FDA MOU Number: 225-12-0001
HERCA MOU Number: 2012/01

MEMORANDUM OF UNDERSTANDING BETWEEN THE HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES AND THE FOOD AND DRUG ADMINISTRATION CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

I. Purpose:

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) as part of the U.S. Department of Health and Human Services and the Heads of the European Radiological protection Competent Authorities (HERCA) share a mutual interest in promoting initiatives related to radiation protection from CT medical imaging. Both FDA and HERCA are referred to individually as a "Party" and collectively as the "Parties." This Memorandum of Understanding (MOU) provides a framework for coordination and collaborative efforts between the Parties.

II. Background:

1. FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. § 301). In fulfilling its responsibilities under The Act, FDA among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, biological products, veterinary products, medical devices and radiological products and the safety and security of foods and cosmetics. To accomplish its mission, FDA must stay abreast of developments regarding medical imaging and communicate with stakeholders about important public health issues. Enhancing cooperation and communication regarding radiation projects will greatly contribute to the FDA's mission.

2. HERCA is a voluntary association between the Heads of the European Radiological protection Competent Authorities in European countries.[1] The objectives of the association are: to build and maintain a network of chief radiation safety regulators in Europe; to promote the exchange of experience and learning from each other's best practices; to discuss, and where appropriate, express its consensus opinion on significant regulatory issues; to develop, by consensus whenever possible, a common approach to radiological protection issues and to have an impact on the practice of radiological protection within the States of HERCA members. Its fields of

[1] By the date of signature of this agreement, 46 radiation protection authorities from 28 European countries officially participate in HERCA.

competence cover radiological protection during the design, construction, operation and decommissioning of nuclear installations and the transport, the storage and the use of radioactive materials and ionizing radiation for industrial, medical, veterinary and research purposes, including the radiation sources of natural origin. It considers radiological protection in normal conditions as well as in the event of incidents or accidents, and the possible consequences of malevolent acts. It addresses the protection of people and the environment against the effect of ionising radiation.

III. Element of Understanding:

In recognition of their shared responsibilities, FDA and HERCA have reached the following Understanding:

1. Each Party will establish a principal point of contact to facilitate the actions carried out under this MOU.

2. The Parties will collaborate in areas of mutual interest. Such collaboration may include providing alerts to the other Party when issues are identified, and exchanging technical and regulatory information.

3. The Parties may participate in scientific discussions regarding radiation protection initiatives, such as optimizing radiation dose from medical imaging and reducing unnecessary radiation exposure to patients from CT.

4. To support their common global goal of improving the safety and effectiveness of CT devices, the Parties may participate in collaborative efforts that support research regarding medical imaging.

IV. General Provisions:

1. This MOU represents the broad outline of the Parties' intention to collaborate in areas of mutual interest. All activities that may be undertaken by this MOU are subject to the availability of resources. This MOU does not affect or supersede any existing or future understandings or arrangements between the Parties and does not affect the ability of the Parties to enter other understandings or arrangements related to this MOU. Nothing in this MOU is intended to create obligations under international or other law.

2. Data Sharing Guidelines: The Parties may enter into separate Confidential Disclosure Agreements (CDAs) pertaining to certain data and information shared in accordance with this MOU. HERCA and FDA will not share any confidential commercial information, trade secrets, or personal privacy information pursuant to this MOU.

V. Principal Points of Contact:

A. For the Heads of the European Radiological protection Competent Authorities:

Olvido Guzmán
HERCA Secretariat
6, Place du,Colonel Bourgoin - 75572 Paris cedex 12 - France
Telephone Number: +33 1 40 19 87 64
Fax : +33 1 40 19 88 36

B. For the Food and Drug Administration:

Simon Choi
Office of the Center Director
Center for Devices and Radiological Health, FDA
10903 New Hampshire Avenue
White Oak 66, Room 5418
Telephone Number: 301-796-5426

Each Party will, in a timely fashion, notify the other of any change of the individual they have designated as their principle point of contact and the name of the new individual.

VI. Term, Termination, and Modification:

This agreement will be effective when accepted by the Parties. This agreement may be modified or terminated by mutual written consent by both Parties or may be terminated by either Party upon a 60 day advance written notice to the other.

This MOU is done in two originals in the English language, both being equally authentic.

APPROVED AND ACCEPTED FOR
HEADS OF THE EUROPEAN
RADIOLOGICAL PROTECTION
COMPETENT AUTHORITIES

By _____
Sigurdur Magnusson
Chairman

Date 1/2 9/12

APPROVED AND ACCEPTED FOR
FOOD AND DRUG ADMINISTRATION

By _____
Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health

Date 2/2/12