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NRC AND FDA SIGN MEMORANDUM OF UNDERSTANDING

Dr. Ivan Selin, Chairman of the Nuclear Regulatory Commission, and Dr. David A. Kessler, M.D., Commissioner of the Food and Drug Administration, have signed a Memorandum of Understanding which coordinates the regulation of medical devices, drugs and biological products that use radioactive materials under the jurisdiction of the NRC.

In stressing the importance of the memorandum, Chairman Selin said: "Our aim in this action is to add to the protection of the public. Both the NRC and the FDA have responsibility for regulating medical devices and pharmaceuticals containing radioactive materials. This memorandum is designed to foster cooperation between our two agencies as well as to provide more effective exchanges of information."

"Devices, drugs and biological products that use radioactive materials can be important in medical treatments and can save lives," Dr. Kessler said. "However, it is vital that they be used safely."

The Food and Drug Administration is responsible for assuring the safety, effectiveness and proper labeling of medical products, i.e., drugs, devices and biologics. The Nuclear Regulatory Commission is responsible for licensing and regulating civilian nuclear facilities and materials and for conducting research in support of the licensing and regulatory process.

Under the terms of the Memorandum of Understanding, the NRC and the FDA will:

-- on request assist each other, to the fullest extent possible, in the investigation of incidents or complaints involving products of mutual regulatory concern;

-- exchange information with respect to investigations with the purpose of providing expert technical assistance to either agency and to assist either agency by reducing or eliminating any duplication of effort;

-- to the extent practicable, share information concerning new technology or methods under development or review, including devices, drugs or other biologics for which regulations have not yet been developed or which are related to the mission of the other agency;

-- offer each other the opportunity to comment on notifications to manufacturers, operators, licensees or patients and to comment on regulations, regulatory guides or other communications that refer to activities, policies or regulations of the other agency; and

-- make the other agency aware of and, to the extent possible, allow participation by a representative from the other agency in any advisory committee which advises on issues covered by the Memorandum of Understanding;

In addition, the NRC, on request, will promptly notify its licensees and the Agreement States (states which, by agreement, have assumed part of the NRC's regulatory authority) of any public health issues or other important user communications initiated by the FDA as the result of joint investigations or other activities involving products of mutual regulatory concern.

The Memorandum of Understanding covers only those medical devices, drugs and biological products using radioactive materials regulated under the Atomic Energy Act of 1954, as amended. The terms "drug" and "device" are defined in the Federal Food, Drug, and Cosmetic Act, as amended, and a "biological product" is either a drug or a device under the Act. Biological products are also regulated under the Public Health Service Act.

Medical devices affected include, but are not limited to: in vitro diagnostic kits (radioimmunoassay), teletherapy and brachytherapy sources, systems and accessory devices. Biologics include, but are not limited to: licensed in vitro diagnostic kits (radioimmunoassay) and certain radiolabeled biologics for in vivo use. Drugs include all those that contain radioactive materials derived from the operation of reactors (byproduct material).

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