisor (other than an employee performing solely clerical, secretarial or administrative functions with regard to such person or its investments) who, in connection with his or her regular functions or duties, participates in the investment activities of the trading advisor or the affiliate; *Provided,* that such employee has been performing such functions and duties for or on behalf of the trading advisor or the affiliate, or substantially similar functions or duties for or on behalf of another person engaged in providing commodity interest, securities or other financial services, for at least 12 months;

(*4*) Any other employee of, or an agent engaged to perform legal, accounting, auditing or other financial services for, the commodity trading advisor of the exempt account or any other employee of, or agent so engaged by, an affiliate of the trading advisor (other than an employee or agent performing solely clerical, secretarial or administrative functions with regard to such person or its investments); *Provided,* that such employee or agent:

(*i*) Is an accredited investor as defined in § 230.501(a)(5) or (a)(6) of this title; and

(*ii*) Has been employed or engaged by the commodity trading advisor or the affiliate, or by another person engaged in providing commodity interest, securities or other financial services, for at least 24 months; or

(*5*) The spouse, child, sibling or parent of the commodity trading advisor of the exempt account or of a person who satisfies the criteria of paragraph (a)(6)(i)(K)(*1*), (*2*), (*3*) or (*4*) of this section; *Provided,* that:

(*i*) The establishment of an exempt account by any such family member is made with the knowledge and at the direction of the person; and

(*ii*) The family member is not a qualified eligible person for the purposes of paragraph (a)(6)(ii)(K) of this section;

(*6*) Any person who acquires an interest in an exempt account by gift, bequest or pursuant to an agreement relating to a legal separation or divorce from a person listed in paragraph (a)(6)(i)(K)(*1*), (*2*), (*3*), (*4*) or (*5*) of this section;

(*7*) The estate of any person listed in paragraph (a)(6)(i)(K)(*1*), (*2*), (*3*), (*4*) or (*5*) of this section;

(*8*) A company established by any person listed in paragraph (a)(6)(i)(K)(*1*), (*2*), (*3*), (*4*) or (*5*) of this section exclusively for the benefit of (or owned exclusively by) that person and any person listed in paragraph (a)(6)(i)(K)(*6*) or (*7*) of this section;

(L) A trust; *Provided,* that:

(*1*) The trust was not formed for the specific purpose of either participating in the exempt pool or opening an exempt account; and

(*2*) The trustee or other person authorized to make investment decisions with respect to the trust, and each settlor or other person who has contributed assets to the trust, is a qualified eligible person;

(M) An organization described in section 501(c)(3) of the Internal Revenue Code (the ''IRC''); *Provided,* that the trustee or other person authorized to make investment decisions with respect to the organization, and the person who has established the organization, is a qualified eligible person;

(N) A Non-United States person;

(O) An entity in which all of the unit owners or participants, other than the commodity trading advisor claiming relief under this section, are qualified eligible persons;

(P) An exempt pool; or

(Q) Notwithstanding paragraph (a)(6)(ii) of this section, an entity as to which a notice of eligibility has been filed pursuant to § 4.5 which is operated in accordance with such rule and in which all unit owners or participants, other than the commodity trading advisor claiming relief under this section, are qualified eligible persons.

(ii) *Persons who must satisfy the Portfolio Requirement to be qualified eligible persons.* With respect to the persons listed in this paragraph (a)(6)(ii), the commodity pool operator must reasonably believe, at the time of the sale to such person of a participation in the exempt pool, or the commodity trading advisor must reasonably believe, at the time such person opens an exempt account, that such person satisfies the Portfolio Requirement in paragraph (a)(5) of this section.

(A) An investment company registered under the Investment Company Act or a business development company as defined in section 2(a)(48) of such Act not formed for the specific purpose of either investing in the exempt pool or opening an exempt account;

(B) A bank as defined in section 3(a)(2) of the Securities Act of 1933 (the ''Securities Act'') or any savings and loan association or other institution as defined in section 3(a)(5)(A) of the Securities Act acting for its own account or for the account of a qualified eligible person;

(C) An insurance company as defined in section 2(13) of the Securities Act acting for its own account or for the account of a qualified eligible person;

(D) A plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of $5,000,000;

(E) An employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974; *Provided,* that the investment decision is made by a plan fiduciary, as defined in section 3(21) of such Act, which is a bank, savings and loan association, insurance company, or registered investment adviser; or that the employee benefit plan has total assets in excess of $5,000,000; or if the plan is self-directed, that investment decisions are made solely by persons that are qualified eligible persons;

(F) A private business development company as defined in section 202(a)(22) of the Investment Advisers Act;

(G) An organization described in section 501(c)(3) of the IRC, with total assets in excess of $5,000,000;

(H) A corporation, Massachusetts or similar business trust, or partnership, limited liability company or similar business venture, other than a pool, which has total assets in excess of $5,000,000, and is not formed for the specific purpose of either participating in the exempt pool or opening an exempt account;

(I) A natural person whose individual net worth, or joint net worth with that person's spouse, at the time of either his purchase in the exempt pool or his opening of an exempt account would qualify him as an accredited investor as defined in § 230.501(a)(5) of this title;

(J) A natural person who would qualify as an accredited investor as defined in § 230.501(a)(6) of this title;

(K) A pool, trust, insurance company separate account or bank collective trust, with total assets in excess of $5,000,000, not formed for the specific purpose of either participating in the exempt pool or opening an exempt

account, and whose participation in the exempt pool or investment in the exempt account is directed by a qualified eligible person; or

(L) Except as provided for the governmental entities referenced in paragraph (a)(6)(ii)(D) of this section, if otherwise authorized by law to engage in such transactions, a governmental entity (including the United States, a state, or a foreign government) or political subdivision thereof, or a multinational or supranational entity or an instrumentality, agency, or department of any of the foregoing.

(7) *United States* means the United States, its states, territories or possessions, or an enclave of the United States government, its agencies or instrumentalities.

(b) * * *

(2) * * *

(i) Exemption from the specific requirements in §§ 4.24 and 4.26(d) with respect to each pool; *Provided,* that any offering memorandum distributed in connection with soliciting prospective participants in the exempt pool be distributed consistent with the requirements of § 4.21 and include:

(A) A description of principal risk factors for the exempt pool, as required by § 4.24(g);

(B) A description of the exempt pool's investment program and use of proceeds, as required by § 4.24(h);

(C) A description of fees and expenses, as required by § 4.24(i);

(D) A description of conflicts of interest, as required by § 4.24(j);

(E) Performance disclosures, as required by § 4.25, with the exception of information required by paragraphs (a)(3) and (c)(2) of § 4.25;

(F) All other disclosures necessary to make the information contained therein, in the context in which it is furnished, not misleading; and

(G) The following statement, prominently disclosed on the cover page of the offering memorandum:

''PURSUANT TO AN EXEMPTION FROM THE COMMODITY FUTURES TRADING COMMISSION IN CONNECTION WITH POOLS WHOSE PARTICIPANTS ARE LIMITED TO QUALIFIED ELIGIBLE PERSONS, AN OFFERING MEMORANDUM FOR THIS POOL IS NOT REQUIRED TO BE, AND HAS NOT BEEN, FILED WITH THE COMMISSION. THE COMMODITY FUTURES TRADING COMMISSION DOES NOT PASS UPON THE MERITS OF PARTICIPATING IN A POOL OR UPON THE ADEQUACY OR ACCURACY OF AN OFFERING MEMORANDUM. CONSEQUENTLY, THE COMMODITY FUTURES TRADING COMMISSION HAS NOT REVIEWED OR APPROVED THIS OFFERING OR ANY OFFERING MEMORANDUM FOR THIS POOL PRIOR TO FIRST USE.''

(3) * * *

(iv) Where the exempt pool is invested in one or more other pools or funds operated by third parties, the commodity pool operator may choose instead to prepare and distribute to its pool participants statements signed and affirmed in accordance with § 4.22(h) on a monthly basis within 45 days of the month-end; *Provided,* that the statements otherwise meet the conditions of paragraphs (b)(3)(i) through (ii) of this section, and that the commodity pool operator notifies its pool participants of this alternate distribution schedule in the exempt pool's offering memorandum distributed prior to the initial investment, or upon its adoption of this reporting schedule, for then existing pool participants.

* * * * *

(5) *Recordkeeping relief.* Exemption from the specific requirements of § 4.23; *Provided,* that the commodity pool operator must maintain the offering memoranda and reports referred to in paragraphs (b)(2), (3), and (4) of this section, and all other books and records prepared in connection with its activities as the pool operator of the exempt pool (including, without limitation, records relating to the qualifications of qualified eligible persons and substantiating any performance representations). Books and records that are not maintained at the pool operator's main business office shall be maintained by one or more of the following: the pool's administrator, distributor, or custodian, or a bank or registered broker or dealer acting in a similar capacity with respect to the pool. Such books and records must be made available to any representative of the Commission, the National Futures Association and the United States Department of Justice in accordance with the provisions of § 1.31 of this chapter.

* * * * *

(c) * * *

(1) * * *

(i) Exemption from the specific requirements of §§ 4.34 and 4.36(d); *Provided,* that any brochure or other disclosure statement delivered by a commodity trading advisor to its prospective qualified eligible person clients be distributed consistent with the requirements of § 4.31 and include:

(A) A description of persons to be identified, as required by § 4.34(e);

(B) A description of principal risk factors, as required by § 4.34(g);

(C) A description of the exempt commodity trading advisor's trading program, as required by § 4.34(h);

(D) A description of fees, as required by § 4.34(i);

(E) A description of conflicts of interest, as required by § 4.34(j);

(F) Performance disclosures, as required by § 4.35;

(G) All additional disclosures necessary to make the information contained therein, in the context in which it is furnished, not misleading; and

(H) The following statement, prominently displayed on the cover page of the brochure or other disclosure statement:

''PURSUANT TO AN EXEMPTION FROM THE COMMODITY FUTURES TRADING COMMISSION IN CONNECTION WITH ACCOUNTS OF QUALIFIED ELIGIBLE PERSONS, THIS BROCHURE OR ACCOUNT DOCUMENT IS NOT REQUIRED TO BE, AND HAS NOT BEEN, FILED WITH THE COMMISSION. THE COMMODITY FUTURES TRADING COMMISSION DOES NOT PASS UPON THE MERITS OF PARTICIPATING IN A TRADING PROGRAM OR UPON THE ADEQUACY OR ACCURACY OF COMMODITY TRADING ADVISOR DISCLOSURE. CONSEQUENTLY, THE COMMODITY FUTURES TRADING COMMISSION HAS NOT REVIEWED OR APPROVED THIS TRADING PROGRAM OR THIS BROCHURE OR ACCOUNT DOCUMENT PRIOR TO FIRST USE.''

* * * * *

(2) *Recordkeeping relief.* Exemption from the specific requirements of § 4.33; *Provided,* that the commodity trading advisor must maintain, at its main business office, the trading brochure or disclosure statement referred to in paragraph (c)(1) of this section, and all other books and records prepared in connection with its activities as the commodity trading advisor of qualified eligible persons (including, without limitation, records relating to the qualifications of such qualified eligible persons and substantiating any performance representations). Such books and records must be made available to any representative of the Commission, the National Futures Association, and the United States Department of Justice in accordance with the provisions of § 1.31 of this chapter.

(d) * * *

(4)(i) Any exemption from the requirements of §§ 4.22, 4.23, 4.24, 4.25, and 4.26 claimed hereunder with respect to a pool shall not affect the obligation of the commodity pool

operator to comply with all other applicable provisions of this part, the Act and the Commission's rules and regulations, with respect to the pool and any other pool the pool operator operates or intends to operate.

(ii) Any exemption from the requirements of §§ 4.33, 4.34, and 4.36 claimed hereunder shall not affect the obligation of the commodity trading advisor to comply with all other applicable provisions of this part, the Act and the Commission's rules and regulations, with respect to any qualified eligible person and any other client to which the commodity trading advisor provides or intends to provide commodity interest trading advice.

* * * * *

■ 3. In § 4.14, revise paragraph (a)(8)(i)(C)(*2*) to read as follows:

§ 4.14 Exemption from registration as a commodity trading advisor.

(a) * * *

(8) * * *

(i) * * *

(C) * * *

(*2*) With the exception of the pool's operator, advisor, and their principals, solely ''Non-United States persons,'' as that term is defined in § 4.7(a)(7), will contribute funds or other capital to, and will own beneficial interests in, the pool; *Provided,* that units of participation in the pool held by persons who do not qualify as Non-United States persons or otherwise qualified eligible persons represent in the aggregate less than 10 percent of the beneficial interest of the pool;

* * * * *

■ 4. In § 4.21, revise paragraph (a)(2) to read as follows:

§ 4.21 Required delivery of pool Disclosure Document.

(a) * * *

(2) For the purpose of the Disclosure Document delivery requirement, including any offering memorandum delivered pursuant to § 4.7(b)(2)(i) or § 4.12(b)(2)(i), the term ''prospective pool participant'' does not include a commodity pool operated by a pool operator that is the same as, or that controls, is controlled by, or is under common control with, the pool operator of the offered pool.

* * * * *

■ 5. In § 4.22:

■ a. Revise paragraphs (a)(4), (c)(7) introductory text, (c)(8), (d)(1) introductory text, (d)(2)(i) introductory text, (f)(2) introductory text, and (f)(2)(iv)(B) and (C); and

■ b. Remove paragraph (f)(2)(iv)(D).

The revisions read as follows:

§ 4.22 Reporting to pool participants.

(a) * * *

(4) For the purpose of the Account Statement delivery requirement, including any Account Statement distributed pursuant to § 4.7(b)(3) or § 4.12(b)(2)(ii), the term ''participant'' does not include a commodity pool operated by a pool operator that is the same as, or that controls, is controlled by, or is under common control with, the pool operator of a pool in which the commodity pool has invested.

* * * * *

(c) * * *

(7) For a pool that has ceased operation prior to, or as of, the end of the fiscal year, the commodity pool operator may provide the following, within 90 days of the permanent cessation of trading, in lieu of the annual report that would otherwise be required by § 4.22(c) or § 4.7(b)(4):

* * * * *

(8) For the purpose of the Annual Report distribution requirement, including any annual report distributed pursuant to § 4.7(b)(4) or § 4.12(b)(2)(iii), the term ''participant'' does not include a commodity pool operated by a pool operator that is the same as, or that controls, is controlled by, or is under common control with, the pool operator of a pool in which the commodity pool has invested; *Provided,* that the Annual Report of such investing pool contain financial statements that include such information as the Commission may specify concerning the operations of the pool in which the commodity pool has invested.

(d)(1) Subject to the provisions of paragraphs (d)(2) and (g)(2) of this section, the financial statements in the Annual Report required by this section or by § 4.7(b)(4) must be presented and computed in accordance with United States generally accepted accounting principles consistently applied and must be audited by an independent public accountant; *Provided, however,* and subject to the exception in paragraph (c)(7)(iii)(B) of this section, that the requirement that the Annual Report be audited by an independent public accountant does not apply for any fiscal year during which the only participants in the pool are one or more of the pool operator, the pool's commodity trading advisor, any person controlling, controlled by, or under common control with the pool operator or trading advisor, and any principal of the foregoing; and *Provided further,* that the commodity pool operator obtains a written waiver from each such pool participant of their right to receive an audited Annual Report for such fiscal year, maintains such waivers in accordance with § 4.23, and makes such waivers available to the Commission or National Futures Association upon request. The requirements of § 1.16(g) of this chapter shall apply with respect to the engagement of such independent public accountants, except that any related notifications to be made may be made solely to the National Futures Association, and the certification must be in accordance with § 1.16 of this chapter, except that the following requirements of that section shall not apply:

* * * * *

(2)(i) Where a pool is organized in a jurisdiction other than the United States, the financial statements in the Annual Report required by this section or by § 4.7(b)(4) may be presented and computed in accordance with the generally accepted accounting principles, standards or practices followed in such other jurisdiction; *Provided,* that:

* * * * *

(f) * * *

(2) In the event a commodity pool operator finds that it cannot obtain information necessary to prepare annual financial statements for a pool that it operates within the time specified in paragraph (c) of this section or § 4.7(b)(4)(i), as a result of the pool investing in another collective investment vehicle, it may claim an extension of time under the following conditions:

* * * * *

(iv) * * *

(B) For all reports prepared under paragraph (c) of this section and for reports prepared under § 4.7(b)(4)(i) that are audited by an independent public accountant, the commodity pool operator has been informed by the independent public accountant engaged to audit the commodity pool's financial statements that specified information required to complete the pool's Annual Report is necessary in order for the accountant to render an opinion on the commodity pool's financial statements. The notice must include the name, main business address, main telephone number, and contact person of the accountant; and

(C) The information specified by the accountant cannot be obtained in sufficient time for the Annual Report to be prepared, audited, and distributed before the Extended Date.

* * * * *

Issued in Washington, DC, on October 3, 2023, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools: Updating the 'Qualified Eligible Person' Definition; Adding Minimum Disclosure Requirements for Pools and Trading Programs; Permitting Monthly Account Statements for Funds of Funds; Technical Amendments—Commission Voting Summary and Commissioners' Statements

Appendix 1—Commission Voting Summary

On this matter, Chairman Behnam and Commissioners Johnson and Goldsmith Romero voted in the affirmative. Commissioner Pham concurred. Commissioner Mersinger voted in the negative.

Appendix 2—Statement of Commissioner Kristin N. Johnson History of Disclosure-Centered Regulation

Federal regulation expressly establishes that customer protection is a core principle of and central to the oversight mission of the Commodity Futures Trading Commission (CFTC or Commission). For almost a century, mandatory disclosure has played a critical role in market regulation, directly shaping the development of the U.S. capital and derivatives markets.[1] Requiring disclosure of material information mitigates inherent asymmetries of information.

The Commission allocates resources among registration and supervision responsibilities and enforcement actions to foster effective oversight of market participants and transactions. This approach not only enhances the integrity of markets, but effectively protects customers from material misrepresentations and fraud.

Congress has judiciously introduced Federal markets legislation, often in response to nationwide or global market-wide crises, and has carefully balanced Federal regulation with the role and significance of state regulatory oversight.

One hundred years ago, Congress passed the Grain Futures Act—the statute that was superseded by the Commodity Exchange Act (CEA) and that established the Grain Futures Administration (GFA, the predecessor of the CFTC)—authorizing the GFA to regulate certain commodity futures. A decade later, in the wake of the stock market crash of 1929 and the conclusion of the roaring '20s—a period characterized by a surging economy and intense market speculation accompanied by pervasive fraud in retail securities markets [2]—Congress adopted the Securities Act of 1933 (the Securities Act). The stock market crash of 1929 triggered staggering losses by retail investors and initiated a long period of industrial decline and widespread unemployment, ultimately leading to deeply depressed macroeconomic conditions.

Consistent with an adage made popular by U.S. Supreme Court Justice Louis Brandeis—''[s]unlight is said to be the best of disinfectants; electric light the most efficient policeman'' [3]—Congress adopted a disclosure-centric approach.

Disclosure increases transparency, reduces asymmetries of information, and mitigates fraud and manipulation as well as other misconduct in our financial markets. In the absence of mandatory disclosures, investors may have limited access to the material information needed to make a reasonable investment decision. Mandatory disclosure neutralizes incentives to misrepresent material information.

It is incumbent upon the Commission to continue to carry out this mandate reflected in the principles of Federal markets regulation and firmly established in the CEA.

Novel Financial Products and Evolving Derivatives Markets

Novel financial products, such as digital assets and innovative technologies like distributed digital ledger or blockchain technology and generative artificial intelligence, increasingly dominate regulatory discourse and popular discussions. The derivatives markets offer futures on digital assets, which are priced on a volatile spot market, employ technology that is highly complex and rapidly changing, and offer novel market structures including market structures designed to permit retail customers direct access to trading and clearing platforms. In some contexts, trading structures eliminate intermediaries such as a futures commission merchants (FCM), raising important questions regarding the best approach for preserving important customer protections such as segregation of customer assets.

As our markets are evolving, more and more vulnerable customers increasingly engage in complex derivatives activities. It is important that these customers have an opportunity to consider critical, material information when making an investment decision. Disclosure serves a valuable role in protecting customers.

Consequently, regulators must continuously revisit regulation to ensure that it remains fit for purpose. Our regulations must keep pace with innovation in our evolving markets. In particular, we must refresh our understanding of which customers may benefit from disclosure when investing, directly or indirectly, in derivatives markets.

* * * * *

I support the notice of proposed rulemaking (NPRM) regarding commodity pool operators (CPOs), commodity trading advisors (CTAs), and commodity pools operated under CFTC Regulation 4.7. The NPRM addresses regulatory gaps that have arisen due to, at least in part, the changing dynamics in the derivatives markets. The proposed amendments adapt the CFTC's existing regulations to reinforce, preserve, and promote customer protection safeguards. CFTC Regulation 4.7 dictates the disclosure obligations of CPOs and CTAs by establishing the test for classifying a natural person as a retail investor to whom extensive disclosures and financial reports must be delivered or a financially sophisticated investor with respect to whom a more streamlined process may be warranted.

Updating Our Understanding of the Legal Standard for ''Financial Sophistication''

Adopted in 1979, part 4 of the CFTC's regulations requires CPOs and CTAs to deliver disclosures and regular financial reports to pool participants or advisory clients.[4] This framework acts as an important layer of protection for customers, by providing customers with material information about the commodity pool or trading platform, which may include investment objectives, past performance record, conflicts of interest, risk disclosures, or other prescribed information.

CFTC Regulation 4.7, adopted in 1992, creates an exemption from certain part 4 requirements for CPOs and CTAs that privately offer or sell pool participations solely to qualified eligible persons (QEPs) pursuant to an exemption under the Securities Act or direct or guide the commodity trading accounts of QEPs. As a result, QEPs or wealthy individuals do not

[1] Mandatory disclosure serves as a theoretical and practical linchpin in capital markets regulation. Unless an offering is otherwise exempt from registration, Section 5 of the Securities Act requires issuers who seek to raise capital to register the offering with the Securities and Exchange Commission (SEC) prior to offering the securities to investors for sale. *See* 15 U.S.C. 77a–77mm. To complete the registration process, issuers must compile and distribute extensive disclosures describing, among other matters, the nature of the issuer's business; the educational and professional profiles of executives appointed to senior management positions and individuals selected to serve on the board of directors; tangible and intangible property; risk factors; and the financial health—current and forecasted earnings and revenues—of the firm.

[2] Investigative Congressional hearings revealed that more than half of the $25 billion in securities distributed between the end of World War I and the stock market crash of 1929 were worthless. H.R. REP. NO. 73–85, at 2 (1933); *see also* U.S. Senate Hist. Off., Subcommittee on Senate Resolutions 84 and 239, *https://www.senate.gov/about/powers-procedures/investigations/pecora.htm.* Detailed accounts of issuers' intentional dissemination of false and misleading information punctuated evidence of fraud and stunning acts of avarice. During this period, securities listed on the New York Stock Exchange declined from a pre-crash high of $89 billion to $15 billion in 1932. One critical investigative report suggested that ''had there been full disclosure,'' issuers' schemes ''could not long have survived the fierce light of publicity and criticism.'' Ferdinand Pecora, Wall Street Under Oath: The Story of Our Modern Money Changers (1939).

[3] Louis D. Brandeis, Other People's Money And How The Bankers Use It, 92 (1914).

[4] 17 CFR 4.7. On January 2, 1979, the CFTC adopted rules for the regulation of CPOs and CTAs. *See* Commodity Pool Operators and Commodity Trading Advisors; Final Rules, 44 FR 1918 (Jan. 8, 1979). These rules became effective April 1, 1979.

receive any of the specific disclosures otherwise provided to non-QEPs or retail investors (*e.g.,* offering memoranda, brochures, or disclosure statements) and receive streamlined financial reporting.

A natural person, investing capital in a commodity pool or whose trading account invests in derivatives, would be a QEP if the individual is an ''accredited investor,'' as defined by the SEC in Regulation D under the Securities Act, and also meets the CFTC's portfolio requirement.[5] The portfolio requirement is designed to ensure that a person's investments reach a specified threshold related to the person's securities portfolio and derivatives account. This functions as a proxy for identifying individuals who, based on the size of their investments, have ''substantial investment experience and thus a high degree of sophistication with regard to investments as well as financial resources to withstand the risk of their investments.'' [6]

Recognizing that classifying individuals as QEPs may result in reduced regulatory protections, it is therefore critical that the Commission is careful in setting out the standard for determining that an individual is a QEP.

An individual customer may experience substantial losses if the market moves against the customer's positions. This concern is heightened by the fact that the participation interests acquired in an exempt pool offering are not registered offerings subject to the SEC's robust public offering disclosure regime outlined in public offering registration obligation.

Commodity pools are commonly hedge funds that may use leverage to magnify returns, engage in speculation, and take directional positions. These types of structured investment strategies may result in amplified losses for customers.

While our markets are undergoing unprecedented changes, robust customer protections must remain consistent and effective. Natural persons who currently meet the outdated thresholds in the portfolio requirement test introduced in 1992 are not necessarily sophisticated investors in today's markets. What's worse, under the existing regulation, individuals that meet the QEP test may not be receiving disclosures to be fully apprised of the risks associated with investing in novel derivatives instruments, whether directly or through a commodity pool, and our evolving markets.

Two-Part Recalibration of Customer Protection Measures

This NPRM has two important objectives.[7]

First, it doubles the financial thresholds of the portfolio requirement test to account for inflation since the exemption was adopted in 1992, thereby recalibrating the standard for determining which pool investors or advisory clients are QEPs.[8] If this proposed amendment is adopted, certain pool participants and advisory clients that do not receive disclosures or receive streamlined financial reporting under the existing regulation will benefit from the full range of customer protection measures in part 4 of the CFTC's regulations. The proposed thresholds are not even as high as those that were originally proposed in 1992, and so I do not find the amended portfolio requirement to be too restrictive or limiting today, more than 30 years later.[9] Perhaps the thresholds could be higher.

Second, the NPRM sets a new minimum standard of disclosure regarding pools and trading programs that must be provided to all QEPs or wealthy investors, while retaining the more robust disclosure and reporting requirements applicable to non-QEPs or retail investors.[10] The adoption of this amendment will result in heightened customer protections for QEPs that currently are entitled to none. I strongly believe that as a market regulator, we must, when warranted, carefully recalibrate how investors participate in our evolving markets to ensure that CPOs and CTAs provide a prospective or actual investor, whether such investor is a QEP or not, with information that is sufficient and adequate to enable the investor to assess the material risks and rewards of the commodity pool or trading program. Disclosure is key to remediating the dangers of information asymmetry.

I appreciate the staff's efforts in heightening disclosure and enhancing customer protections and their cooperation in implementing my comments to refine the preamble and regulatory text concerning the specific disclosures that will be required under the proposed rule.

I am looking forward to thoughtful comments and responses from market participants. In particular, I welcome perspectives on the potential impact of the proposed rule changes on natural persons who are investing in exempt pools operated by a CPO, or are advisory clients of a CTA, that is relying on the exemptions under CFTC Regulation 4.7 and navigating our complex and evolving derivatives markets.

Appendix 3—Dissenting Statement of Commissioner Summer K. Mersinger

I regrettably dissent from the Commission's [1] proposed rulemaking to amend Rule 4.7,[2] which for the past 30 years has provided exemptions to registered commodity pool operators (''CPOs'') and commodity trading advisors (''CTAs'') that operate commodity pools or trading programs for Qualified Eligible Persons (''QEPs''). I say ''regrettably'' because there are two aspects of this proposal that are consistent with views I have expressed before, and which I support.

First, I agree that it is time for the Commission to consider increasing the monetary thresholds in the ''Portfolio Requirement'' in the definition of a QEP in Rule 4.7(a) to account for inflation. As I previously have stated, ''I believe that it is incumbent upon the CFTC, like any regulatory agency, to continually review its rule set to evaluate whether rules . . . need to be updated because they have simply failed to keep up with the times.'' [3]

Second, I support proposing a process in our rules that would permit CPOs relying on Rule 4.7 to elect an alternate account statement schedule that is consistent with exemptive letters issued regularly by the Commission. This schedule would address the fact that our current rule is not workable in the context of funds-of-funds, and also would generate more frequent reporting. As I previously have stated, ''when one of our rules needs to be fixed because it is unworkable, ambiguous, or inefficient, corrective action by notice-and-comment rulemaking is the gold standard because it allows the Commission to hear from stakeholders and develop regulatory solutions that provide certainty.'' [4]

However, I cannot support the proposal to narrow the scope of the historical exemptions in Rule 4.7 by imposing universal disclosure requirements to QEPs. It represents a ''mandate first, evaluate later'' approach based on assumptions, speculation, and poor

[5] 17 CFR 4.7(a)(3)(ix) and (x). The portfolio test applies to certain legal entities and natural persons. Generally, the portfolio test is satisfied if the natural person owns securities of unaffiliated issuers and other investments with a market value of at least $2,000,000 (Securities Portfolio Test); has on deposit with an FCM for such person's account at least $200,000 in initial margin, option premiums, or minimum security deposits (Initial Margin and Premium Test); or owns a portfolio of funds and assets that, when expressed as percentages of the first two thresholds, meet or exceed 100%. 17 CFR 4.7(a)(1)(v).

[6] Exemption for Commodity Pool Operators With Respect to Offerings to Qualified Eligible Participants; Exemption for Commodity Trading Advisors With Respect to Qualified Eligible Clients, 57 FR 34853, 34854 (Aug. 7, 1992). To clarify, in respect of natural persons, the portfolio requirement does not facilitate the concurrent use of an exemption from registration under the Securities Act and the CFTC Regulation 4.7 exemption because the QEP status is not completely harmonized with the accredited investor status of the SEC.

[7] The NPRM also revises the timing of certain pools' periodic financial reporting, based on long-standing no-action letters, to permit funds of funds to provide account statements within 45 days of the month-end rather than 30 days of the quarter-end and makes technical adjustments to reorganize CFTC Regulation 4.7 to improve its structure and utility (*e.g.,* to fix cross-references).

[8] The Commission is proposing to update the portfolio requirement's thresholds by doubling the Securities Portfolio Test to $4,000,000 and the Initial Margin and Premium Test to $400,000.

[9] As originally proposed in 1992, the portfolio requirement had two components: (1) $5,000,000 in securities or (2) $1,000,000 deposited as initial margin and options premiums with an FCM for commodity interest trading. 57 FR at 34855.

[10] The new minimum standards will require the disclosure of principal risk factors, investment programs, use of proceeds, custodians, conflicts of interest, fees and expenses, and past performance, and the retention of disclosures as business records.

[1] This Statement will refer to the Commodity Futures Trading Commission as the ''CFTC'' or the ''Commission.''

[2] CFTC Rule 4.7, 17 CFR 4.7.

[3] Opening Statement of Commissioner Summer Mersinger Regarding CFTC Open Meeting on June 7, 2023, section regarding Amendments to part 17 Large Trader Reporting Requirements Proposed Rule (June 7, 2023), available at *https://www.cftc.gov/PressRoom/SpeechesTestimony/mersingerstatement060723.*

[4] Dissenting Statement of Commissioner Summer K. Mersinger Regarding CFTC's Regulatory Agenda, section entitled '' 'Kicking the Can Down the Road' Rather than Working on Rulemaking Solutions'' (January 9, 2023), available at *https://www.cftc.gov/PressRoom/SpeechesTestimony/mersingerstatement010923.*

sourcing. It also fails to fulfill certain fundamental functions of sound notice-and-comment rulemaking.

Rule 4.7 in Brief

Rule 4.7 provides exemptions for registered CPOs and CTAs operating commodity pools and trading programs restricted to QEPs (''4.7 CPOs and CTAs'') from, among other things, disclosure, recordkeeping, and use-and-filing requirements that otherwise would apply pursuant to the CFTC's rules. The rationale for the exemptions is that QEPs are sufficiently financially sophisticated, and have sufficient leverage and resources, to protect their own interests when participating in such pools and trading programs.

As explained in the Proposing Release, the definition of a QEP is bifurcated into two categories: (1) those pool participants or advisory clients that need to satisfy a ''Portfolio Requirement'' to be considered a QEP; and (2) those that do not. The Portfolio Requirement, in turn, can be met by satisfying either a Securities Portfolio Test of $2 million or an Initial Margin and Premium Test of $200,000, or a combination of the two.[5]

The Commission is proposing to double the monetary thresholds of the Portfolio Requirement in the QEP definition to $4 million for the Securities Portfolio Test and $400,000 for the Initial Margin and Premium Test. This proposal is intended to account for inflation since Rule 4.7 was adopted in 1992.

The ''Mandate First, Evaluate Later'' Approach to Disclosures to QEPs Is Not Good Government

At the same time, the Commission also is proposing to narrow the scope of Rule 4.7 by eliminating a significant portion of the current disclosure exemptions available to 4.7 CPOs and CTAs, thereby imposing universal disclosure requirements to QEPs. This is a ''mandate first, evaluate later'' approach to regulation that I strongly oppose.

1. We May Already be Taking Care of the Stated Concern

The Proposing Release begins by observing that the number of 4.7 CPOs and CTAs, and the number of commodity pools and trading programs relying on Rule 4.7, have ballooned over the years.[6] It then states its primary justification for significantly narrowing the scope of the 4.7 exemptions by imposing universal disclosure requirements to QEPs as follows:

The definition of QEP in Regulation 4.7 encompasses a broad spectrum of market participants from large fund complexes and other institutional investors with significant assets under management to individuals with varying backgrounds and experience, each of which has vastly different resources available to insist upon the disclosure of information regarding the offered 4.7 pool or trading program and then to analyze whatever information is provided.[7]

Yet, this justification fails to consider that the increasing numbers of pools and trading programs relying on Rule 4.7, and of QEPs that may not have the wherewithal to protect their interests, may result from the erosion in the Portfolio Requirement's monetary thresholds due to inflation—which the Commission is now proposing to address. If the Commission appropriately adjusts the Portfolio Requirement thresholds for becoming a QEP to return them to levels comparable to when the Commission adopted the disclosure exemptions in Rule 4.7, then there is no logical reason why it should also eliminate those disclosure exemptions with respect to QEPs that still satisfy the new (higher) thresholds and are entirely capable of protecting their interests.[8]

In short: Before imposing universal disclosure requirements that many QEPs do not need, the Commission should evaluate whether adjusting the Portfolio Requirement, as it is proposing to do, will address its stated concern about differences between QEPs. As regulators, we should always evaluate first, and then, if appropriate, adopt regulations based on the results of that evaluation. This proposal's ''mandate first, evaluate later'' approach has it exactly backwards.

2. We Should Not Act Based on Speculation and Assumptions

Another rationale the Proposing Release offers for imposing universal disclosure requirements to QEPs is that ''the Commission has . . . witnessed a significant expansion and growth in the complexity and diversity of commodity interest products offered to QEPs via 4.7 pools and trading programs,'' and ''product innovation in the commodity interest markets has continued at a rapid and unrelenting pace.'' [9] The primary examples cited are swaps and digital assets.

Yet, the Proposing Release offers no evidence to support its paternalistic conjecture that QEPs may not appreciate the nature of the risk associated with trading swaps in commodity pools and trading programs that rely on the exemptions in Rule 4.7. And there is no logical reason why such swap trading should now require a significant narrowing of the exemptions in Rule 4.7 more than a decade after Congress enacted a full regulatory regime for swaps in the Dodd-Frank Act [10]—which the Commission has fully implemented. The Proposing Release does not cite to any provision of the Dodd-Frank Act or its legislative history suggesting Congress felt that the development of swap trading warranted a reconsideration of the scope of the exemptions provided by Rule 4.7 in general—or universal disclosure requirements to QEPs in particular.

As for digital assets and technological innovation, the Proposing Release recognizes that it is relying on mere speculation. It candidly acknowledges that: (1) ''Given the relatively recent development of digital assets, *it remains unclear* as to whether the underlying markets . . . are subject to market fundamentals similar to those of the traditional commodities''; and (2) ''As the financial system continues to experience a period of rapid evolution in the era of artificial intelligence and other technological advancements, the Commission expects to see continued development of novel investment products that . . . *may* in fact deviate from the typical operations of markets now subject to the Commission's oversight.'' [11]

Throughout the 30 years since Rule 4.7 was adopted, there has been a steady expansion of the number, complexity, and diversity of available derivatives products, and derivatives markets have undergone transformational changes resulting from technological innovation (none greater than the migration from open-outcry pit trading to all-electronic trading). Yet, through it all, there has never been any suggestion that the exemptions under Rule 4.7 needed to be significantly narrowed as a result.

We should not act based on what we don't know. More specifically, we should not impose universal disclosure requirements to QEPs based on speculation about hypothetical future developments. As markets continue to evolve and innovate as they always have done, we as regulators should evaluate first and then adopt regulations only as appropriate based on the results of that evaluation. Once again, this proposal has it exactly backwards.

3. The Justifications for Acting Now Are Poorly Sourced

Certainly, regulators must often act quickly when confronted with urgent circumstances. But that is hardly the case here.

The Proposing Release contains no indication that QEPs are clamoring for the Commission to require disclosures by 4.7 CPOs and CTAs. Indeed, one of the principal sources cited in support of the assertion that there is a problem that needs to be addressed is a roundtable—on CPO risk management practices—convened by CFTC staff way back in 2014.[12]

Other support for the claim that the Commission needs to act consists of footnote citations to individual cases of alleged wrongdoing by 4.7 CPOs and CTAs. These footnotes cite news clippings reporting on allegations in deposition testimony, statements of litigation counsel, and litigation documents—with no indication whether these allegations were proved to be true.[13] And in some of the cases, it appears

[5] *See* Proposing Release at 7–9.

[6] *See id.* at 5–6.

[7] *Id.* at 16.

[8] The analysis of costs and benefits in the Proposing Release suggests that there is reason to believe the proposal to increase the Portfolio Requirement's monetary thresholds may take care of the stated concern based on differences in QEPs' ability to protect their interests. It states: ''To the extent persons who meet the higher Portfolio Requirement thresholds are (on average) more financially sophisticated or resilient than those who no longer qualify, this proposed amendment [to increase the Portfolio Requirement thresholds] should result in individuals and entities, both QEPs and non-QEPs, being offered pools and trading programs that are regulated in a manner commensurate with their respective needs for customer protection.'' Proposing Release at 66–67.

[9] *Id.* at 19, 20.

[10] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010) (''Dodd-Frank Act'').

[11] Proposing Release at 21 (emphases added).

[12] *See id.* at 16–17.

[13] *See id.* at 17–18 n.46–47. Footnote no. 46 also cites to a CFTC reparations case from 2018 that

that the 4.7 CPO or CTA was alleged to have committed fraud, or violated the Commission's existing requirement ''to provide all disclosures necessary to make information provided, in the context in which it is furnished, not misleading.'' [14]

Overall, the sourcing in the Proposing Release is woefully insufficient to support a proposal to impose universal disclosure requirements to QEPs on 4.7 CPOs and CTAs. There is no reason the Commission cannot undertake a proper evaluation of whether there really is a problem that needs to be addressed and, if so, the appropriate means to address it.

The Commission has a variety of tools at its disposal to undertake such an evaluation. For starters, our staff could convene a roundtable specifically devoted to this issue, so that the Commission would not have to look to comments at a roundtable in another context that occurred nine years ago. The Commission or staff also could issue a Request for Comment or an Advance Notice of Proposed Rulemaking—both tools that have been utilized recently [15]—in order to evaluate the necessity of taking action (and what action might be appropriate to take).

In sum: Given its poor sourcing, the proposal to impose universal disclosure requirements to QEPs is a solution in search of a problem. The Proposing Release fails to justify its ''mandate first, evaluate later'' approach. The Commission should evaluate first, and act later based on that evaluation, if appropriate, consistent with established principles of good government.

The Proposal Fails To Fulfill Fundamental Functions of Sound Rulemaking

A sound notice of proposed rulemaking is characterized by, among other things: (1) transparency as to the agency's plans; and (2) requests for comment on key issues. This Proposing Release is deficient on both counts.

1. The Commission Should Be Fully Transparent About Its Plans

The Proposing Release is not fully transparent about the Commission's plans on two key issues.[16] First, it says little about how the proposed amendments to Rule 4.7 would be implemented. This is especially critical with respect to the proposed increases to the Portfolio Requirement monetary thresholds, which would create a class of pool participants and advisory clients that qualify as QEPs under existing Rule 4.7, but would no longer qualify as QEPs under amended Rule 4.7.

Would these ''former QEPs'' be permitted to make additional investments in commodity pools and trading programs that are exempt under Rule 4.7 and in which they currently are investing? The Proposing Release explains that it would continue the requirement of existing Rule 4.7(a)(3) [17] that a CPO must assess QEP status at the time of sale of a pool participation, and that a CTA must do so at the time the person opens an exempt account.[18] But it does not explain that, as a result, ''former QEPs'' would not be able to make additional investments in exempt commodity pools they are currently participating in (although they could make additional investments to trading programs in these circumstances).

I appreciate the rationale of existing Rule 4.7(a)(3) with respect to a participant in an exempt commodity pool whose financial resources drop below QEP thresholds. But I am not sure that same rationale should apply where a participant drops below QEP thresholds because the Commission is ''moving the goalposts'' by increasing those thresholds. I imagine there may be QEPs that are comfortable with their 4.7 CPOs, pleased by the performance of the 4.7 exempt pools in which they are participating, and satisfied with the information disclosures they have received—and that would like to be able to contribute additional funds to those investments.

The Commission should be forthright that the proposal would deny them this opportunity if they fall on the wrong side of the increased thresholds being proposed, and seek comment from potentially affected QEPs specifically on that issue. To shroud the issue in mystery in the Proposing Release is inconsistent with sound notice-and-comment rulemaking.

Second, the Proposing Release does transparently reveal that the CFTC would use universal disclosure requirements to QEPs imposed on 4.7 CPOs and CTAs as ''an additional level of oversight'' by ''incorporating the review of [the new mandatory disclosures] into existing examination processes used by the Commission . . .'' [19] What it does not reveal, however, is where the Commission plans to find the resources for ''an additional level of oversight'' by reviewing the disclosures that would be required of the approximately 1700 CPOs and CTAs that rely on Rule 4.7 with respect to thousands of commodity pools and trading programs.[20]

What Commission programs or functions will have to be cut or curtailed in order for it to perform this new task? The public is entitled to know whether the CFTC's review of required disclosures to QEPs that are capable of protecting their own interests may come at the expense of, say, reductions in enforcement resources to prosecute those who defraud retail customers, or the Commission's oversight of derivatives exchanges and clearinghouses for which we are responsible by statute. But once again, the Proposing Release is silent.[21]

2. Putting the ''Comment'' Back in ''Notice-and-Comment'' Rulemaking

It is somewhat startling how few questions the Proposing Release asks regarding its proposed amendments to Rule 4.7. Most notably, it does not even request comment on the foundational question of whether universal disclosure requirements to QEPs are needed. As discussed above, the Commission's justifications for the proposed requirements are poorly sourced and based largely on assumptions and allegations—but the Proposing Release does not ask the public if those assumptions and allegations are accurate.[22] It appears that the Commission has already made up its mind that universal disclosure requirements to QEPs are necessary, and is not interested in whether QEPs, other market participants, or the public agree with that.

Nor does the Proposing Release ask: (1) whether current QEPs that fall below the increased Portfolio Requirement monetary thresholds for QEP status should be permitted to make additional investments in a commodity pool exempt under Rule 4.7; or (2) whether reviewing mandatory disclosures to QEPs that are able to protect their own interests is an appropriate use of the Commission's limited resources.

Accordingly, since the Commission declines to ask these questions, I will. I invite comment—especially, but not exclusively, from QEPs—on the following questions regarding the amendments that the Commission is proposing to Rule 4.7:

1. Do QEPs agree that the Commission should impose universal disclosure requirements on 4.7 CPOs and CTAs? Why or why not?

2. Is the Commission correct in its preliminary belief that universal disclosure requirements to QEPs are necessary to address unequal bargaining power of QEPs? Would they be necessary if the Commission's proposed increases to the Portfolio Requirement monetary thresholds in the QEP definition are adopted?

3. Is the Commission correct in its preliminary belief that universal disclosure requirements to QEPs are necessary in light

resulted in a default judgment and thus was not litigated.

[14] CFTC Rules 4.7(b)(2) (CPOs) and 4.7(c)(1) (CTAs), 17 CFR 4.7(b)(2), 4.7(c)(1).

[15] *See* Request for Comment on the Impact of Affiliations on Certain CFTC-Regulated Entities (June 28, 2023), available at *https://www.cftc.gov/PressRoom/PressReleases/8734-23,* and Risk Management Programs for Swap Dealers, Major Swap Participants, and Futures Commission Merchants, 88 FR 45826 (July 18, 2023), respectively.

[16] One of the Commission's Core Values is ''Clarity,'' *i.e.,* ''Providing transparency to market participants about our rules and processes.'' *See* The Commission, CFTC Core Values, Clarity, available at *https://www.cftc.gov/About/AboutTheCommission.*

[17] CFTC Rule 4.7(a)(3), 17 CFR 4.7(a)(3).

[18] Proposing Release at 12.

[19] *Id.* at 26 and 23, respectively.

[20] *See id.* at 5–6 (citing statistics).

[21] The Commission also should be more transparent about the estimates in its analysis required by the Paperwork Reduction Act (''PRA''). The Proposing Release estimates the annual burden hours per response of the disclosures proposed to be required of 4.7 CPOs and CTAs to be 1.5 hours. *See* Proposing Release at 56 (CPOs) and 59 (CTAs). But the Proposing Release does not explain how it arrived at this estimate—which strikes me as very low.

[22] After presenting its justifications for imposing universal disclosure requirements to QEPs, the Proposing Release ''requests comment on all aspects of the proposed amendments *outlined below* that would require certain information be disclosed to prospective QEP pool participants and advisory clients under Regulation 4.7 . . .'' Proposing Release at 27 (emphasis added). That is, the Proposing Release requests comment on the disclosures to QEPs ''outlined below'' that it is proposing to require of 4.7 CPOs and CTAs—but not on the *preceding* discussion of whether universal disclosure requirements to QEPs are needed in the first place.

of significant expansion and growth in the complexity and diversity of commodity interest products offered to QEPs via 4.7 pools and trading programs, and in light of the rapid pace of innovation in the commodity interest markets?

4. Is the Commission correct in its preliminary belief that the development of markets for swaps and digital assets necessitates universal disclosure requirements to QEPs?

5. Are there alternative, more tailored, means by which the Commission could achieve its policy objectives than the universal disclosure requirements to QEPs that it is proposing? If so, please describe.

6. Should QEPs under existing Rule 4.7 that would no longer qualify as QEPs under the proposed amendments to the Portfolio Requirement thresholds in Rule 4.7 be permitted to contribute additional funds to exempt commodity pools operated by 4.7 CPOs in which they currently are participating? Why or why not?

7. Should the Commission impose universal disclosure requirements to QEPs that are capable of protecting their own interests in order to incorporate the review of such disclosures into its existing examination processes if such review comes at the expense of other Commission responsibilities? Why or why not?

8. To what extent will the proposed universal disclosure requirements to QEPs impact the benefits that 4.7 CPOs and CTAs derive from relying on the exemptions in Rule 4.7? Is it likely that 4.7 CPOs and CTAs will decide to no longer rely on the remaining exemptions afforded by Rule 4.7 if the proposed universal disclosure requirements to QEPs are adopted?

9. If a 4.7 CPO or CTA is registered as an investment adviser with the SEC and not subject to an exemption regarding disclosures required by the SEC, should the CFTC accept compliance with disclosures required by the SEC as sufficient to satisfy the proposed universal disclosure requirements to QEPs under Rule 4.7, too?

10. Is the Commission's PRA estimate of 1.5 annual burden hours per response for the disclosures proposed to be required of 4.7 CPOs and CTAs appropriate? If not, what would be an appropriate estimate?

Conclusion

Given my support for certain aspects of this proposal, and given my support for obtaining public input on initiatives to improve our rulebook generally, I wish that I could support the issuance of the Proposing Release. Unfortunately, because of its ''mandate first, evaluate later'' approach to the issue of disclosures to QEPs by 4.7 CPOs and CTAs, and its serious omissions in transparency and requests for comment, I cannot do so. Accordingly, I respectfully dissent.

Appendix 4—Concurring Statement of Commissioner Caroline D. Pham

I respectfully concur on the Notice of Proposed Rulemaking Regarding Commodity Pool Operators, Commodity Trading Advisors, and Commodity Pools Operated under Regulation 4.7: Updating the ''Qualified Eligible Person'' Definition; Adding Minimum Disclosure Requirements for Pools and Trading Programs; Permitting Monthly Account Statements for Funds of Funds; Technical Amendments (CPO/CTA NPRM), because I am concerned that the proposed changes for commodity pool operators (CPOs) and commodity trading advisors (CTAs) offering to or advising sophisticated clients, or ''qualified eligible persons'' (QEPs), are burdensome and unnecessary for entities that are already subject to extensive CFTC regulation or banking, securities, insurance, or other financial services regulation.[1] I thank staff in the Market Participants Division for their engagement with my office on the CPO/CTA NPRM.

I reiterate the concerns in my prior dissent on the CFTC's proposed amendments to Form PF.[2] This CPO/CTA NPRM, like the CFTC's proposed amendments to Form PF, seem to impose overly broad obligations that would be burdensome and unnecessary for sophisticated clients, and would present operational challenges and costs without a persuasive cost-benefit analysis under the Commodity Exchange Act.

In a time of economic challenges, including rising inflation, we must be careful when considering proposals that could inhibit positive economic activity that supports American businesses and jobs. I look forward to hearing from commenters as to the proposed amendments, including practical implementation issues and the relative costs and benefits of the proposal.

[FR Doc. 2023–22324 Filed 10–11–23; 8:45 am]

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[1] *See* Exemption for Commodity Pool Operators with Respect to Offerings to Qualified Eligible Participants; Exemption for Commodity Trading Advisors with Respect to Qualified Eligible Clients, 57 FR 34853 (Aug. 7, 1992).

[2] *See* Dissenting Statement of Commissioner Caroline D. Pham Regarding the Proposed Amendments to Form PF, U.S. Commodity Futures Trading Commission (August 10, 2022), *https://www.cftc.gov/PressRoom/SpeechesTestimony/phamstatement081022*.

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