MEMORANDUM OF UNDERSTANDING
BETWEEN THE
U.S. FOOD AND DRUG ADMINISTRATION
AND THE
U.S. NUCLEAR REGULATORY COMMISSION

I. Purpose

The United States Food and Drug Administration (FDA) and the United States Nuclear Regulatory Commission (NRC) (each a "Party" and collectively "the Parties") agree to collaborate and coordinate on regulatory programs regarding (1) products that utilize byproduct, source, or special nuclear material; and (2) products that may be impacted by release of byproduct, source, or special nuclear material. This memorandum of understanding (MOU) establishes a framework for collaboration between FDA and NRC to facilitate information-sharing activities related to these products. This MOU does not impact the independence of the FDA and the NRC or either agency's authority to fulfill its responsibilities.

II. Authority

FDA has authority to enter into this MOU pursuant to section 1003 (c) of the Federal Food, Drug, and Cosmetic Act (21 USC 393(c)).

NRC has authority to enter into this MOU pursuant to section 161.c (42 USC 2201(c)) and 161.f (42 USC 2201(f)) of the Atomic Energy Act of 1954, as amended (42 USC 2201).

III. Background

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and the safety of the nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA advances the public health by supporting the development of innovative technologies that help to make medical products safer and more effective and available to more patients. As a part of the goal of protecting the public health by ensuring the safety of (a) products that utilize radioactive byproduct, source, or special nuclear material, and/or (b) products that may be impacted by the release of byproduct, source, or special nuclear material (together, hereinafter, "the products covered under this MOU"), FDA seeks to coordinate and collaborate with NRC, and to share information, where appropriate.

NRC is tasked with licensing and regulating nuclear facilities and material, and for conducting research in support of the licensing and regulatory process, as mandated by the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and in accordance with the National Environmental Policy Act of 1969, as amended, and other applicable statutes. The NRC's responsibilities include protecting public health and safety, protecting the environment, and safeguarding materials to ensure the common defense and security.

FDA and NRC have a mutual regulatory interest in the products covered by this MOU that are the subject of the parties' regulatory, research, and review activities.

IV. Substance of Agreement

Under this MOU, the Parties may seek opportunities to participate in collaborative efforts, in furtherance of their respective objectives and as permitted under appropriate statutory authority and applicable law, as resources permit, to:

- Identify Point(s) of Contact: Each party will identify one or more point(s) of contact specific to the applicable regulatory program(s) to ensure that the agencies promptly exchange the information described below, to enable FDA and/or NRC to initiate appropriate compliance, follow-up, or other actions. Each agency will notify the other within 30 calendar days when there is a change in a point(s) of contact.

- Notify of Product Complaints, Allegations, Medical Incidents, or Emergencies: The NRC and the FDA agree to inform each other, as appropriate and permitted by law, as soon as possible, but no later than 30 calendar days whenever either agency identifies a significant product complaint, allegation, medical incident, or emergency that involves the products that are covered by this MOU or becomes aware through notification, inspection, or surveillance mechanisms at either agency of a significant potential public health problem such as a malfunction, failure, or medical incident involving a product covered by this MOU:

    - For purposes of this agreement, the term “complaint” means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of any product covered by this MOU.

    - For purposes of this agreement, the term “allegation,” means a declaration, statement, or assertion of impropriety or inadequacy associated with NRC-regulated activities of any product covered by this MOU, the validity of which has not been established.

    - For purposes of this agreement, the term “medical incident” means any undesirable experience associated with the use of a medical product.

    - For purposes of this agreement, the term “emergency” means a life-threatening situation.

- Conduct Inspections: The Parties may consider performing joint inspections or other collaborations when appropriate and as permissible by law, and as resources permit. Joint inspections or observer invitations can be requested or extended by either agency to ensure that information obtained from an inspection is collected, shared, and acted upon in a timely and coordinated manner. Both Parties will make reasonable efforts to accommodate such requests, pending availability of personnel and current FDA or NRC priorities. In addition, both Parties will discuss providing technical expertise for planning, performance, or review in areas of mutual interest, subject to program priorities and availability of funds and personnel.

- Conduct Investigations: FDA and NRC may assist each other to the extent appropriate and as permissible by law, and as resources allow, to investigate incidents, complaints, or other situations involving products covered by this MOU. Assistance will not interfere

with either agency's usual processes for reviewing notifications, investigations, and/or inspections.

- Notify NRC Licensees and Agreement States[1]: Upon request by the FDA, the NRC will promptly notify NRC licensees and Agreement State Program Directors of any public health issues or other important user communications initiated by the FDA and intended for public dissemination. This information could be the result of joint investigations or other activities involving products covered by this MOU.

- Review and Analyze Premarketing and Pre-Licensing Activities: To the extent permitted by Federal law and regulations, or by explicit permission from the owner of the information and to the extent agency time and resources permit, the FDA and the NRC may share information concerning jointly regulated products, new technology or methods under development or review, including devices for which regulations or the NRC's 10 CFR Part 35, Subpart K guidance(s) are being, or has not yet been, developed and that are of mutual regulatory interest.

  The Parties anticipate that the information they share may include, but is not limited to:

  - design, chemical, and physical form of the material;
  - manufacture/preparation;
  - prototype testing;
  - quality assurance and control;
  - labeling per regulatory requirements;
  - intended use;
  - safety analysis;
  - installation;
  - servicing;
  - leak testing;
  - operating instructions;
  - emergency/safety instructions;
  - status of regulatory reviews of mutual interest; and
  - information regarding licensing actions and marketing clearances or approvals and public announcements of these actions.

- Collaborate on Other Activities: If practicable, the FDA and the NRC will offer each other the opportunity to comment on notifications (*e.g.*, to manufacturers, operators, licensees, or patients) of mutual interest to the agencies. The FDA and the NRC may also offer each other the opportunity to comment on regulations, guidance, or other communications if practicable, that refer to activities, policies, or regulations of the other agency that are of mutual regulatory interest. If practicable, the documents will be provided prior to issuance.

[1] Pursuant to Section 274 of the Atomic Energy Act of 1954, as amended, Agreement States have entered into agreements with the NRC whereby the NRC has discontinued its regulatory authority for certain radioactive materials and regulatory authority for these radioactive materials has been assumed by the state.

V. Exchange of Non-Public Information

FDA and NRC intend for the following principles and procedures to govern the sharing of non-public information, as resources permit, between the two parties.

The FDA and the NRC recognize and acknowledge that information exchanged with FDA that contains any of the following types of information must be protected from unauthorized use and disclosure:

(1) confidential commercial or financial information, such as the information that would be protected or exempt from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA) (5 USC 552(b)(4));

(2) personal privacy information, such as the information that would be protected or exempt from public disclosure pursuant to Exemptions 6 or 7(C) of the FOIA (5 USC 552(b)(6) or (7)(C)); or

(3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 USC 1905)), the Privacy Act (5 USC 552a), other FOIA exemptions not mentioned above (5 USC 552(b)), information compiled for law enforcement purposes, such as information that would be protected or exempt from public disclosure pursuant to FOIA Exemption 7(E) (5 USC 552(b)(7)(E)), the FD&C Act (21 USC 301 et seq.), the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191), Section 319L(e) of the PHS Act (42 U.S.C. § 247d-7e(e)), and disclosure restrictions subject to 41 USC 2101- 2107 (Procurement Integrity Act) and 48 CFR 3.104 (Federal Acquisition Regulation).

Pursuant to sections 301(j), 520(c), 535(d), and 537(e) of the FD&C Act (21 USC 331(j), 360j(c), 263g(d), and 263i(e)), FDA will not reveal to any NRC representatives any information entitled to protection as a trade secret or confidential commercial or financial information relating to devices obtained by FDA under sections 513, 514, 515, 516, 518, 519, 520(f), 520(g), or 704 of the FD&C Act (21 USC 360c, 360d, 360e, 360f, 360h, 360i, 360j(f), 360j(g), 374). Trade secrets or confidential commercial or financial information obtained under the preceding sections will not be revealed unless there is in place a written authorization from the owner of the requested trade secret or confidential commercial or financial information that permits FDA to reveal such information to representatives of NRC. Such authorization may be obtained in the form attached as Appendix B to this MOU. In all cases, any written request submitted to FDA for confidential or other non-public information must contain all substantive requirements of 21 C.F.R. § 20.85.

The Parties will label all non-public information, including confidential and/or trade secret information, accordingly, and establish proper safeguards to ensure that information shared under this MOU shall be used and disclosed solely in accordance with applicable laws, regulations, and this MOU. Access to such information shared under this MOU shall be restricted to authorized employees, agents, and officials of FDA and NRC who require access to perform their official duties in accordance with the uses of information as authorized by this MOU. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information; and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws.

Contractors, their subcontractors, and/or agents requiring access to the information shared under this MOU will be required to sign an agreement by which they will commit to keep the information confidential and will be required to comply with the policies and procedures to ensure confidentiality. Except as otherwise permitted under this MOU, the Parties agree that information shared pursuant to this MOU will not be further disclosed without the written permission of the sharing Party or as required by law with advance notice to the originating Party. In the event further disclosure is required by law, the disclosing Party shall consult with the sharing Party prior to such disclosure. For example, the disclosing Party will notify the sharing Party before responding to any judicial order that compels the release of shared non-public information, so that the Parties may determine the appropriate measures to take, including, where appropriate, legal action.

Additionally, all federal agencies and contractors supporting FDA and NRC must comply with the security requirements set forth in the Federal Information Security Management Act (FISMA), E-Government Act of 2002 (Pub. L. 107-347, 116 Stat. 2899, 44 USC § 3541 et seq., by implementing appropriate security controls.

The Parties agree to notify each other within 30 calendar days of any actual or suspected unauthorized disclosure of information shared under this MOU.

The Parties agree to follow their existing FOIA processes, including those governing consultation and referral. If a Party that has received information shared under this MOU receives a FOIA request for information shared by the other Party pursuant to this MOU, the receiving Party will refer the request to the information-sharing Party for that latter agency to respond directly to the non-Party requestor regarding the release of the information and whether it is releasable. In such cases, the Party making the referral will notify the non-Party requestor that a referral has been made and that a response will be issued directly from the other Party. The receiving Party will leave to the sharing Party all final disclosure decisions concerning records received from the sharing Party, including decisions on whether the records are responsive and whether they must be disclosed. Accordingly, the receiving Party will not indicate to the FOIA requester whether the sharing Party has responsive records or releasable records.

The Parties agree to share information to the maximum extent possible in furtherance of the purposes of this MOU. However, each Party agrees that a Party may decide not to share information or expertise in response to a particular request made to or by the other Party for information, or to limit the scope of information and expertise shared in response to a particular request. A decision not to share information in response to a specific request may be based on several factors, including, for example, the amount of resources necessary to fulfill the request, the reasonableness of the request, the responding Party's priorities, or legal restrictions. The Parties further agree that a Party may on its own initiative elect to share information pursuant to procedures established above, to further the purposes of this MOU. In the event the Parties cannot reach consensus on a decision to share or not share information, the information is not required to be shared under this MOU.

The Parties agree that nothing in this MOU shall be construed to prevent a disclosure required by law or legal process. Notwithstanding this provision, the requesting Party will promptly notify the sharing Party before complying with any judicial order that compels the release of non-public information shared pursuant to this MOU, or any other attempt by a third party to obtain shared non-public information by compulsory process, including a subpoena, discovery request, or litigation complaint or motion, so that the Parties may determine the appropriate measures to

take, including, where appropriate, legal action (e.g., to provide an opportunity for the other Party to intervene in the legal proceeding and attempt to block the disclosure, if appropriate). This MOU does not prohibit disclosure of information that is available publicly or when authorized in writing by the information owner.

Nothing in this MOU shall be construed to prevent a Party from complying with an official request of the United States Congress, the Office of Inspector General, or the Government Accountability Office. The requesting Party will promptly notify the sharing Party of any attempt by Congress, the Office of Inspector General, or the Government Accountability Office, to obtain shared non-public information so that the Parties may determine the appropriate response and measures to take to protect the information from disclosure. The Parties shall consult before complying with any request to obtain shared non-public information, so that the Parties may determine the appropriate measures to take, including, where appropriate, legal action.

The Parties agree that termination of this MOU does not relieve them of their confidentiality obligations established under this MOU, including their obligations to safeguard and limit access to all information provided pursuant to this MOU.

This MOU does not address and has no effect on the application of, or compliance with any requirement or restriction on disclosure for national security purposes.

VI. General Provisions

This is an MOU between the FDA and the NRC wherein the Parties agree and understand that this MOU is non-binding and shall not create or give rise to any legally binding obligations upon the Parties to perform any activities or provide any funding. This MOU does not affect or supersede any other existing or future agreements or arrangements between the Parties. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Parties operate.

Neither this MOU nor any individual provision of this MOU shall be deemed to restrict, modify, or otherwise limit the application or enforcement of any laws of the United States with respect to matters specified herein, nor shall anything in the MOU be construed as modifying the existing authority of either agency.

VII. Resources

Each Party is responsible for all costs of its personnel, including pay and benefits, support, and travel. Each Party is responsible for supervision and management of its personnel.

VIII. Points of Contact

Name and Mailing Address of Participating Agencies

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

and

Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852-2738

IX. Points of Contact

All points of contact will establish and maintain a list of points of contacts within their organizations. These lists will designate specific persons for day-to-day contact on matters related to this MOU. These lists, with current work phone numbers and work email addresses, will be exchanged among the points of contact.

Points of contact are located in the following organizations:

A. For the Food and Drug Administration

Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993
Telephone: 301-796-5500

B. For the Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards
11545 Rockville Pike
Rockville, MD 20852
Telephone: 301-415-0595

Each Party may change its point of contact upon reasonable written notice to the other Party.

X. Effective Date, Duration, Termination

This MOU becomes effective upon the signature of authorized representatives of both Parties and remains in effect with an option to renew five years from the effective date, unless terminated or superseded. This MOU may be modified at any time by mutual written consent or terminated by either Party upon 90 calendar days written notice.

XI. Approval

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION

Jeffrey E. Shuren -S

Digitally signed by Jeffrey E. Shuren -S
Date: 2023.12.20 19:48:43 -05'00'

Jeffrey Shuren, M.D., J.D., Director — Date
Center for Devices and Radiological Health

APPROVED AND ACCEPTED FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Signed by Lubinski, John on 11/13/23

John W. Lubinski, Director — Date
Office of Nuclear Material Safety and Safeguards

OFFICAL RECORD COPY

APPENDIX A

Process for Information Sharing

Pursuant to Section V of the Memorandum of Understanding (MOU) entered into by the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Food and Drug Administration (FDA), "[t]he Parties agree to share information to the maximum extent possible in furtherance of the purposes of this MOU. However, each Party agrees that a Party may decide not to share information or expertise in response to a particular request made to or by the other Party for information or may decide to limit the scope of information and expertise shared in response to a particular request." Nothing in the process described below changes Section V.

When, under the current MOU, staff at the NRC or the FDA request from the other Party information that may contain confidential or other non-public material, the request should be in writing but can be made by email. The request need only identify the subject for which information is requested. Although a more specific description of the information requested may be helpful, it is not required for purposes of making a request. However, the following language should be included in the request:

> "Handling of information shared under this request will be governed by the terms of the 2023 FDA-NRC Memorandum of Understanding. We agree not to disclose any shared information except as provided therein."

With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing, but can be by email, that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it is not required for purposes of responding to a request. However, the following language should be included in the response:

> "Pursuant to the 2023 FDA-NRC Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. It may not be disclosed or shared in any manner except as provided by the 2023 FDA-NRC Memorandum of Understanding."

With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.

APPENDIX B

Confidentiality Commitment

The U.S. Nuclear Regulatory Commission (NRC) and the U.S. Food and Drug Administration (FDA), frequently coordinate interagency efforts and are responsible for, inter alia, researching, setting and enforcing standards and regulations to enable safe and effective medical device use in the United States. As part of participation in meetings, discussions, or other communications, I understand that I may be exposed to information that is trade secret, confidential commercial or financial information, personal privacy information, or pre-decisional or deliberative information that has been provided to, or belongs to, an agency or department that is a member of the collaborative group.

I, on this _____ day of _____, 20__, hereby agree that I shall not release, publish, or disclose such information, including disclosure in publications and public meetings, and I shall protect such information in accordance with all applicable laws relating to my receipt of non-public information in connection with my participation in NRC/FDA activities, and that I may be subject to disciplinary action and, in some cases, administrative, civil and/or criminal penalties as prescribed by law for unlawful disclosure of such information. I shall use such information in accordance with my official duties and shall share such information only with individuals who either (1) are employed by, or a contractor of, the originating government agency that provided the information to me or to my agency and are authorized to have access to the information by virtue of their duties, or (2) are employed by, or a contactor of, a collaborating agency and have themselves signed a Confidentiality Commitment.

Signature: _____
Date: _____
Type or Print Name: _____
Agency: _____
Supervisor Signature (if applicable): _____
Date: _____
Type or Print Supervisor Name: _____