CHAPTER 86 – RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY

SUBJECT: **Compliance Testing of Radiation Emitting Electronic Products at Winchester Engineering & Analytical Center (WEAC)**	IMPLEMENTATION DATE 01/01/2023
	COMPLETION DATE 01/01/2023

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
For specific product codes please refer to product code builder: http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm See Product Codes Search Engine for All Radiation-emitting Electronic Products: http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/PerformanceStandards/ucm135508.htm	86006A Microwave Ovens 86006D Diagnostic X-ray Equipment 86004 Cabinet X-ray Equipment 86006E Non-Medical Lasers 86006G Sunlamps and Sunlamp Products

This compliance program supersedes the following compliance program:
CPGM 7382.006: Compliance Testing of Electronic Products at WEAC, dated September 30, 1994

Copies of specific product inspection and field test checklist and forms are included by reference in Compliance Program (CP) 7386.001 Inspection and Field Testing of Radiation Emitting Electronic Products, Attachments B – D.

WEAC AND CDRH REPORTING REQUIREMENTS

1. Copies of the following documents should be sent electronically to the CDRH Document Control Center at dccradhealth@fda.hhs.gov:

   - Analytical Worksheet, endorsed Sample Summary and Collection Reports
   - Field test reports and documentations, etc.
   - Establishment Inspection Reports (EIR), FDA-483, including attachments and exhibits are reported electronically through ORA procedure before assigning to CDRH.

2. WEAC will identify and track samples, record work results and sample disposition, through the Field Accomplishments and Compliance Tracking System (FACTS), per ORA procedure.

3. WEAC will report to CDRH on progress of ongoing testing of electronic product samples, and sample disposition of the loaned samples, as needed.

4. CDRH will notify WEAC about regulatory action taken pursuant to violative laboratory sample reports.

Table of Contents for Compliance Program 7386.006

PART I - BACKGROUND

The Federal Food, Drug and Cosmetic Act, Subchapter C – Electronic Product Radiation Control Act (the Act) and subsequent regulations are intended to safeguard the public from radiation hazards associated with electronic products. In addition to general requirements directed towards all electronic products capable of producing hazardous radiation, the Act authorizes the Center for Devices and Radiological Health (CDRH) to promulgate performance standards imposing additional requirements on specific electronic products of special concern from a radiation safety standard point. Performance standards have been issued for the products listed in 21 CFR 1020 through 1050.

Certain radiation-emitting electronic products and devices are tested at the FDA's Winchester Engineering and Analytical Center (WEAC) to determine their compliance with the applicable performance standards. WEAC's Engineering Branch performs analyses of electronic products and medical devices which range in complexity from thermometers, optical lenses, and surgical and examination gloves, to apnea monitors, infusion pumps, diagnostic x-ray equipment, laser products, microwave ovens, sunlamps, ultrasonic therapy, and so on. Violative findings provide the foundation for various compliance actions, all of which aim to protect the public from hazardous or unnecessary radiation exposure from radiation-emitting electronic products.

WEAC receives device samples for testing from various sources. Device samples may include devices implicated in a death or injury, devices collected during inspections of manufacturers, suspected quack devices collected by the Office of Criminal Investigations (OCI), import samples, or samples from other sources. Seizures, injunctions, criminal prosecutions, induced recalls, automatic detention, follow-up site inspections, and delayed or denied premarket approvals or 510(k)s for new devices are all potential regulatory actions that can ultimately result from violative findings in laboratory analysis.

WEAC's Engineering Branch also performs analysis of electronic products under the provisions of the Act. This work includes measurement of microwave ovens for actual and potential microwave radiation leakage, measurement and evaluation of laser product compliance, measurement of the ultraviolet component of sunlamps as well as the functionality of their safety timers, etc. The latter analyses are particularly important in light of studies indicating that the thresholds for development of malignant melanomas from ultraviolet radiation exposure from sunlamps and sunlamp products may be lower than previously thought. Some product samples tested at WEAC are subject to both medical device and electronic product regulations.

Diagnostic x-ray machines, including mammography machines, are evaluated for radiation safety as well as adherence with technical claims made for the device. Laser products and ultrasonic therapy devices undergo similar evaluations for radiation safety and device performance.

As part of the Agency's efforts to protect the public from dangerous emission of radiation from laser products, WEAC staff also performs inspections and investigations of manufacturers, trade exhibitions, and laser light shows. Inspections are also domestically and internationally conducted at laser and microwave oven manufacturing facilities.

PART II - PROGRAM / IMPLEMENTATION

A. OBJECTIVES

This is a continuing, non-statistical compliance program intended to:

1. Conduct laboratory testing of electronic radiation-emitting products.
2. Determine whether electronic radiation-emitting products meet applicable radiation Performance Standards as defined in the Act.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. WEAC responsibilities include:

   a) Receive samples for testing from multiple sources, including manufacturers on a loan basis, import sample collections, field investigation, inspection, consumer product complaint reports, Medical Devices Report (MDR) submitters, MEDWATCH submitters, Accidental Radiation Occurrence (ARO) submitters.
   b) Purchase samples for testing.
   c) Complete sample collection reports as products arrive.
   d) Conduct laboratory tests of electronic products.
   e) Conduct destructive/endurance testing, when necessary, after consultation with CDRH.
   f) Return loaned samples (Laboratory Class 1 and 2 only) to manufacturers upon completion of testing, with CDRH concurrence.
   g) Retain non-compliant Laboratory Class 3 samples in custody pending CDRH's direction.
   h) Coordinate sample collections with the Office of Import Operations (OIO) and the Office of Medical Devices and Radiological Health Operations (OMDRHO) at the ORA.

2. CDRH responsibilities include:

   a) Monitor noncompliance trends for radiation-emitting products subject to the U.S. performance standards.
   b) Coordinate with WEAC on obtaining samples of radiation-emitting products from manufacturers or importers.
   c) Coordinate with WEAC on obtaining samples from import detention, investigation, inspection, consumer complaint, Medical Device Reporting (MDR) submitter, MEDWATCH submitter, Accidental Radiation Occurrence (ARO) submitter and other sources.
   d) Assist WEAC in preparing for inspections of manufacturers, such as preparing lists of manufacturers, contact information, addresses, compliance status/history, etc.
   e) Issue administrative and regulatory actions to manufacturers and importers. CDRH actions against manufacturers/importers may include additional information letters, Notification of Defect or Failure to Comply Letters, Program Disapprovals, civil penalties, Warning Letters, Untitled Letters.

f) Provide periodic status reports on noncompliance trends, listing of unresolved non-compliances and special reports upon request by the ORA.
g) Provide ORA/OMDRHO and WEAC with information concerning the manufacturer's corrective action plans for the noncompliance.
h) Advise ORA and WEAC of legal opinions, interpretations of laws, regulations, and testing procedures, including those compliance cases, and advisory opinions which impact on their responsibilities in testing radiation emitting electronic products under U.S. Federal performance standards.
i) Monitor and evaluate test records, assignments, and correspondence relating to this compliance program to identify trends or problems with the program.
j) Resolve specific program questions with ORA and WEAC as soon as they are identified.

3. OMDRHO responsibilities include:

a) Serve as subject matter experts on program operations in sample collections of radiation-emitting electronic products and medical devices in radiological health.
b) Provide advice and counsel in collecting samples and associated operations including emergency response activities to CDRH and WEAC.
c) Support the development of policy and guidance for compliance testing of radiation-emitting electronic products at WEAC.
d) Monitor emerging issues and advancements in technology and recommend program improvements for compliance testing at WEAC as necessary.
e) Develop and maintain cooperative relationships with WEAC and CDRH.

4. OIO responsibilities include:

a) Provide direction, assistance, management, and oversight of sample collections in field import operations, including conducting field investigations and compliance activities.
b) Serve as the Agency focal point for headquarters/field relationships on all import programs, operations, and problems.
c) Coordinate sample collections in the Agency's import activities with the U.S. Customs and Border Protection, including procedures, policies, and operations, as well as coordinating activities with other Federal agencies and foreign governments with border responsibilities through inter-Agency agreements, memoranda of understanding, and informal working relationships.
d) Provide subject matter expertise and direction for the development of import policies and new import procedures regarding sample collections.
e) Coordinate with ORA Office of Policy, Compliance and Enforcement to provide support and direction for designated compliance and recall operations that cut across programs regarding sample collections.
f) Develop and maintain cooperative relationships with WEAC and CDRH.

PART III - INSPECTIONAL

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PART IV - ANALYTICAL

1. Analyzing Laboratory: WEAC

2. Analyses to be Conducted

Receiving, handling, custody and disposition of electronic products follow the procedures in the referenced laboratory procedure:

ORA Laboratory Manual, Volume III, Section 2, "Chain of Custody – Sample Handling"

https://www.fda.gov/media/74006/download

3. Methodology - Laboratory Test Procedures

Sample analysis and testing is performed in accordance with documented WEAC laboratory test procedures.

4. Reporting

Provide CDRH with a completed Analyst Worksheet and properly endorsed sample summary after testing following ORA/WEAC procedure.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

WEAC receives samples for testing from various sources and performs the laboratory tests and analysis. CDRH is responsible for the final review of the laboratory tests and analysis made under this program and for the issuance of administrative or regulatory actions. For non-compliant radiation-emitting products, CDRH, with the awareness of the appropriate ORA Division Compliance Branch, will determine what regulatory actions and enforcement strategy are needed to bring the products back into compliance and/or remove products from the U.S. marketplace that pose a risk to public health. Exceptions where ORA Divisions have direct reference authority in certain areas are noted in Chapter 4 of the Regulatory Procedures Manual (RPM). CDRH is available for consultation in assessing product noncompliance or developing regulatory and enforcement strategy. Appropriate administrative or regulatory actions that may be taken, but not limited to, are:

- Issuance of a notification of non-compliance letter or defect (warning or untitled letter)
- Regulatory meeting
- Additional information request email/letter
- Concern notification email/letter
- Phone call or teleconference
- Recommendation for a follow-up inspection
- Detention upon entry or recommendation for import alerts
- Repair or replacement of product under an approved corrective action plan
- Imposition of civil penalties and/or injunction
- Seizures

Appropriate follow-up actions should be determined by CDRH or in consultation with CDRH to ensure consistency in how requirements for radiation- emitting products are enforced. Notification letters can be combined with warning letters when an electronic product is also a medical device. To determine the appropriate regulatory action, the ORA Divisions (Direct Reference) and CDRH should consider test findings, public health significance of objectionable conditions, firm's history, firm's responsiveness, and whether noncompliant issues are widespread and continuing.

Additional information for administrative or regulatory actions is provided in CPGM 7386.001, Part V - Regulatory Philosophy and Strategy.

PART VI - REFERENCES, ATTACHMENTS AND PROGRAM CONTACTS

A. REFERENCES

1. Subchapter C Electronic Product Radiation Control of Chapter V of the Federal Food, Drug, and Cosmetic Act

   https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-v-drugs-and-devices

2. Title 21 Code of Federal Regulations, Subchapter J. Radiological Health

   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=1000&CFRPartTo=1050

3. Summary of The Electronic Product Radiation Control Provisions of The Federal Food, Drug, And Cosmetic Act

   https://www.fda.gov/radiation-emitting-products/laws-and-regulations-radiation-emitting-products/summary-electronic-product-radiation-control-provisions-federal-food-drug-and-cosmetic-act

4. FDA Regulatory Procedures Manual, Chapter 7, Attachment F and Chapter 6

   https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual

5. Compliance Policy Guide 7133.23, Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products

   https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073913.htm

6. Investigations Operations Manual (IOM)

   https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual

7. Regulatory Procedures Manual (RPM)

   https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual

8. ORA Laboratory Manual, Volume III, Section 5, “Analysts on Inspection”

https://www.fda.gov/science-research/field-science-and-laboratories/field-science-laboratory-manual

9. Forms - https://www.fda.gov/about-fda/reports-manuals-forms/forms

10. Field Science - Laboratory Manual

    https://www.fda.gov/science-research/field-science-and-laboratories/field-science-laboratory-manual

11. LM Contact

    https://www.fda.gov/science-research/field-science-laboratory-manual/lm-contact

12. ORA home page

    https://www.fda.gov/about-fda/office-global-regulatory-operations-and-policy/office-regulatory-affairs

13. Electronic Product Radiation Control home page

    https://www.fda.gov/Radiation-EmittingProducts/default.htm

B. PROGRAM CONTACTS

Office of Regulatory Affairs (ORA)

See ORA Directory for contact information for ORA Headquarters and Field Offices:
https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/contactora/default.htm

U.S. Food & Drug Administration
Winchester Engineering & Analytical Center (WEAC)
109 Holton Street, Winchester, MA 01890
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Phone: (781)756-9700
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WEAC management: https://fda.sharepoint.com/sites/insideFDA-ORA-Labs/SitePages/WEAC.aspx

Center for Devices and Radiological Health

CDRH management structure and contact information:
https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffice

s/ucm127854.htm

Contact CDRH at RadHealth@fda.hhs.gov for support in planning and executing inspections and field tests, classification of items of non-compliance, and for interpretation and current policy on EPRC requirements.