

The requests below identify statutory triggers and ask HHS to clarify them and preserve a transparent record if later action relies on this inquiry.

1. Authority, lead component, and scope. The notice says it is conducted under "21 CFR subpart J" without identifying a part or section. FDA describes the electronic-product radiation regulations as 21 C.F.R. Chapter I, Subchapter J (Radiological Health). Please correct the citation, identify the specific statutory authority for each contemplated output, identify the HHS component responsible for exercising each relevant function, and identify any applicable delegation or internal assignment of responsibility between OASH and FDA/CDRH. Distinguish general public-health research under 42 U.S.C. § 241 from the electronic-product radiation-control program under 21 U.S.C. §§ 360ii-360kk and from any development of binding performance standards.

2. Section 360ii coordination. Please identify the federal/state agencies and relevant professional, industry and labor organizations with which HHS has maintained liaison or consulted in developing this inquiry, particularly as to measurement/testing and standards. For each, identify the subject and approximate date of consultation, the relevant issue addressed, and whether substantive input will be reflected in the evidence synthesis. A non-confidential summary is sufficient where underlying communications are protected.

3. Section 360jj threshold. Is this RFI, or any report planned from it, intended to perform, update or support any study described in 21 U.S.C. § 360jj(a), including studies concerning existing federal/state controls and gaps, the need for specified commercial/industrial standards, or measurement procedures? If yes, identify the applicable subsection, participating/invited agencies and organizations, and whether a report to Congress is contemplated. Please explain how HHS will preserve any dissenting view for inclusion where § 360jj(c) applies and the dissenter requests it. If not, please clarify why the work is not being conducted as one of those statutory studies.

4. Section 360kk contingency. Does HHS contemplate that this inquiry or a resulting assessment may be used to develop, amend or support electronic-product performance standards under 21 U.S.C. § 360kk? If yes, please identify the intended statutory pathway and explain how HHS will document consultation with relevant federal/state agencies, professional organizations and affected interests, and consideration of the factors enumerated in § 360kk(a)(1). Before prescribing a standard, § 360kk(f) requires consultation with the Technical Electronic Product Radiation Safety Standards Committee; please identify the process HHS would follow. If no standard development is contemplated, please state that the RFI itself does not change existing standards.

5. Scientific synthesis and peer review. Will HHS use a systematic review protocol? Please identify or publish search sources/dates, inclusion/exclusion criteria, outcomes, risk-of-bias methods, treatment of null/contradictory studies, protocol deviations, and methods for distinguishing biological response, adverse health outcome, association and causation. Will HHS determine whether any proposed synthesis is

"influential scientific information" or a "highly influential scientific assessment" under applicable OMB/HHS peer-review policies? If so, please identify the required peer-review process and disclose the plan and results to the extent required by those policies.

6. Exposure categories and measurement. Please separate power-frequency fields from RF, and distinguish product emissions, consumer-device exposure, occupational exposure, communications infrastructure and environmental exposure. For each, identify applicable metrics, frequency bands, exposure pathways, dosimetry/measurement methods, uncertainty and whether evidence is measured, modeled or self-reported. For cumulative exposure, identify any validated aggregation model and justify additivity or dose-equivalence assumptions.

7. Information quality, advisory groups and records. If HHS disseminates a synthesis or assessment, please identify the applicable HHS Information Quality Guidelines, correction mechanism, and peer-review status. If a covered external advisory committee provides collective advice, identify the applicable FACA charter, membership and public-record process. Please preserve records documenting the scope, authority, scientific methods and interagency coordination consistent with 44 U.S.C. § 3101 and applicable records schedules.

8. Publication and future process. Please publish a non-confidential interagency coordination summary, the final review protocol, evidence tables and material limitations for any resulting assessment. Identify whether HHS intends merely to conduct research or issue nonbinding recommendations, or whether separate rulemaking may be considered. Nothing in this voluntary RFI substitutes for statutory consultation or any notice-and-comment procedure required for later binding action.

Requested. Please (1) correct the incomplete "21 CFR subpart J" citation and identify the actual statutory authority; (2) state whether this inquiry or its planned synthesis is being conducted under 21 U.S.C. § 360ii, any specified study in § 360jj(a), or a process that may support performance standards under § 360kk; (3) summarize applicable interagency consultations and the intended process for scientific assessment/peer review; (4) preserve the records required by applicable law; and (5) distinguish nonbinding research/recommendations from any separate binding action subject to its own statutory authority and procedures.

Respectfully submitted,