FINAL DRAFT
As of 13 September 2023

FDA CIRCULAR
No. _____

SUBJECT : Recognition of Accredited Technical Service Providers for Radiation Dosimetry of Individual Monitoring Services

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I. BACKGROUND

The Food and Drug Administration, though the Center for Device Regulation, Radiation Health, and Research (FDA -CDRRHR) is mandated to regulate radiation facilities and activities that uses radiation devices, pursuant to Republic Act No. 9711 or the Food and Drug Administration Act of 2009. And to protect radiation workers from the effects of ionizing radiation, access and arrangements for individual monitoring services are required under Annex C of the Department of Health (DOH) Administrative Order No. 2020-0035 or the Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorizations.

On 2-11 October 2022, the FDA -CDRRHR and the Philippine Nuclear Research Institute (PNRI), as the two (2) regulatory bodies mandated to regulate ionizing radiation sources, jointly hosted the International Atomic Energy Agency (IAEA) Occupational Radiation Protection Appraisal Service (ORPAS) for the independent assessment and evaluation of all the aspects of the country's occupational radiation protection program against international safety standards.

The IAEA ORPAS Team emphasized that the role of technical service providers within the framework of protection and safety is crucial to radiation protection. Formal procedures or guidelines for the approval, recognition, or authorization of individual monitoring, calibration services and other services related to occupational radiation protection should be in place pursuant to the IAEA General Safety Requirements (GSR) Part 1, Requirement 13.

Additionally, the issuance of Department of Health (DOH) Administrative Order (AO) No. 2022-0022 or the Basic Radiation Protection and Safety Standards on the Use of Ionizing Radiation Devices in Planned Exposure Situations on 30 June 2022, provided updated standards and guidelines for safety and protection against ionizing radiation emitted by radiation devices in line with IAEA GSR Part 3.

Annex B, Part 4.F – Occupational Exposure Assessment of DOH AO No. 2022-0022 requires licensees and employers for the availability of arrangements for the assessment of the occupational exposure of workers using individual monitoring devices from appropriate or approved dosimetry service providers that operate under a quality management system.

In view thereof, there is a need to operationalize such requirements and provide specific guidelines to recognize technical service providers with quality management systems as part of FDA-CDRRHR's authorization requirements for radiation facilities.

II. OBJECTIVE

This Circular is hereby issued to recognize technical service providers for radiation dosimetry of individual monitoring services used in radiation facilities and activities within the mandate of the FDA, pursuant to DOH AO No. 2020-0035 and as part of FDA-CDRRHR's authorization requirements for ionizing radiation facilities.

III. SCOPE

This Circular shall apply to ionizing radiation facilities and activities under the jurisdiction of the FDA as defined in DOH AO No. 2020-0035, 2022-0022, and in the Implementing Rules and Regulations of Republic Act No. 9711 or the Food and Drug Administration Act of 2009. This shall also apply to the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM), subject to the applicable provisions of Republic Act No. 11054 or the "Organic Law for the Bangsamoro Organic Autonomous Region in Muslim Mindanao" and its subsequent laws and issuances.

IV. DEFINITION OF TERMS

For the purposes of this issuance, the following terms shall be defined:

A. **Individual monitoring service** – refers to monitoring using measurements by equipment worn by individuals for radiation dosimetry.

B. **Personal Dose Equivalent** – refers to the dose equivalent in soft tissue below a specified point on the body at an appropriate depth.

C. **Radiation dosimetry** – refers to the study, measurement, method of measurement, or instrument of measurement of radiation dose.

D. **Technical Service Providers** - refers to individuals, companies, or laboratories providing technical services relating to radiation protection and safety, such as services for personal dosimetry.

V. GUIDELINES

A. Only Philippine Accreditation Bureau of the Department of Trade and Industry (DTI-PAB) or International Laboratory Accreditation Cooperation's Mutual Recognition Arrangement (ILAC-MRA) accredited Technical Service Providers (TSP) for **ISO/IEC 17025**, with scope of specific tests and measurements for **Personal Dose Equivalent**, shall be recognized by FDA for radiation dosimetry of individual monitoring services, as part of the requirements for the authorization of an ionizing radiation facility under FDA-CDRRHR.

B. Radiation facilities shall check the website of DTI-PAB Conformity Assessment Bodies (CABs), under Testing Laboratories, at https://www.dti.gov.ph/pab/cabs/ for the current list of accredited technical service providers covered under this Circular or at the official website of ILAC at https://ilac.org/, for those laboratories under MRA.

C. In cases where the current accreditation of laboratory services procured by radiation facilities have expired, a period of one (1) year shall be given, from date of expiration, to allow for the reaccreditation process of the current laboratory or for the transition and procurement of other accredited dosimetry laboratory services by the authorized radiation facility.

VI. TRANSITORY PROVISIONS

Authorized radiation facilities currently subscribed or having existing arrangements for Technical Service Providers providing individual monitoring services not recognized pursuant to these guidelines shall be given one (1) year from the issuance of this Circular to comply.

VII. SEPARABILITY CLAUSE

If any part, term of provision of this Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Order shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term, or provision.

VIII. PENALTY CLAUSE

Non-compliance to the provisions of this Circular shall merit regulatory action under Section VII of DOH AO No. 2020-0035 which include suspension, cancellation, or revocation of existing authorizations including closure of the facility, preventive measure orders, and imposition of administrative fines and penalties for violation of Republic Act 9711 or the "Food and Drug Administration Act of 2009" and Book III, Article XI of its Implementing Rules and Regulations.

IX. MONITORING AND REVIEW

Within three (3) years of its implementation, this Circular shall be reviewed and evaluated to determine whether the policy's objectives, impact, and effectiveness were achieved.

X. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register and shall remain effective until such time that accreditation guidelines for technical service providers for radiation facilities are promulgated as separate issuance.

DR. SAMUEL A. ZACATE
Director General

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