CSIR-NPL establishes an apex-level calibration facility for defibrillator analyzer and defibrillator machine

The 'New Medical Device Rule 2017' emphasizes the need of establishing Test and Calibration centres, as notified by the Government of India, for medical device calibration to provide quality control regulation in the health sectors[1].

To play an active role and to meet these needs in the country, the Council of Scientific and Industrial Research-National Physical Laboratory (CSIR-NPL), New Delhi is promoting quality measurements in the domain of biomedical metrology. CSIR-NPL under its mission project is working with different stakeholders for fulfiling the societal needs of the nation in the healthcare sector.

CSIR-NPL has the responsibility of realizing the units of physical measurements based on the International System of Units (SI units) under the subordinate legislations of Weights and Measures Act, 1956 (reissued in 1988 under the 1976 Act). It also has the statutory obligation to realize, establish, maintain, reproduce and update the national standards of measurement and calibration facilities for different parameters. Being the 'National Measurement Institute' (NMI) of India, CSIR-NPL aims to establish calibration facility pertaining to medical devices, as the measurement traceability flows down from it to various laboratories (Figure 1).

In the medical equipment market, quality control is a challenging issue. Given such a huge market and continuous technological growth in biomedical instruments being used in hospital settings for diagnosis, surgery and other purposes, it becomes imperative to ensure proper functioning of such instruments. Calibrating medical instruments ensures their accuracy and precision. At present, most of the medical equipment get their traceability either from NMIs outside India and thus drain huge amount of foreign exchange, or are being calibrated by the manufacturers themselves which sometimes raises the serious issue of catastrophic variability in the measured value.

Recently, we have established an apex-level calibration facility for defibrillator analyzer by installing a set-up of a primary standard of defibrillator with its physical parameters traceable to national standards. This facility is a first-of-its kind in India to cater to quality assurance in healthcare. Defibrillator analyzer is used for the calibration of defibrillators, which are life-saving electronic biomedical equipment used to restore the normal heart rhythm of a patient by applying an energy pulse during sudden cardiac arrest. Thus it is mandatory to have defibrillator installed at public places, offices, airports, railway stations, ambulances, hospitals, etc. Defibrillator works by supplying biphasic pulse to patients in the energy level range 50–360 J. It is critical to supply required energy to patients according to physiological conditions. Thus, it is essential to calibrate the defibrillator analyzer and in turn the defibrillator with high precision, according to the accuracy requirement of the energy function specified in the international standard (IEC 60601-2-4) for medical electrical equipments. The individual parameters involved in the measurement of discharge energy $[E = \int_0^T [V(t)]^2 \cdot \mathrm{d}t/R]$, viz. discharge voltage (V), load resistance (R) and discharge time (t) have been traced to national standards. These physical parameters are the major sources of uncertainty in energy measurement. The combined uncertainty in energy measurement has been calculated by taking into account the sources as given in Figure 2.

Traceability of the measurement result is linked with calibrated standards (voltage, resistance and time) used for the calibration of defibrillator analyzer. Figure 3 shows a flow chart to demonstrate the measurement traceability. Figure 4 shows a set-up of the calibration facility.

Figure 1. Traceability pyramid.

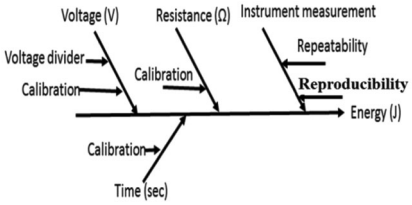

Figure 2. Cause and effect diagram (fish bone diagram) for depicting uncertainty components involved in energy measurement of defibrillator analyzer.

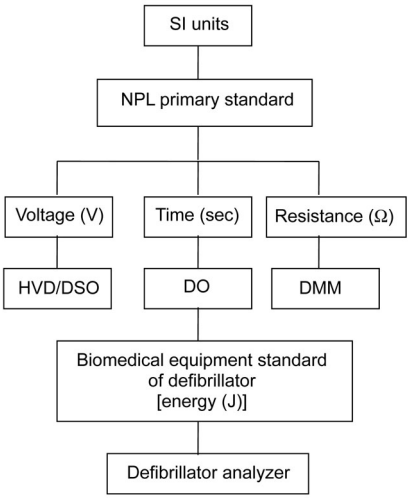

Figure 3. Flow chart of traceability chain of primary standard of defibrillator with traceable supporting equipment of high voltage divider (HVD), digital oscilloscope (DO) and digital multimeter (DMM).

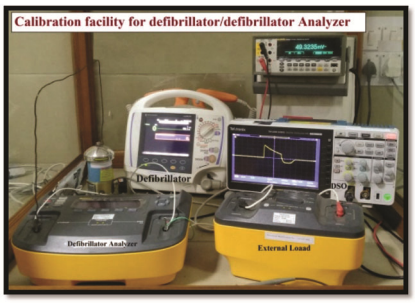

Figure 4. A set-up of calibration facility for defibrillator analyzer and defibrillator machine.

This facility provides services to various stakeholders from 1 September 2018. The calibration services have already been provided to some biomedical testing and calibration laboratories across the country.

The efforts of CSIR-NPL in setting up apex-level calibration and testing facilities of various other biomedical devices are in progress. This will pave the way for fulfilment of the 'The Medical Device Rule 2017' to have 'Centres of Excellence for Calibration and Testing' in the field of biomedical metrology at par with international standards.

1. *The Gazette of India*, Extraordinary, Part II, section 3, sub-section (i), Registration No. D. L. 33004/99, notified on 31 January 2017.

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MEETING REPORT

Understanding the universe through mega science projects*

India's first global, mega science exhibition 'Vigyan Samagam' began on 8 May 2019 in Mumbai and will continue until 7 July 2019. Then, it will travel to Bengaluru, Kolkata and New Delhi. It is an 11-month journey for the exhibition – pushing the frontiers of science.

The exhibition showcases the role of India in the world's major international science projects – CERN (European Organization for Nuclear Research), FAIR (Facility for Antiproton and Ion Research), INO (India-based Neutrino Observatory), ITER (International Thermonuclear Experimental Reactor), LIGO (Laser Interferometer Gravitational-wave Observatory), SKA (Square Kilometer Array) and India TMT (Thirty Meter Telescope).

'Vigyan Samagam' exhibits the workings of the universe. From the discovery of the Higgs boson particle to that of the gravitational waves from the merger of neutron stars and black holes, it throws light on crucial questions related to the origin of the universe and its evolution in various stages. It highlights India's contribution towards the world's science and technology innovations and research, especially in the fields of space science and nuclear technology.

V. K. Saraswat (member of NITI Aayog), K. VijayRaghavan (Principal Scientific Advisor to the Government of India), Kamlesh N. Vyas (Secretary, Department of Atomic Energy and Chairman, Atomic Energy Commission), Ashutosh Sharma (Secretary, DST), A. D. Choudhury (Director General NCSM), Frederick Borday (Director of Accelerators and Technology representing CERN) and Andreas Baun (Ambassador of Switzerland to India) graced the event. Other eminent scientists like P. Chidambaram, Anil Kakodkar, S. Banerjee, R. K. Sinha and S. Basu were also present at the occasion.

Saraswat inaugurated the first edition of 'Vigyan Samagam'. He expressed hope that the exhibition will bring society and the scientific fraternity together to discuss the exciting world of science in a lucid way. Also, it will act as a new science gateway that will satisfy the curiosity of millions of visitors, including researchers, students, science aspirants and families.

In his keynote address, VijayRaghavan strongly encouraged the participation of industries with all mega science projects. According to him, the exhibition would create awareness and enthuse scientific temper amongst students, and industrial participation would assist in the development of technological capacity in India.

The exhibition will travel to the Visvesvaraya Industrial and Technological Museum, Bengaluru (29 July 2019 to 28 September 2019). It will then move to Science City, Kolkata (East Topsia) (4 November 2019 to 31 December 2019) and will reach the National Science Centre, New Delhi (21 January to 20 March 2020). The exhibition will permanently be in New Delhi thereafter and will be maintained by NCSM.

*A report on the exhibition 'Vigyan Samagam' organized by Department of Atomic Energy, Department of Science and Technology and National Council of Science Museums on 8 May 2019, at Nehru Science Centre, Mumbai.

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