

The Report on China's Medical Equipment Inspection Work under Legal Metrological System



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The Report on China's Medical equipment Inspection work under Legal Metrological System (General Programme)

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1. General Review of China

China is located in eastern Asia, along the Pacific West coast, covering 9.6 million square kilometers, including 3 million square kilometers of sea area, ranking third in the world. Chinese provincial level administration districts involve 4 municipalities, 23 provinces, 5 autonomous regions, 2 special administrative regions and the capital—Beijing.



China is the world's most populous country with a total population of 1.37 billion and is unified by the Han nationality as the main multi-ethnic country and Chinese is the commonly used language. In 2013, the annual GDP is 56.8845 trillion yuan with an yearly growth of 7.7% according to comparable prices.

In 2013, the national total of health expenditure was expected to reach 3.16615 trillion yuan, with 2326.8 yuan per capita health expenditure. The total health

expenditure accounted for 5.57% of GDP. By the end of 2013, the total of health personnel is 9.79 million, with an increase of 0.674 million persons and 7.4% of growth. In 2013, the national medical and health institutions treated 7.31 billion patients, with an increase of 0.42 billion and 6.1% of growth.

2. Legal Metrology in China

China approved and promulgated the Metrology law in September 6th 1985 via the Standing Committee of the National People's Congress. Since the promulgation of the Metrology Law, our country has formed the legal metrology system with some metrology laws and matching regulations; established the standard system of metrological benchmarks based on the international system of units, including a considerable number of metrological standards close to or reached the international advanced level; set up all levels of institutions of metrological technology which save the measurement base, standards and carry out metrological verification, calibration. The national measurement system has formed, and the undertaking has also entered a new stage.

In view of the vast imbalance in regional economic development and transportation and the traffic telecommunication is not developed, China's legal metrology supervision system is based on administrative management, uniformly led by the Central Committee, taken charge of by the local governments which are the administrative institutions to supervise the implementation of metrology laws, regulations and rules.

The government's administrative functions are mainly to be responsible for the implementation of legal measurement units in the locals, for planning verification and calibration network, for assessing standards of measurement and calibrating laboratories, for supervising measurement devices' manufacturing, sales, and usage, for implementing compulsory verification of measurement devices of trade, security, health and environmental protection usages, for carrying our supervision and inspection of the commodity, and for organization of supervisors to mediate disputes, and supervise the implementation of laws.

The implementation of compulsory verification on some important measuring instruments is an important part of their official legal metrology in many countries. In view of different countries' situations, directories of metrology instruments verified compulsorily are slightly different. In China, in addition to the compulsory verification of the standards of grade of quality transfer system, the directories are mainly used to 60 kinds of measuring instruments in the departments of trade settlement, medical and health, safety and environmental monitoring, which are compulsorily verified in regular periods. Among them, the number of verification in medical and environmental protection has increased and showed the upward trend with the improvement of life quality.

3. Legal Metrology in Chinese Medical Metrology

The aim of medical metrology verification is to achieve the uniform of measurement units in medicine and to ensure the accuracy and consistency of various

human measuring parameters, in order to realize the accurate diagnosis and precise treatment. Since the issue of the Metrology Law of People's Republic of China in 1986, there has been 60 items and 117 kinds of devices which should be compulsorily verified, including 40 items and 76 kinds of devices relevant to medical and health, covering more than half of the total. Medical metrology has become the main content of the mandatory test.

After unceasing development of Chinese medical metrology, we has set up a great number of medical measuring standards which obtained certifications authorized by national or relevant technical institutions. The medical metrology is expanding. At present, the national medical metrological verification network has been initially formed, and has a relatively complete system of measurement technology.

With the accelerated process of digital medical equipment, the automatic detection and comprehensive parameter test will become the future trend of the development of medical metrology. However, because our country medical metrology started comparatively late, the technology is relatively backward; the domestic verification cannot satisfy the requirements of verification of advanced medical measuring devices. On the other hand, many medical institutions, as the main body of quality management of medical devices, focus only on devices' purchase and usage, ignore the accuracy and standardization of the management of medical measurement equipment, and don't coordinate with metrological institutions to get medical device periodically verified, resulting in insecurity, inaccuracy and invalidity of medical devices in use.

4. The Compilation of this Album of Reports

To comprehensively reflect the basic situation of medical device testing in China, and to provide reference for APLMF members, in May 2013, Chinese Measurement Association began planning and organizing all provincial and urban metrology institutions to investigate the work of medical metrology in different regions. In January and June 2014, the association held preparation meetings, invited all provincial and urban metrology representatives to discuss the compilation of the reports of Chinese medical metrology, and finally decided that Shandong, Shanxi, Henan, Jiangsu, Heilongjiang, Inner Mongolia, Fujian, Chongqing, Ningbo (Zhejiang), Suzhou (Jiangsu), and Chengdu (Sichuan) (See Figure 1 for geographic location) would write their own report and then were compiled.

The National Quality Supervision and Inspection Center for Medical Metrology Instrument Products assists Chinese Measurement Association to collect and compile the album of reports. The National Quality Supervision and Inspection Center for Medical Metrology Instrument Products (referred to as the National Medical Metrology Center) is currently the only national products quality inspection institution of medical measuring instruments approved and authorized by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China(AQSIQ). The National Medical Metrology Center accepts the supervision and inspection of medical measurement devices, evaluation of new patterns of products, and inspection entrusted by enterprises. In August 2014, National

Medical Metrology Center successfully passes the acceptance check and review from an expert team organized by AQSIQ.

Some units in charge of writing reports are located in the eastern developed area of China, some in the central plains areas, and others in relatively remote border areas, which is very representative, reflecting the comprehensive situation of China's medical metrology. This album is a reference to APLMF members for experiences exchanges and promoting the development of medical metrology in each county.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Heilongjiang Area)

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1. Basic Situation of Heilongjiang Province

1.1 Overview

Heilongjiang province is located in the northeast of China, across 14 longitude and 10 latitude in the east-west and north-south direction separately, with the most northerly location and the highest latitude in China. The provincial annual average temperature is mostly between -4°C and 5°C . Winter is long and cold, summer is short, spring and autumn is dry and cool, annual precipitation is from 400 mm to 650 mm. The north and east of province is Russia border, the West is adjacent to the Inner Mongolia autonomous region, the south border on Jilin province. The whole province covers 473000 square kilometers in total (including Jiagedaqi and songling district), after Xinjiang, Tibet, Inner Mongolia, Qinghai, Sichuan, ranking the sixth in the country.



Land conditions in Heilongjiang province ranks first in the country, existing 11.8707 million hectares of arable land, soil organic matter content here is higher than in other regions of the country. Heilongjiang province is abundant in mineral resources, with relatively complete mineral species.

In 2012, provincial birth rate was 7.30‰, mortality rate was 6.03‰ and natural population growth rate was 1.27‰. In 2013, birth rate dropped to 6.86‰, mortality rate increased to 6.08‰, natural population growth rate dropped to 0.78‰. At the end of 2012, that was 38.34 million permanent residents, the same period in 2013, resident population was 38.35 million, more than the previous year 10000 people, the proportion of urban population increase over the previous year by 0.5%, the proportion of population aged 65 increasing by 0.5% over a year ago. The sixth national census in 2010 showed that, 0-14 years old had a population of 4580422 people, accounting for 11.96%, 15-64 years old had a population of 30543478 people, accounting for 79.72%, the population aged 65 and over was 3188324 people, accounting for 8.32%, in the 13 cities(prefecture-level city) of the entire province.

Main Components of Population Sheet:

Index	Year-end (million people)	Proportion (%)
At the end of the year the total permanent residents	38.35	100.0
Urban	22.01	57.4
Rural	16.33	42.6
Male	19.29	50.3
Female	19.05	49.7
0-14 years old	4.50	11.7
15-64 years old	30.25	78.9
65 years old and over	3.58	9.4

In early 2014, 2013 GDP data of 31 provinces and municipalities was released by the national bureau of statistics one after another, Guangdong GDP reached 6.2164 trillion Yuan, won the 'national champion', Heilongjiang ranked seventeenth. In 2013, Heilongjiang provincial gross domestic product (GDP) was 1.43829 trillion Yuan, growth of 8% over the previous year. The provincial per capita GDP was 3.860198 trillion Yuan, lower than the national average.

1.2 Medical Condition

Outpatient service case: top 10 of total number of cases are upper respiratory tract infection(6.43%), bronchitis(4.56%), vaginitis(2.70%), hypertension(2.67%), cholecystitis(2.34%), diabetes(2.21%), gastritis(1.99%), gallstone(1.92%), tuberculosis(2.11%), gastroenteritis(1.27%).

Inpatient case: top 10 of total number of cases are gallstone(10.95%), cholecystitis(4.43%), bronchitis(4.10%), pneumonia(3.60%), tuberculosis(3.46%), diabetes(3.10%), hypertension(2.77%), cirrhosis(2.52%), upper respiratory tract infection (2.23%), icterus neonatorum(1.64%), coronary disease(1.70%). Common and frequently encountered diseases have become the main impact factors of population health.

Disease mortality: data from Heilongjiang provincial center for disease prevention and control shows that, in the third investigation on resident mortality and causes of

death in this region, top 5 causes of death were cerebral vascular disease, malignancy, heart disease, respiratory disease, injury and poisoning, accounting for 90.21% of the total number of deaths. The mortality of cerebro vascular disease has become the first cause of death of local residents, because Heilongjiang is in the mid latitude, with long and cold winter, it is a typical area of high incidence of cerebro vascular disease which was caused by cold in the north alpine area of China. Coupled with the local residents like to drink hard liquor, have a habit of eating high salt, high fat and pickled food, all above become the important causes of cerebral hemorrhage and cerebral infarction undoubtedly.

Comparison table about annual outpatient reception of Heilongjiang province and the national

Region	Patient	Outpatient&Emergency	Observation	Health examination	Emergency mortality rate	Observation mortality rate	Visit average
Total	6888329 138	6529935754	64980116	367026769	0.07	0.05	5.10
East	3476499 796	3319324771	27400946	157526053	0.07	0.08	6.22
Mid	1787703 199	1664153087	16527157	106150072	0.08	0.04	4.21
West	1624126 143	1546457896	21052013	103350644	0.07	0.03	4.46
Beijing	1852974 79	182762557	2965518	5423137	0.08	0.06	8.95
Liaoning	1752550 41	158642538	3008438	8044780	0.14	0.06	3.99
Jilin	9742807 8	86030281	536465	4384017	0.11	0.11	3.54
Heilongjiang	1152858 49	103624553	543977	6867418	0.12	0.20	3.01

Medical and health service agencies at all levels in Heilongjiang province is perfect. At the end of 2013, 9558 health institutions in total, in which the number of hospitals and health centers are 1993, the number of center for disease control and prevention is 174. 190000 beds in health institutions, hospitals and health centers have 172000 beds. The number of health professional is 207000, in which there are 80000 physician and licensed assistant doctors, 74000 registered nurses. The number of center for disease control and prevention (epidemic prevention station) is 174, 5000 persons are health professionals. The number of sanitary supervision and inspection institution are 153, 3000 persons are health professionals. The number of health clinic in towns and townships are 996, in which there are 20000 beds, 19000 health professionals. The new rural cooperative medical system covering the 15.3 million rural populations, in fact, the population of farmers who participate in the rural cooperative medical system are 15.21 million, an increase of 5.1%.

comparison table about hospital grade of Heilongjiang province and the national

the National	Heilongjiang province
1624 Grade III hospitals (including 989 Grade III Class A hospitals)	77 Grade III hospitals (including 61 Grade III Class A hospitals)
6566 Grade II hospitals (including 3680 Grade II Class A hospitals)	314 Grade II hospitals (including 91 Grade II Class A hospitals)
5962 Grade I hospitals (including 2306 Grade I Class A hospitals)	226 Grade I hospitals (including 159 Grade I Class A hospitals)
13384 public hospitals 9786 private hospitals	707 public hospitals 289 private hospitals

In some hospitals, instruments in department of medical imaging, nuclear medicine and radiotherapy account for more than 60% of fixed asset of the entire hospital, about half of these instruments are associated with ionizing radiation.

1.3 Quality Supervision

1) Administrative management and technical supervision

Medical metrology instruments are used for clinical diagnosis and treatment of diseases, which quantity whether reliable and accurate relate to body health and life safety of people, also have a direct impact on the quality of medical services and the credit of medical institutions. Therefore, the medical metrology instruments are always the important objects of legislation and supervision management of all the countries in the world. At the same time, an important content of quality and technical supervision work is measurement of medical appliance of medical institutions, which is one of the main responsibilities of quality and technical department vested by the state. Quality control over medical measuring instruments and equipments by metrology inspection, can improve application quality and safety of medical measuring instruments and equipments, protect the safety of medical treatment immensely and reduce the medical risk.

2) The functions of measuring management in technical supervision management in our region

In recent years, the quality supervision departments at all levels from the overall situation of the implementation of the state concerned about people's livelihood and service development, taking the development of medical instruments measurement as a key task of the global, giving full play to the advantages of metrology technology, helping all levels of medical institutions strengthen the allocation and management of all kinds of medical appliances, conduct medical instrument measuring service, play an important role in technical support and promotion for medical apparatus management of them.

Firstly, find out the base of large-scale medical equipment using in medical institutions at all levels fundamentally, through developing provincial metrology inspection work of large-scale medical equipment. Accordingly, set up a statistical database of large-scale medical equipment in use in the province, make use of provincial quality supervision bureau website with news outlets to release the information used in a variety of large-scale medical equipment to the whole society.

In the second, reinforce the measurement service for medical treatment, promote the spirit of important documents positively, such as *Metrology Law of the people's Republic of China*, *Catalogue of the Compulsive Calibrating Working Measuring Instruments of the people's Republic of China*, *the Regulations on Handling of Medical Accidents*, *Notice on Strengthening Supervision and Management of Medical Compulsive Calibrating Measuring Instruments* promulgated by the former state bureau of quality and technical supervision and *Notice on Strengthening the Management of Medical Measuring Instruments* promulgated by general office of the ministry of health. Urge medical institutions at all levels to strengthen the management of medical instruments and equipments, examination rate of medical instruments and equipments from all levels of medical institutions increases year by

year. Finally, promote the medical metrological work vigorously. Our center and the provincial quality supervision departments at all levels carry out the propaganda actively which as the 'measurement service health' as the theme, inspecting domestic medical appliance such as blood pressure monitor and blood glucose meter for the masses for free, appraised by all circles of the society very well, achieving great social benefits.

With the fast development of society and economy, especially rapid increase in demand for medical services by the people, the metrology inspection tasks of medical measurement for the whole province will be more arduous. The provincial quality supervision departments at all levels determine to implement the testing duties of quality supervision departments on medical device conscientiously, to improve the administrative ability, to make efforts to improve the measuring inspection and management job of provincial medical devices to a new height, under the correct leadership of the provincial party committee, the provincial government and the state administration of quality supervision.

3) The role of metrology technology institution in our region

Heilongjiang provincial institute of measurement and verification is a legal metrological verification institution set up according to law by the state, it is authorized the designation of 10 categories 140 items public standard instruments, passed the examination of national legal technical institution(authorized metrological verification project 236 items, quantity inspection project 5 items) and certification of CNAL(approved 289 calibration items and 55 inspection items), it is also the magnitude traceability center of Heilongjiang province and energy audit institution approved by the provincial development and reform commission. The area of laboratory is 8700 square meters, 28000 square meters of experimental base has been built in Songbei district. Our institute has 135 professional technical personnel, in which there are 32 professor level senior engineers, 34 senior engineers, 30 engineers, one doctoral candidate and 16 master degree candidate have been fostered by now, college degree or above accounting for 90% of all staff. Metrology inspection projects on ten subjects have been developed which associated with national economic development. Medical metrology is one of characteristics of our institute, since 2004, medical inspection department was established to begin to specialize in medical metrology inspection, in 2011, according to the relevant laws and regulations and the document spirit, our institute submitted Heilongjiang provincial metrology inspection center of medical instrument to be built to the provincial bureau, and passed. Moving laboratory of this center completed authorized examination in March 2012, 19 verification and 34 calibration projects passed the certification. The accuracy of medical instrument is an important part of people's livelihood metrology, and affects people's health and safety directly. The establishment of Heilongjiang provincial medical instrument inspection center can improve the medical device inspection level in our province, improve the medical apparatus examination rate, promote the medical metrology development, build a safe and harmonious medical environment, do a better service to the enterprise, common people, and people's livelihood metrology.



Heilongjiang provincial metrology inspection center of medical instrument mainly rely on Heilongjiang provincial institute of measurement and verification. Through integration, new construction and continuous development of medical equipment inspection projects, this center can carry out several verification and calibration projects, for instance, cardiovascular and ECG machine, electrocardiogram monitor, B-mode ultrasonography, blood cell analyzer, biochemical analyzer, medical CT machine, X-ray machine, nuclear magnetic resonance, laser source, hemodialysis machine, defibrillation monitor, multi parameter monitor, ventilator, Eelisa reader, high frequency electricity knife. In all above projects, verification of medical CT machine was developed in 1998, nuclear magnetic resonance was developed in 2005, linear accelerator and gamma knife were developed in 2010, above jobs are at the forefront of the country. Seven local specifications have been drafted, which make the inspection work had basis, and also create a nicer economic and social benefits.

4) Legal metrology system in our region and regulations of ionizing radiation medical diagnosis instrument in this system

According to the relevant provisions in *Metrology Law of the people's Republic of China, Rules for the Implementation of the Metrology Law of the people's Republic of China, Verification Regulation of the Compulsive Calibrating Working Measuring Instruments of the people's Republic of China*, measuring instruments of ionizing radiation diagnosis instrument, blood-pressure meter, B-mode ultrasonography, electrocardiogram, lens meter, eye-detecting lens box etc. subject to compulsory verification, which shall not be used until be verified and passed by legal metrology verification institution annually, new purchased medical metrology instruments should be verified firstly, can be used if and only if have qualifications. One year is the metrological verification cycle of medical equipments, if beyond re-testing period, medical equipment will not be able to use anymore. The metrology work has the very strong uniformity, accuracy, sociality and legality.

2. Medical Verification Situation of Heilongjiang Province

2.1 Development Situation, Nature and Assignment of Medical Measurement

Every year, more than 300 hospitals accept verification, all kinds of medical instruments inspected over 3000 pieces, medical institutions and consumers show the welcome and praise, excellent social benefits obtained.

Metrology is a career, and also a major administrative function of the quality supervision department, which making the unified and accurate mensuration come true. Catalogue of the *Compulsive Calibrating Working Measuring Instruments of the people's Republic of China* contains 60 compulsive verification items (116 kinds), in which 40 medical measuring instruments items (76 kinds) involved, about 50 kinds can be carried out for the moment. Quality control over medical measuring instruments and equipments by metrology inspection, can improve application quality and safety of medical measuring instruments and equipments, protect the safety of medical treatment immensely and reduce the medical risk.

2.2 The Number of Medical Verification Personnel and Equipment

At present, there are eight persons engaging in inspection work, including three postgraduates in our center. More than 30 inspection items can be carried out, involving X-ray machine, medical CT machine, accelerator, gamma knife, cardiovascular and ECG machine, magnetic resonance, dialysis machine, defibrillator, ventilator, high frequency electricity knife, B-mode ultrasonography, Eelisa reader, blood cell analyzer, biochemical analyzer. Most of instruments used in inspection were produced by fluke, ALK and NT, can meet the corresponding specifications and inspection requirements.

2.3 Legal Metrology Documents of Diagnostic Equipment in Ionizing Radiation Medical Field

Laws and regulations such as *Metrology Law of the people's Republic of China, Catalogue of the Compulsive Calibrating Working Measuring Instruments of the people's Republic of China, Verification Regulation of the Compulsive Calibrating Working Measuring Instruments of the people's Republic of China, No.6,1998, Notice on Use and Management of Compulsive Calibrating Measuring Instruments of*

Medical Institution jointly issued by the ministry of health and state bureau of technical supervision, No.257,2009, *Notice on Strengthening the Management of Medical Measurement Instruments in our Province* issued by quality and technology supervision of Heilongjiang province, homologous verification regulations and calibration specifications.

2.4 The Situation of Medical Verification

Most of medical instruments often be used with high frequency and long hours, unable to carry, inspection work almost entirely need to be done on the spot, Heilongjiang provincial metrology inspection center of medical instrument establish moving laboratory, purchase and design mobile inspection vehicle, integrate all of our projects related to medical metrology, seek to achieve on-site inspection, resources sharing and benefit maximization as much as possible. Medical inspection moving laboratory can develop on-site verification and calibration work in connection with medical instrument, which has the characteristics of convenient, fast, high efficiency etc., it also solve the on-site inspection problem of medical metrology apparatus effectively, carry out on-site verification and calibration work of medical instrument throughout the province.

Carry out inspection to military hospital (armed police Heilongjiang corps hospital). Since the army has its own measuring management system, we have not carried out inspection to military medical institutes, but we inspected 120 medical measuring instruments of armed police Heilongjiang corps hospital, our attitude and quality towards work praised by their leadership.

During laboratory opening showcase month activity, also busy working period of inspection, comrades overcame difficulties, set up inspection site of blood pressure and blood glucose meter for citizens for free, 150 appliances were inspected in total, inspected CT machine for the fifth hospital of Harbin city, and cooperated press interview, Heilongjiang comprehensive news reported this activity, which obtained welcome and praise from citizens and the hospital. From the beginning of free inspection activities, as long as the public come to inspect we are warmly received and inspect for free, although there is no benefit, honor was wined for our institute, social impact and visibility was expanded. Free opening inspection activities let the people understand the metrology inspection, strengthen the communication with the community and improve the quality awareness of the whole society.

Exploring new markets and new field of inspection actively, communicating with more than 10 companies repeatedly, taking a variety of ways to establish good relations of cooperation. For the non-strong inspection items, different hospital takes a different approach. Zuyan, Sanjing kidney disease hospital, Children's hospital, the Second hospital of city and Provincial TB control institute are typical examples, by using of some laws and regulations and doing ideological work to principal again and again, contacting with each hospital many times, finally, the hospital above all agree to inspect, social and economical benefit are very obviously.

Apply for research project positively, biochemical analyzer standard substance (key science-technology project of province), UV filter(key science-technology project of province), standard substance of blood cell analyzer(self-made project of provincial

science and technology department), all above have finished and passed the identification. Standard filter of ELIASA transmittance, UV filter, holmium glass filter and praseodymium neodymium glass filter have been manufactured in batches.

**Full-automatic biochemical analyzer
standard substance**



**Semi-automatic biochemical analyzer
standard substance**



Standard filter of ELIASA transmittance

Technical indicators and brief descriptions:

1. uncertainty: $U=0.01A$, $k=2.0$

2. nominal value of absorbance:

02A、05A、10A、15A

3.constant wavelength:

405nm、450nm、492nm、620nm

model: MB1

meet JJG861-2007 verification regulation of
enzyme mark analyzer



Standard filter of ELIASA interferometer

Technical indicators and brief descriptions:

1. uncertainty: $U=1.0\text{nm}$, $k=2.09$
2. nominal value of absorbance peak:
405nm、450nm、492nm、620nm

model: MB1

meet JJG861-2007 verification regulation of
enzyme mark analyzer



Establishment of moving laboratory of Heilongjiang provincial metrology inspection center of medical instrument is a very good opportunity, which improving the medical device inspection level in our province, improving the medical apparatus examination rate, through on-site inspection, a lot of people trust in the accuracy and security of the hospital instrument, meanwhile, social and medical institutions understand the process and significance of inspection work, that also let metrology into the market, into the enterprise, into the community, let advanced service, tracking service, field service come true, let the service for common people, enterprise, administrative law enforcement more effectively and timely.

2.5 Equipment Research on X-ray Machine, CT, PET-CT and Electron Accelerator

1) Institution of ionizing radiation equipment in using unit

	number of pieces	main equipment model	Manufacturers	use cases of per day month year
X-ray machine	4	X122,TU51,X709C,M-38, XD52,18DK	WANDONG, SIEMENS, SHIMADZU	60 times per day, 1500 times per month, 18000 times per year
CT	4	Light Speed, Bright Speed, Brilliance, SOMATOM, CT-C2800	GE,SIEMENS, PHILIPS, HITACHI, NEUSOFT	100 times per day, 3000 times per month, 42000 times per year
PET-CT	2	GE Discovery LS4, GE Discovery TM STE, Siemens Biography Sensation16, Biography 64 HR	GE, SIEMENS, PHILIPS	15 times per day, 200 times per month, 2400 times per year
Electron accelerator	1	Elekta Compact	ELEKTA	5 times per day, 120 times per month, 1200 times per year

2) The main measuring parameters of ionizing radiation equipment: dosage, resolving power.

3) Equipments control dosage automatically according to the conditions preset by manufacturer, the operator can also hand control the amount of radiation.

4) The calibration and verification conditions of ionizing radiation equipment: using institutes do self-calibration every day or irregularly, equipment manufacturers do maintenance regularly, legal metrology department carries out periodic calibration and verification.

5) The calibration and verification cycle: using institutes apply for verification, legal metrology departments do periodic verification and issue metrological verification certificate if qualified.

6) The calibration or verification certificate report: the qualifications of issuing certificate institute, our institute and center passed the examination of national legal technical institution, certification of CNAL and metrology authorization of provincial bureau.





- 7) The radiometric design and standard of radiometric quantity: in accordance with the requirements of the state regulations.
- 8) Quantity dissemination of ionizing radiation equipment: can be traced to the national standards.
- 9) The use environment of ionizing radiation equipment: temperature, humidity and radiation protection equipment of most medical institutes meet the requirements.
- 10) Radiation protection of the patient: establish the patient radiation records in some institutes.
- 11) Radiation protection of operators: most of institute have been established operator radiation records, have self defending equipment, personal vacation and economic subsidies etc..
- 12) The appearing amount, situation and consequences of medical negligence caused by ionizing radiation leakage or improper protection: less medical negligence caused by ionizing radiation leakage or improper protection occurred, but in the practical work, phenomenon of doing not enough prompts to the patients and their families still exist.

2.6 Work Experience and Achievements of Legal Metrology in Heilongjiang Provincial Medical Field

1) Mutual cooperation of measurement and medical care in our region

For doctors, measurement of medical measuring equipment whether accurate relate to the diagnosis and treatment of the patient's condition, also relate to the treatment or rescue to the patient whether success or not, which are highly related to the life safety of the patient, as it were. Quality control over medical measuring instruments and equipments by metrology inspection, can improve application quality and safety of medical measuring instruments and equipments, protect the safety of medical treatment immensely and reduce the medical risk. We take the development of medical instrument measurement as a key task all the time, giving full play to the advantages of metrology technology, helping all levels of medical institutions strengthen the allocation and management of all kinds of medical appliances, conduct

medical instrument measuring service, play an important role in technical support and promotion for medical apparatus management of them. Most of medical institutions can apply for verification on schedule.

2) Service consciousness of metrology in medical field

Through the supervision and inspection, urge medical institutions at all levels to strengthen the management of medical instrument and equipment, to increase investment, to expand new projects and new field, further to the medical institutions at all levels to do inspection works of the medical devices, to provide powerful technical support for the medical management of medical institutions at all levels of the province.

Carry out free inspection work every year, inspecting glass, sphygmomanometer and blood glucose meter without charge for citizens, developing 'opening laboratory' centralized display activities to open laboratory and proceed on-site inspection for members of the public and the medical institutes, On one hand ,solve practical problems, acquaint people in all walks of life with our work contemporaneously.

Work closely with the metrology division of provincial bureau, law enforcement team of institute and bureau of city, downtown, district, supervise and investigate the refused and unqualified hospital, take the opportunity that is the provincial bureau hangs online publicity with verification situation of CT machine to notice and contact with refused institute in turn by calling, explain laws and regulations and complete the verification work on more than ten hospitals, for institutes which refused verification many years, we take every possible means and never give up, solve the big and difficult problem through various efforts, that lay a good foundation for developing compulsory verification of provincial medical metrology instrument smoothly.

3) Development trend of ionizing radiation medical testing equipment which metrology personnel facing

With the rapid development of science and technology, high tech equipments have been widely used in medical field, which play a very crucial role in improve the accuracy of diagnosis and treatment effects. While in the medical instrument and equipment in use, the vast majority of that is measuring instruments. According to the demand of medical metrology, Heilongjiang provincial metrology inspection center of medical instrument further enhance the technology capacity building of medical measurement which meet the needs of market development, establish and complete medical metrology inspection system. Set up verification device of compulsory measuring instrument, such as CR,DR,DSA, accelerator, gamma knife gamma knife, breast machine and the laser source, set up standard verification device of ultrasonic power meter and verification device of ultrasonic doppler, set up calibration device of multi-parameter monitor, pipette, audiometer, infant incubator, infusion pump, electrolyte analyzer and blood glucose meter. By the environmental conditions of Jiangbei national quality inspection center, we work hard for carrying out type evaluation of medical instrument project based on completion of center construction and inspection work. Provide service of quality control for medical institutes.

Before the end of 2015, covering 80% inspection projects of medical measuring instrument managed according to law will be established, more than 90% projects will be covered in three years, which is the construction target.

Provincial medical center plan to establish medical inspection laboratory with advanced equipments and first-world environment in Jiangbei experimental base, move inspection laboratories will be consummated, 95% projects can realize the on-site inspection. Strive to set up medical inspection laboratories which own twelve inspection personnel, fifty inspection projects, advanced equipments, topping environment and advanced moving laboratory in three years, achieve three-in-one that is scientific research, inspection and quality control, realize the inspection of compulsory, user needed and important medical metrology instruments is our target.

4) Work experiences on medical inspection

Draft local regulations, carry out important medical instrument inspection timely.

Combine law enforcement authority with the provincial bureau, regional bureau and law enforcement team of institute, promoting key projects and compulsory projects to be carried out. Try to have a greater breakthrough in the aspect of medical measuring instrument inspection. In the verification of medical measuring instruments, adhering to principles and do not miss, suggesting to repair or block up if unqualified, strengthening the supervision of unqualified instrument.

Set up moving laboratory, increasing the intensity of services, providing a package of services for the hospital.

3. Conclusion

As a provincial metrology institute of China, very honored to have the opportunity to introduce some legal metrology works of our region to the APLMF organization. I hope some work experience presented in this report can do some favor to APLMF members. Welcome APLMF members to our institution for communication and investigation.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Inner Mongolia Area)

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1. Local Briefing

1.1 Area Profile

Inner Mongolia Autonomous Region, located in the northern border of the People's Republic of China, is China's third largest province with a total area of 118.3 square kilometers, and shares the northern border with Mongolia and Russia. The region is classified in scope of economic integration of the Beijing-Tianjin-Hebei. Located in the Eurasia, Inner Mongolia is the temperate continental monsoon climate, four distinct seasons. There are nearly 25 million residents in Inner Mongolia, among which, about 13 million men and 12 million women are included. Because of its unique location and geographical advantage, Inner Mongolia becomes one of the provinces which have ample resources in China, especially with coal resources leading the country. In recent years, economic growth rate of Inner Mongolia has maintained the lead in the whole country because of the rapid development of energy abundant region promoted by country's economic growth. Moreover, factors such as many ports along the Inner Mongolia border and close economic and technical cooperation with Beijing, Tianjin, northeast and northwest area help the region convert resource advantage into economic advantage quickly.

1.2 Medical Treatment Conditions

Inner Mongolia has 23394 medical treatment and health organizations. And there are 572 tertiary hospitals (among them, 49 class-3 hospitals, 214 class-2 hospitals and 173 class-1 hospitals are included) and 119 institutions of disease prevention and control. At the same time, there are 13384 tertiary hospitals in the whole country, and the numbers of above-mentioned three types of hospitals are respectively 1624, 6566 and 5962. Thus it can be seen that the number of medical institutions set in Inner Mongolia falls short of the local requirement when considering its area and population, and total number of hospitals in the region is one of dozens of national ones. On the other hand, those data reflect the fact that there will be a great increase space in application of ionizing radiation medical equipments. Moreover, except for accident death, the rest of the deadly diseases are ranked in malignant tumor, heart disease, cerebrovascular disease and chronic lower respiratory disease order. Being located in border area and local people's drinking and eating meat diet custom have caused much more heart head blood-vessel disease cases, so the ionizing radiation medical

equipment is widely used in the region.

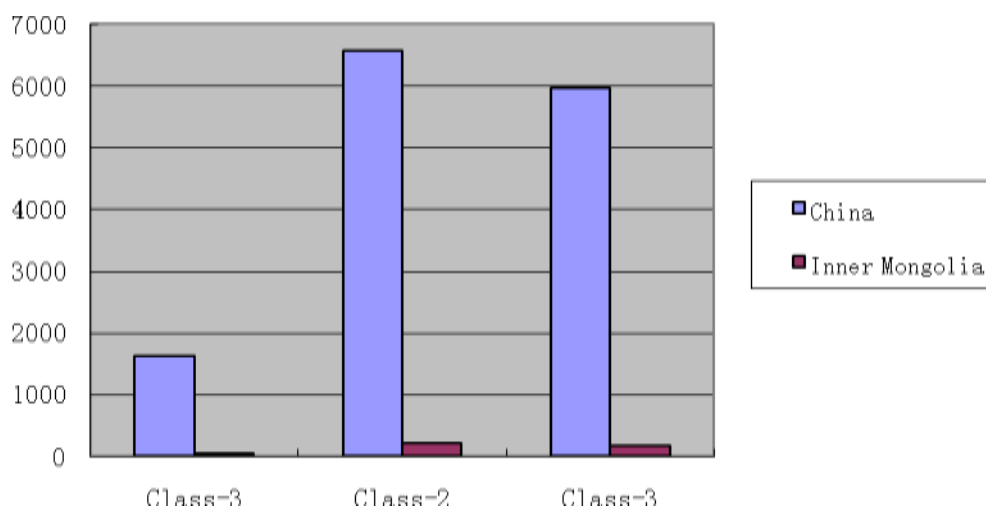


Figure 1 Comparison of number of hospital in Inner Mongolia and China

1.3 Quality Supervision

Inner Mongolia Bureau of Quality and Technical Supervision (IMBQTS) is a directly affiliated institution run by the people's government of Inner Mongolia autonomous regions, and in charge of the quality and technical supervision work in Inner Mongolia autonomous region, meanwhile, mainly responsible for unified management of metrological work of the whole region. IMBQTS has the responsible for the implementation of legal measurement units and national metrology system. And it also IMBQTS' responsibilities to organize establishment and management of public standards of measurement in the autonomous region, formulate local metrological verification regulations and technical specifications, control the verification of measuring instruments, organize quantity-value transmission and guarantee the accuracy of quantity-value. IMBQTS also conduct regulation and supervision on sold measuring behavior, and carry out supervision and administration over the legal or authorized metrological verification institutions and measuring notarization service institutions.

Founded in 1955, Inner Mongolia Institute of Metrology and Testing (IMIMT) is a social benefit public institution subordinated to IMBQTS and authorized by General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), having independent legal personality. IMIMT consists of five research branches concerning length, thermo engineering, mechanics, electromagnetism and chemistry, and five research centers including National Center of City Energy Measurement (Inner Mongolia), Inner Mongolia Verification Branch of National Oil & Gas large Flowrate Measurement Station, National Type Evaluation Laboratory of Nonautomatic Weighing Instruments (Inner Mongolia), Inner Mongolia Center of Reference Materials Engineering Technology Research and Inner Mongolia Center of Quality Supervision & Inspection on measuring Instruments. The institute has obtained the People's Republic of China Certificate of Metrological Authorization to legal Metrological verification Institution, passed through the laboratory approval of China National Accreditation Service for Conformity Assessment (CNAS), IMIMT

undertakes the responsibilities of research and establishment of the top standards of measurement and public standards of measurement of Inner Mongolia autonomous region, and is also in charge of quantity-value transmission works within the corresponding administrative area. In accordance with the Law on Metrology and its implementation regulations, IMIMT performs compulsory verification and other verification tasks within authorized scope and carries out testing, calibration, quantity-inspection of metering instruments.

IMIMT has established 133 items of public standards of measurement (among them, 49 items are national ones and 84 items are provincial ones), and been authorized 631 items of verification, calibration and testing by national or regional legal metrological verification institutes. An integrated traceability system has been set up in the institute, the quantity-value transmission scope have covered the whole corresponding administrative area and concerned various industries and public institutions. The institute has 6600 m² area of working house and 540 m² of constant temperature laboratory space, and possesses 1500 sets instruments. IMIMT now has 301 staff members, 2 are awarded with PhD, 71 with Master's degree and 159 with minimum university degree, which occupies 53% of total staff members, 9 professorate senior engineers, 27 senior engineers, 42 engineers and 95 junior engineers. Among them, there are experts enjoying special allowances, national or regional experts with outstanding contributions, and supervisors of master students. There are 56 people acting respectively as directors of the National Measurement Standard Platform Board of Management, members of the AQSIQ technology committee, and national or regional judges and assessors in metrology.

1.4 Legal Measurement

Metrological work is marked by its unity, accuracy, sociality and legality. Strictly according to relevant regulations in the law on metrology of the People's Republic of China, Rules for the implementation of the law on metrology of the People's Republic of China and Acts for verification management of measuring instruments that should be compulsorily verified of the People's Republic of China, IMIMT exercise compulsory verification of working measuring instruments used in hospitals and listed in the compulsory verification catalogue such as medical radiation resource, sphygmomanometer, ultrasonic source for medical ultrasonic diagnostic instrument, electrocardiogram (ecg), lensmeter and trial lenses set, and those which have been checked as qualified can be used. Verification period for medical instruments is generally no longer than one year, and those which exceed the prescribed time limit shall not be used.

2. The Conditions of Medical Metrological Test in Inner Mongolia

2.1 The Profile of Medical Metrological Test in Local Area

Although the level of medical care in Inner Mongolia autonomous region is not of the top throughout the country, quality and efficiency of medical institutions' work have improved obviously in recent years. Development of medical and health provide

health support for the coordination, comprehensive and sustainable development of economic and society. At the same time, it also contributes to the development of health-relevant industries such as medicine, medical instrument, food and fitness.

Medical Engineering Testing Center (METC) of IMIMT specializes in medical metrological verification and calibration, to ensure the performances of statutory measuring instruments are under control and to provide relevant technical supports. METC of IMIMT has played a constructive role in medical metrological test field of the autonomous region, and keeps up with the front and trend of the domestic and foreign medical metrology subject closely, and strengthens basic research in medical measuring technology. We have engaged in improving construction of traceability system of medical measuring instruments, enhancing metrological work that is relevant to people's livelihood. And we have brought along the metrological work of the whole region and promoted the building of metrological laws and regulations and supervision system to provided technical support for improving diagnosis and treatment of medical and health institutions and safeguarding people's safety and health of Inner Mongolia. METC took on the task of formulating local verification regulations and calibration specifications of "medical multi-parameter monitor", "blood dialysis machine" and "medical magnetic resonance imaging (MRI) system". In comparison of quantity value of "air kerma rate of X-ray radiation source used in medical diagnosis" organized by national ionizing radiation metrology technical committee, we got satisfactory result, and which shows that our quantity value is accurate and reliable in this test items and our capability of verification and testing meets the requirement. We participated in seminar on measuring technology of medical ionizing radiation between both sides of the Strait organized by the Chinese Society for Measurement, and engaged in modification of application guide for measuring of medical ionizing radiation instruments under legal metrology system of APEC region.

At present, there are 12 peoples in Medical engineering testing MEMTC of IMIMT, including 2 senior engineers, and 4 of them are postgraduates. nineteen test items are carried out, including medical diagnostic X-ray source, medical diagnostic X-ray radiation source for spiral computed tomography, accelerator, heart eeg machine, magnetic resonance (NMR), blood dialysis machine, defibrillation apparatus, breathing machine, high frequency electric knife, ultrasonic source for medical ultrasonic diagnostic instrument and so on. Standards of measurement used in our work were developed and made by famous company such as Fluke, ALK and NIMTT (China), and met the testing requirements of corresponding technological specification. The relevant documents which is the basis of the metrological test work are as follows: law on metrology of the People's Republic of China, Rules for the implementation of the law on metrology of the People's Republic of China, Catalogue of measuring instruments that should be compulsorily verified of the People's Republic of China, Acts for verification management of measuring instruments that should be compulsorily verified of the People's Republic of China, the notice regarding to measuring instruments that should be compulsorily verified in medical institutions and their management jointly issued by the Ministry of Health and

AQSIQ , and other verification regulations and calibration specifications.

2.2 Investigation on Ionizing Radiation Instruments

Numbers of ownership of ionizing radiation instruments of hospitals at all levels are different. According to incomplete statistics, there are nearly 2000 medical diagnostic X-ray sources within the scope of Inner Mongolia region, four hundred medical diagnostic X-ray radiation sources for spiral computed tomography, forty PET - CT and forty electron accelerator. And the top market share manufacturers are Wan-Dong (Beijing), TOSHIBA, GE, SIEMENS and PHILPS.

The main measurement parameters for ionizing radiation instruments are dose index, kerma, kerma rate and quality of radiation output, etc. Radiation dose of ionizing radiation instruments are generally set by manufacturers according to the relevant standards and controlled by the machine automatically, and sometimes, can also be controlled by the operator's hand-adjusting. Calibrations and verifications of Ionizing radiation instruments are realized by way of a combination of daily or irregular self-calibration by users, regular maintenance by manufactures and periodic verification and calibration by legal metrology institutions. If the user applies for verification to metrology administrative department, the legal metrological verification organ designated by metrology administrative department will conduct verification and grant certificate after the instrument is proved qualified by check. Our institute is appropriately qualified by having passed through examination of the national service of legal metrological verification, the laboratory approval of CNAS and authorized by IMBQTS. The standard of the designed radiation quantity of ionizing radiation device is strictly in accordance with national regulations. Quantity value of ionizing radiation equipment can be traceable to national primary standard. Temperature, humidity, radiation protection devices of most of the medical institutions are meet the practical demands.

Measurement instruments in most of the local hospitals are verified and calibrated by the legal metrological verification organs periodically. Management systems in the first class hospitals are normally and properly. They apply for verifications according to the required period in relevant regulations and record information of using and verification of the instruments every year, meanwhile, carry out daily maintenance in line with factory's demand. And working environment of their meets the needs of the instruments and is in accordance with requirements of the environmental protection department. At the same time, archives of radiation for patients are built, protective equipment are equipped for operators, protective records are set up and measures such as give a vacation and handing out economic compensation for radiation are implemented in those hospitals. Up to now, medical accidents caused by ionizing radiation leaks or improper protection have never occurred in the region.



Picture 1 Medical Diagnostic X-ray Radiation Source for Spiral Computed Tomography



Picture 2 Medical Diagnostic System of Magnetic Resonances Imaging (MRI)

2.3 Legal Metrology Work in Field of Medical Measuring in Inner Mongolia

Metering or checking of medical instruments is coordinated well with working conditions of medical institutions and properly arranged in Inner Mongolia. Medical instruments are generally tested by local legal metrological organs who have established corresponding standards of measurement, and our institute gives technical guidance and excises random inspections. Metrological testing works are usually carried out by our institute for those medical institutions that are located in remote

area with backward measuring technology or have not built relevant standards of measurement and belong to the provincial capital city in Inner Mongolia. We have taken advantages of our measuring techniques and engaged in metrological testing in medical institutions at all levels, helping them strengthen management of medical apparatus and instruments and offering technical consulting services, etc.

In the process of the routine testing, IMIMT lays special stress on improving service consciousness. METC of IMIMT actively take part in research work on ionizing radiation and metrological comparison at home and abroad, furthermore, it focus on assisting medical institutions to regulate metrological management and assuring accuracy and reliability of quantity value. IMIMT undertakes metrological testing of more than 1000 medical instruments every year, including medical diagnostic X-ray radiation source for spiral computed tomography, medical diagnostic X-ray sources, ultrasonic source for medical ultrasonic diagnostic instrument, electrocardiogram machine, heart eeg machine and blood dialysis machine. According to the actual situation of medical and health institutions, we arrange time properly to offer door-to-door testing and checking. In order to ensure measurement instruments are operated correctly and properly and guarantee people's health and life safety, we also provide timely repairs and calibrations once any damage or deviation of measuring instruments are found and give equipment operators targeted guidance on instrument-operating.

With the rapid development of science and technology, high-tech equipment has been widely used in medical field, which played a significant role to improve the accuracy of the diagnosis and treatment effect, in the meantime, higher demand is needed to be satisfied for metrological testing technology, So we focus on strengthening the construction of medical metrology capability and improving testing level. New testing and calibration projects on "measurement about social welfare" are widely carried out to improve the social influence and service ability. First of all, to organize examination and assessment of standard-building projects in field of medical measurement, perfect file management of those projects, and strengthen the construction of testing ability and improve metering level; Secondly, to expand test projects of medical instruments such as cleanliness testing in the operating room or laboratory in accordance with measuring requirements for the medical instruments of medical institutions; Thirdly, to carry out "X-ray security checker" testing work, and which is related to accuracy and reliability of the data of the checker in civil aviation airport, customs services, post services and stations, and is very important to personal safety and social stability with remarkable social benefit. Finally, to complete selecting and buying measurement standard device for the "nuclear magnetic resonance (NMR)" instruments and setting up corresponding standard and conduct relevant calibrations for the medical institutions of the whole region.

Legal metrology in Inner Mongolia was conducted with obvious geographical characteristics. Firstly, economic and cultural environment on which it depends is at a disadvantage; secondly, allocation of resources, comprehensive strength and development basis are started late and with a low level; thirdly, employee quality also has a big gap with other developed cities. However, with the deepening the reform of

our country provides great opportunities to the development of Inner Mongolia, which also makes our legal metrological work gradually standardize in the field of medical application. We have focus on improving service consciousness of medical metrology for several years, and some advices on how to respond to the development of metrological testing of ionizing radiation medical instruments are summarized as follows:

Firstly, we took actions to rev up publicity to improve awareness of metrology law of the whole society. We gave the law on metrology of the People's Republic of China and other related law or regulations a lot to public through taking advantages of television, radio and newspapers, and giving out publicity materials of metrology. A series of on "metering benefits to people" activities were carried out. For example, we measured household blood pressure for free for citizens throughout the year, and stepped into populous communities and commercial streets to disseminate metering knowledge and relevant laws to public to let known that verification and calibration of measuring instruments is of great importance, especially those that related to people's health and life safety. In this way, a good atmosphere of social concern and support is built, and a favorable pattern of covering government's driving, hospital's coordinating, public concern and the relevant administrative department's conducting has shaped.

Secondly, we strived to get the whole medical check-ups going by means of "compulsory verification" in Inner Mongolia. Because medical institutions are the main target of conducting metrological testing for medical instrument, we organized relevant employee of medical institutions to study the law on metrology of the People's Republic of China and other related laws and regulations to enhance their consciousness of metrological law. We conducted compulsory verification effectively in conformity with the related legal provisions to make the users realize the importance and necessity of periodic verification and calibration. And those who did not understand the significance of metrological testing in the past learned the point and gave a positive cooperation in the process of verification and calibration after our hard work.

Thirdly, we established information management platform to improve the supervision and management. We have built management information platform of measurement instruments and medical instruments in use in hospital within our own administrative division and helped medical institutions establish and perfect gage list and registration for the record. Through this platform, information containing all basic info of medical instruments, verification qualified status, overdue use, the date users asked for verification and the date metrological institutions completed the task was shared, and which makes metrological verification organs improve efficiency and quantity of their work greatly.

Finally, we increased investment on the measurement equipment and enhanced abilities of technical staff. In recent years, in order to meet the requirements verification work and raise the recognition of the importance of metrological verification in medical department constantly, IMIMT sped up the improvement of the technical equipments and ask technical staff to promote their own comprehensive

quantity. In order to adapt to the demands of their own current job and that of metrological testing in medical measurement in the future, employee engaged in technical work are required to learn and know well basic metrological knowledge, furthermore, they needed to understand and master medical-relevant knowledge and techniques as much as possible.

3. Conclusions

The above is a brief introduction and work experiences of IMIMT on the metrological measuring of ionizing radiation medical instruments and legal metrology. With the development of modern science and technology, more and more medical measuring instruments used in medical research, clinical diagnosis and treatment in medical field. Whether the quantity values of medical instruments is accurate or its function is reliable directly influences the effect of diagnosis and treatment, and is related to people's health and life safety. Therefore, metrological testing in medical field is a long and arduous task, while with huge development space.

Thank you very much for providing us such an opportunity to learn, share and communicate. It is an honor to share my ideas with you in the forum; meanwhile, I will carefully listen to the advanced experiences of other member states and regions in order to improve our work. We hope that all the information in this report could be helpful for other member states. Finally, we sincerely invite APLMF members to come to Inner Mongolia, and to visit IMIMT and communicate with us!

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Chongqing Area)

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1. A Brief Introduction of Chongqing

Chongqing city is located in the southwestern part of the upper reaches of the Yangtze River, inland Chinese, plains transition zone downstream cross longitude 105 ° 11'~110 ° 11', latitude 28 ° 10'~32 ° 13' in Qinghai Tibet Plateau and the Yangtze River. Chongqing lies to the east of Hubei Province, Hunan Province, south of Guizhou Province, west of Sichuan Province, north of Shanxi province. East-west 470 kilometers long, north-south width of 450 kilometers, the total area of 82400 square kilometers. Chongqing is the largest area of the city China, registered a total population of 33 million people. In 2013, the city's gross domestic product (GDP) reached 1.2657 trillion yuan, complete the public finance budget income 169.3 billion yuan.

2. Chongqing Region Ionizing Radiation Quality Supervision

According to *METROLOGY LAW OF THE PEOPLE'S REPUBLIC OF CHINA*: exposure meters, medical radiation sources, radiation monitorings, exposure rate meters, radioactive surface contamination meters, personal dosimeters, radiation measurement instruments are kind of compulsory certification of measuring instruments. Chongqing Bureau of Quality and Technology Supervision is the Chongqing government's functional departments, be responsible for the unified management of metrological work in the city. Chongqing Academy of Metrology and Quality Inspection is responsible for carrying out class including ionizing radiation measuring instruments compulsory verification and transfer of the measuring values, ensure the uniformity of the national system of units of measurement and the accuracy and reliability of the values of quantities. Chongqing Environmental Protection Bureau subordinate Radiation Environment Monitoring Station is responsible for supervision and administration of the city's radiation and radiation environment and monitoring; Radioactive waste repository management and maintenance, management of radioactive sources; Nuclear safety emergency and investigation and handling of the accident. Chongqing Health and Family Planning Committee subordinate Chongqing Center for Disease Prevention and Control is responsible for the occupational health examination, radiation workers personal dose monitoring radiation workers. The three government departments division of different, have

different emphases, together complete the supervision and administration of the quality and safety of ionizing radiation.

3. The Region's Legal Metrology Technology Institutions

Chongqing Academy of Metrology and Quality Inspection is the Chongqing municipal government set up the national legal metrological verification, quality inspection, calibration test research institute, a nonprofit public welfare institution for the society, has the independent legal status and the third party impartiality, is tested and approved by the national metrology and certification of national legal inspection agencies, also is approbated by the laboratory of China National Committee Testing/Calibration Laboratories (CNAL) recognition. Chongqing Academy of Metrology and Quality Inspection has specialized in medical metrology laboratory, it has established 17 public standards of measurement, including Medical Diagnostic X-ray Radiation Source Verification Apparatus, X- γ rays Standard Apparatus Used in Radiation Protection, X- γ rays, Standard Apparatus Used in Radiotherapy, Medical Diagnostic X-ray Radiation Source for Computer Tomography (CT) Verification Apparatus, Ultrasonic Sources for Medical Ultrasonic Diagnostic Equipment Verification Apparatus, Laser for Medicine Verification Apparatus etc.. We can calibrate medical diagnostic X-ray radiation sources, medical diagnostic X-ray radiation source for computer tomography (CT), X and γ radiation dose equivalent (rate) meters and monitors used in radiation protection, X and γ radiation Air Kerma ratemeters for environmental monitoring, personal dose equivalent rate warning devices for X and gamma radiation, direct reading personal dose equivalent (rate) monitors for X and gamma radiation, ultrasonic sources for medical ultrasonic diagnostic equipment, laser for medicine and other measuring instruments, basically covers the measure specified in the compulsory verification catalogue of compulsory verification medical measuring instruments. Chongqing Academy of Metrology and Quality Inspection is responsible for the work of the main city medical measurement calibration, the six subsidiary branches in the region are responsible for calibration of medical measured.

4. The Region Medical Institutions

At present, Chongqing city has thousands of all kinds of medical and health units, including 28 third-grade class-A hospitals, 64 two-grade class-A hospitals, 15 two-grade class-B hospitals.

Our city has 118 units with radioactive sources 1630, 1484 units have ray device 3006 sets, all kinds of radiation monitoring and alarm instrument about 6000 pieces. We used questionnaire survey, data collection and on-site inspection combined, investigated the main urban area of Chongqing city 15 municipal hospital, 15 district hospitals and 30 community health service centers and township hospitals radiological diagnosis and treatment, the results showed that:

	PET-CT	Medical Linear Accelerators	CT	X-ray machine	The major manufacturers	Daily radiology outpatient amount
15 municipal hospitals	2	9	21	60	GE SIEMENS Shimadzu	200~300
15 district hospitals	0	1	15	30	GE Beijing Wandong Shimadzu	100~200
30 community health service centers and township hospitals	0	0	0	30	Beijing Wandong	10~30

60 hospitals were established by radiation workers personal dose monitoring health records and archives, while the establishment of emergency rescue team of radiation protection and radiation accidents leading group, formulated the radiation emergency preparation, processing, reporting regulations. Radiation workers are held radiology staff card, each year to participate in the occupation health inspection and personal dose monitoring. To carry out the radiological diagnosis and treatment of hospitals are equipped with protective equipments and personal dosimeters; Nuclear medical treatment in hospital are equipped with radioactivity meter and surface contamination instrument. Radiation place with ionizing radiation warning marks、work lights and related procedures。Every hospital has a radiation safety permit and radiological license. In addition to the X-ray machine, CT, other ionizing radiation measuring instruments, such as X-ray, gamma radiation dose equivalent (rates) and detector, personal dose equivalent rate alarming device, surface contamination instrument PET-CT, medical linear accelerator, radioactivity meter etc., Chongqing Academy of Metrology and Quality Inspection did not carry out verification and calibration before 2014, therefore, these equipment verification rate had been low.

5. The Region to Carry Out the Medical Work Experience

Chongqing Bureau of Quality and Technology Supervision attaches great importance to medical metrology work, as early as 1998, together with the Chongqing Municipal Health Bureau jointly issued the "Chongqing Medical and Health Unit Metering Management Approach", including medical X-ray radiation source, the medical management of measuring instruments are clearly defined. In 2008, Chongqing Bureau of Quality and Technology Supervision organized "health metering into hospital" activity; In 2009 to carry out the "Service Measurement into Community Villages and Towns" activity; This year in conjunction with the

Chongqing Health and Family Planning Committee launched the "Grassroots Medical Metrology Benefits People Projects" pilot work.

In the early 1990s, Chongqing Academy of Metrology and Quality Inspection has been carrying out the medical diagnostic X-ray radiation sources metrological verification. For more than 20 years, through the metrological verification and calibration, guarantee the quality of medical diagnostic X radiation source imaging and accurate and reliable, and strengthened the protection of X-ray, guarantee the majority of patients and radiation workers health and radiation safety. In this year's launch of the "Grassroots Medical Metrology Benefits People Projects" pilot work, the Chongqing Institute of Metrology free verified more than 120 community health service centers and township hospitals in medical X-radiation, prompting hospital discontinued and out of a batch of unqualified equipment. Since the second half of this year, Chongqing Bureau of Quality and Technology Supervision decided to free verification work scope gradually extended to the whole city more than one thousand community health service centers and township hospitals, for the majority of the people to create a safe environment.

In order to improve the ionizing radiation measurement equipment verification rate, Chongqing Academy of Metrology and Quality Inspection established "X and γ rays Standard Apparatus Used in Radiation Protection", "X and γ rays Standard Apparatus Used in Radiotherapy" two public standards of measurement, can carry out most of the verification of ionizing radiation measuring instruments such as X and gamma radiation dose equivalent (rate) meters and monitors used in radiation protection, X and Gamma radiation Air Kerma ratemeters for environmental monitoring, personal dose equivalent rate warning devices for X and gamma radiation, direct reading personal dose equivalent (rate) monitors for X and gamma radiation, surface contamination instrument, has greatly helped client unit.

6. Conclusion

- 1) We are honored to introduce our work to APLMF.
- 2) Hope this report presents some experience can help APLMF member states.
- 3) Welcome APLMF members to work in Chongqing Academy of Metrology and Quality Inspection for communication, field trip.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Shanxi Area)

Fan Dawang
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1. Introduction to Shanxi Province

Shanxi province is so named for its geographic location at the west side of Taihang Mountain in North China. The population is 34 million residing in 118 counties of 11 municipalities that covers the area of 153,600 square kilometers. The pillar industries are coal production, power generation, metal smelting, chemical engineering and mechanical manufacturing, taking important role in China. Shanxi serves as the prominent base of energy production, heavy industry and chemical engineering and makes significant contributions to the economic development in the country.

A cynic saying in Shanxi goes as “Contribution to the nation and pollution to Shanxi”. The development of energy production, heavy industry and chemical engineering is accompanied with the increasingly serious pollution, far higher than the national average. As a result the environmentally related diseases have been steadily rising. According to the incomplete data from the administrative department of health the hospital outpatient visits astoundingly went up by 29 times in the past 10 years. The top three diagnoses are the malignant tumor, cardiovascular disorder, and the respiratory ailments. The economic development was not achieved without costs. The empirical studies have shown the positive correlation of development vs. pollution; and the pollution vs. disease occurrence. The Shanxi Provincial Hospital of Oncology well illustrates such relationship. The hospital's healthcare revenue increased to 20⁺ billion RMB from less than 10 billion RMB in 10 years. At present the public concern increasingly focuses on the environmental protection, pollution control, and disease prevention.

The ever-increasing public demand for healthcare promotes the quick development of healthcare institutions in Shanxi province. Shanxi has 446 large and mediate-sized hospitals, among which 224 are of Grade 2A, and 31 of Grade 3A. There are 374 privately-own hospitals and 1,185 rural and community clinics. In spite of this the medical capacity is far from being able meet the demand for quality healthcare. Starting in 2014, Shanxi province increases the investment on the public medical services. The branch hospitals are being built under the prominent healthcare institutions such as the Shanxi Provincial Children's Hospital, the Shanxi Provincial Hospital of Oncology, the Taiyuan Municipal Central Hospital. Meanwhile, the local hospitals are being expanded and renovated in many municipalities like Yunchang,

Linfen, Datong, Xinzhou, and Jincheng, as a part of relieving the tensions for public healthcare services.

2. Applicator of Ionizing Radiation in Medical Instruments

The biomedical engineering has become the important part in medical service, which is accompanied with the quality assurance of medical instruments based on metrical measures. In developed countries the governments supervise the safety and effectiveness of medical equipment by encouraging/supporting the manufactures to practice their own metric control system to ensue the patient's safety in the medical care process. While the importance of medical metrology has been increasingly addressed by the public, the government protection is necessary to the quality control and assurance of medical equipment, in which the metrological service plays essential role.

The ionizing radiation is the important technology in clinical practice for both diagnosis and treatment, therefore being widely adopted in the medical institutions in the world. Such instruments offer clear images for diagnosis and treatment, and the machines have developed from the earlier roentgenoscope and fluoroscope to present CR, DR, digital mammography, angiography, dental image machine, digital gastrointestinal image machines, surgery cameras, CT, electron linear accelerator, X-ray scalpel, γ -knife, and PET-CT, etc. The data show that in Shanxi province there are 9 X-ray scalpels and γ -knives, 32 electron linear accelerators, 345 CTs, 530 surgery cameras, 276 digital mammography instruments, 54 angiography instruments, and 1,640 CRs and DRs. The medical equipments generally satisfy the need for healthcare service.

3. Capacity Building of Medical Metrology in Local Metrological Institutions

The advancement of medical metrological instruments put forward higher requirements for the metrological service institutions, calling for high-end laboratory setup and staff development to fulfill such important mission. Under the prevailing administrative system the medical equipment testing institutions are directed by the technology supervision bureau at provincial, municipal and county level. Such vertical governance ensures the uniform metric standards, responsibility distribution, and respective enforcement. At provincial and municipal level there are 12 comprehensive laboratories for testing medial instruments. The metrological institutions at county level mainly test the common instruments such as sphygmomanometer and oxygen pressure meters without special laboratories. At municipal metrological institutions perform the tests corresponding to their capacity, and the provincial institute conducts the tests that are beyond capacity of the lower metric services.

The Shanxi Provincial Institute of Metrology was founded in 1958. In earlier years the test of medical instruments were scattered in various laboratories. In 2000 the Center for Medical Equipment Test was established for testing/calibrating the medical

instruments. The development in the past 10 years enables the Center to perform 14 tests under the public metric standard system, covering 29 categories including the sphygmomanometer, electronic sphygmomanometer, dynamic sphygmomanometer, sphygmomanometer electroencephalograph, ECG monitor, multi-parameter monitor, defibrillator, optometry unit, lensometer, optometric test box, hemodialysis machine, respirator, diasonograph, CR, DR, teeth x-ray machine, gastrointestinal image machines, 276 digital mammography machine, surgery camera, CT, nuclear magnetic resonance, linear accelerator, radioactivity calibrator, biochemical analyzer, hematology analyzer, enzyme analyzer, urine analyzer, electrolyte analyzer, and pipettor. The planned tests includes those for anesthesia machine, Infant incubator, Spirometer, infusion pump, high frequency electrotome, x-ray knife, and γ -knife, etc. The Shanxi Provincial Institute of Metrology aims at the first-rate metrological institution to cover all the medical instruments in Shanxi. It makes persistent efforts in capacity building to satisfy the demands from the hospitals for metrological services in standard of accuracy, efficiency and safety.

4. Promotion of Medical Instrument Tests under Legal Metrologic system

The Chinese law of metrology defines the mandatory test/calibration for the metric instruments in four areas of trade settlement, environmental monitoring, safety protection, and healthcare service. Under the law the “Directory of Metric Instrument of Mandatory Tests and Calibration of PRC” was issued, covering the instrument with the sources of ultrasound, laser and radiation for medical uses (three-source-based medical instruments, in abbr.), Sphygmomanometer, ophthalmotonometer, audiometer, electrocardiograph, and electroencephalograph, etc. The law and the directory lay the legal foundation on the mandatory test/calibration of most medical instruments, thus promoting the work in the field.

However, in May 2002 one executive order caused powerful stirs involving the mandatory test/calibration medical instruments. The Ministry of Health (MOH) issued the “Administrative Reply on Confirming that the X-ray Diagnostic and Radiation Treatment Instruments Are Not in the Category of Metric Instruments”, in response to a provincial consultation titled “The Consultation on Clarifying the Testing/Calibrating Institution for the X-ray Diagnostic and Radiation Treatment Instruments”. As a result the hospitals take the document as the shield to refuse the metric institution but turn to the provincial/municipal health supervision institute or Center for Disease Control for CT test/calibration. The metric institutions fell into dilemma across the nation, and the mandatory test/calibration of metric instruments for medical use was at risk of being out of control.

Later the General Administration of Quality Supervision, Inspection and Quarantine issued the “Notice on Strengthening the Supervision over the Metric Instruments of ‘three-source-based medical instruments’”, which intends to bring the test/calibration for medical instruments back to the legal track. However, the consequence of the MOH’s document is so serious that the testing staffs frequently encounter obstacles and difficulties in performing the test/calibration for CTs in

hospital, which may refuse the tests and/or the payment for the testing cost. The Shanxi Provincial Institute of Metrology sticks to the legal basis on the mandatory tests/calibration for the ‘three-source-based medical instruments in the enforcement of law of metrology, and carry out in administrative practice including the correction of any action against the law. The Institute gets active liaison with the supervision authority to keep the hospitals informed of the relevant laws and regulation prior to mandatory test/calibration. Meanwhile the supervision authority issued the orders for action and/or imposes the penalty against the hospitals that refuse such test/calibration. In the past several years more 20⁺ hospitals were fined with the total amount of more than 2.1 million RMB. The order of rectification was issued to more than 50 hospitals. The law-enforcement actions have effectively regulated the market of metric test/calibration for medical instruments. So far the metric test/calibration has generally covered all the hospitals at the Grade 2B or higher, generating satisfactory social benefits.

5. Recommendations on metric test/calibration for medical instruments

1. It is necessary to further strengthen the popularity of the metric laws and regulations to enhance the public awareness of the legal metrology among the hospitals and the public as a whole.

2. The planned amendment of the law of metrology offers the opportunity for improving the legal and technical framework of metric test/calibration for medical instruments to keep pace with the rapid development of medical equipment and devices.

3. The mandatory test/calibration for medical instruments is for public good, therefore it is necessary to waive the charges on such metric services. This will not only alleviate the costs of healthcare institutions but also provide with incentives for test/calibration, thus improving the effectiveness in general.

4. The development of the metric institution should be strengthened to combine the general supervision and specific monitoring. This will systematically improve the comprehensive ability of the metric administration and be good for regulating the behaviors of both hospitals and the metric service providers.

5. The capacity building should be planned through good coordination for the institutions of metric test/calibration for medical instruments to improve the overall service ability. The medical equipments are generally similar in types and models, making it easier to formulate the capacity building standards at the provincial level. The financial support is necessary for the development of metric test/calibration for medical instruments. The inter-regional exchange and collaboration is also needed for balanced and comprehensive improvement in the field.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Shandong Area)

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1. General Situation of Shandong Province

1.1 Overview

Shandong is located on the east coast of Chinese and the lower reaches of the Yellow River. With a total land area of 157,100 square kilometers, Shandong Province covers 1.6% of the territory of China. The province has, with the capital of Jinan City, up to January 2014, 17 municipalities under its jurisdiction, including 137 county-level districts, 48 municipal districts, 29 county-level cities and 60 counties.

The population of Shandong is 97.333 million, with 16.11% of the 0-14 years of age, 72.94% of the 15-65 years of age and 10.95% of over 65 years of age.

Since 2007, Shandong has ranked the third across the nation in terms of economic power. Its GDP value in 2013 totaled 5.46843 trillion RMB yuan, which was increased by 9.6% calculated at comparable prices. The per capital GDP is 56.323 thousands yuan (9094 dollars according to the annual average exchange rate), with the increase of 9.0%.

1.2 Medical Condition

It's reported that heart diseases, malignancies, cerebral vascular diseases, gastroenteritis and etc. are the main kinds of illnesses in China. Take the city of Weifang, Shandong for an example. According to the report of Weifang Health Bureau on the health status of residents in 2013, the above-mentioned heart diseases, malignancies and cerebral vascular diseases are the top three causes of citizens' deaths, which reflects that Shandong illness condition is basically the same with the whole country.

According to statistics, in 2013, the province had 75,475 health and family planning agencies, of which were 1,783 hospitals, 1,643 health centers, 2,308 community health service stations and clinics, health centers, medical offices and village clinics. There were 489,700 beds in medical agencies in Shandong. Its health and family planning agencies had 287,300 medical facilities which were valued more than ten thousands yuan, of which hospitals had 222,400 ones (173,400 in general hospitals and 27,600 in traditional Chinese medicine hospitals) and health centers had 27,600. The whole value of these medical facilities in the province was 96.913 billion yuan, of which hospitals had 76.077 billion yuan (general hospitals, traditional

Chinese medicine hospitals had 3.985 billion yuan) and primary medical establishments had 3.119 billion yuan.

Medical ionizing radiation plays an extremely important role in medical treatments. The province's hospitals above the county-level have their medical ionizing radiation equipments such as medical diagnosis X-ray machines and CT machines and some developed town clinics brought similar diagnostic facilities. Most of three-grade hospitals and some of two-grade hospitals are equipped with medical electron accelerators, medical remote ^{60}Co radiotherapy machines and other equipments for ionizing radiation therapy. According to incomplete statistics, the province had more than 600 medical CT machines; it had a total of over 100 medical electron accelerators and medical remote ^{60}Co radiotherapy machines. These applications of medical equipments for ionizing radiation played a vital part in disease diagnoses and treatments for patients. The radiation dose's accuracy and limit value, the imaging quality and other metrological features are first-hand related to the effects of diagnoses and treatments and patients' medical security.

1.3 Shandong Quality Supervision

Shandong Provincial Bureau of Quality and Technical Supervision is in charge of the provincial standardization, metrology, quality, certification and accreditation, safety management of special equipment, as well as administrative law-enforcement. Metrology management is one of its important obligations.

The metrological verification organizations set up by the metrological administrative departments of the people's government above county level in Shandong province is the legal metrological verification organizations. The hierarchical and sub regional metrology organization network set up in Shandong province is the guarantee to realize the metrological verification and calibration.

Shandong Institute of Metrology is a legal metrological verification institution set up by the people's Government of Shandong Province, the main duties: responsible for research to build the province's metrological benchmark and public standards of measurement, for quantity value transfer; to carry out the research of the measurement of science and technology and testing methods; engaged in metrological verification, calibration and inspection work; to carry out energy measurement's data acquisition, detection and technical service work.

2. Shandong Province's Inspection of Medical Equipment

2.1 Introduction of Our Inspection of Medical Equipment

Since 1986 "Metrology Law of the people's Republic of China" was promulgated and implemented, the metrology work has been actively carrying out in our province's medical and health system. In Shandong Province, metrology institutions at all levels, medical metrology has become a very important work, the majority of metrology institutions have set up medical metrological verification departments, specifically responsible for metrological work and calibration on the medical measurement instruments in the regional medical institutions. But there are still many problems.

Some medical units are lack of awareness of metrology; medical equipments escape detection or are undetected; and periodic verification are always prolonged, resulting in the increase of accidents and disputes of medical treatments.

Shandong province attaches great importance to the work of metrological verification of medical instruments. To protect people's health and medical safety, regular or irregular campaigns have been carrying out, which are oriented to institutions that use medical measuring instruments. The campaigns also popularize metrology knowledge, implement metrology work, carry out supervision and inspection on medical measurement instruments, and inspect and penalize institutions which are not periodically calibrated according to the laws and regulations.

In the field of medical ionizing radiation metrology, all kinds of medical radiation sources have been included in the national compulsory verification catalogue, and periodically verified by all levels of metrology institutions according to the relevant regulations, which is due to the usage of medical ionizing radiation treatments to the masses of the people and this is related to people's health and life safety.

In recent years, Shandong Institute of Metrology's inspection on medical equipment starts with measurement instruments on the basis of the laws and regulations of metrological technology. The institute is equipped with a number of high-grade, precise and advanced instruments and equipment, recruits high-tech talents with doctoral or master degrees, strengthens capacity development and research breakthroughs and gets achievements in the field of medical metrology. At present, we are equipped with over 200 medical testing instrument, whose original value are 10 million yuan, some of which are at the international advanced level, such as Constant Voltage X-Ray System produced by YXLON International X-Ray GmbH, 3D Beam Analyzer by Germany PTW-Freiburg GmbH, Electrophysiological Detection System by US Fluke Corporation. There are 38 persons in the department of medical device inspection in Shandong Institute of Metrology, including 9 professors, 17 senior engineers, 8 engineers, and 3 assistants, and 4 with doctoral degree, 8 with master's degree, and 25 with bachelor's degree. The laboratory's personnel is doctor-oriented, masters as the backbone, and bachelors as the main force, which has a clear structure and reasonably professional inspection team.

Our institute has established 32 public metrology standards in the field of medical metrology, achieved 41 calibration qualifications of national laboratory accreditation, 50 testing qualifications, 9 authorized pattern evaluation. Some verification devices are in the leading national level, such as the verification device of ionizing radiation protection instrument, the verification device of radon measuring instrument, and the audiometer calibration devices. In 2010, General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) approved to set up the national quality supervision and inspection center for medical metrology instrument products which would do assignments given by the state to supervise and inspect the quality of medical measuring instruments, and to evaluate new product patterns, and accept inspection tasks entrusted by enterprises. Now, the center has successfully passed the AQSIQ acceptance check.

2.2 The Usage and Verification of Ionizing Radiation Measurement Instruments

in Shandong

At present, the province's 17 cities and some county-level metrological verification institutions have established measurement standards on medical diagnostic X-ray machines, and have been carrying out in their regions the metrology verification of medical diagnostic X-ray instruments in all levels of metrological technology institutions. Shandong Institute of Metrology has set up measurement standards of medical CT machines, medical electron accelerators, DSA and other large medical measuring instruments, carried out verifications and calibrations of this kind of measuring instruments in the province. The measurement standard devices used by the metrology institutions regularly carry through at the higher level institutions measurement traceability of metrology standards and benchmarks in order to ensure the validity of measurement standards.

Shandong Institute of Metrology is located in Jinan, the capital city of Shandong Province. The institute's department of medical equipment testing is mainly in charge of the medical equipment testing within each large provincial hospital in Jinan, including medical diagnostic X-ray radiation sources. At present, only Shandong Institute of Metrology has established metrology standards on medical CT radiation sources, in charge of the periodic metrological verification of the medical CT machines used by each medical institution in the seventeen cities. The department also established metrology standards on external beam radiotherapy radiation sources to verify periodically medical electron accelerator and medical remote ^{60}Co treatment machines. We issue verification certificates to the qualified machines, allowing them to be used normally. If we find the unqualified, the hospitals will contact the manufacturers to repair the machines which will be re-examined in order to guarantee patients' medical safety.

It's found that large hospitals have good quality controls of medical metrological instruments, and improve the radiation protection measures. The operators are trained so they are familiar with the performance of machines. There are files of operators' dose monitoring, and the operators are distributed the dose monitoring protection equipment, such as personal dosimeters, the personnel radiation doses are also regularly checked, which protected operators' radiation safety. They can do regular maintenance to the radiation devices for their better conduction and performance and for usage needs. However, some smaller hospitals didn't have standards on the administration of radiation operators and of the instruments; the operators were not good at technical performance and cannot deal with smaller faults made by machines timely. Staff's ability and related system need to be reinforced.

In 2013, Shandong Institute of Metrology conducted periodic verifications of the province's large-scale medical equipment, such as medical CT machines, nuclear magnetic resonance imaging machines, electron accelerators and ^{60}Co therapeutic machines. The verified machines are 566 medical CT machines, 220 MRI machines, 109 medical accelerator treatment machines and 4 ^{60}Co therapeutic machines (Table 1 shows the distribution of verification). Our institute is responsible for periodic verification of medical diagnostic X-ray machines and DSA in provincial hospitals. There are 151 X-ray machines and 23 DSA machines verified.

Take the verification of medical CT machines as an example. The current medical CT machines with excellent performance were largely produced by GE, PHILIPS or other foreign companies. CT machines were calibrated according to the national metrological verification regulations. It was found that CT value and noise are the most common unqualified items, which accounted for 24% and 22% of the total unqualified items. Medical devices have worked for prolonged time, and hospitals tend to ignore machines' maintenance and calibration, which are the main causes of the above-mentioned issues. In addition, the unqualified proportion of scanning thickness is higher, covering 19%, which caused the scanning thickness is small, resulting in difficulty in detecting small lesions. Some CT machines' resolution is not qualified, what's worse, they make severe artifacts, which tend to be misdiagnosed and delay medical treatments.

We found in the verification of radiotherapy equipment that ionization chambers of calibration equipped in hospitals are often not calibrated due to the reasons of journey and funds. We also found that about 40% accelerators need to adjust the dose. If the dose is too large, the non-diseased tissues will be radiated, resulting in radiation damage, acute radiation sickness and even endanger patients' life securities; if the dose is too little, the destructive effects on diseased tissues are greatly lessened. There are about 20% accelerators are unqualified in uniformity and symmetry, resulting in part of non-diseased tissues radiated, instead of diseased tissues getting treatment.

2.3 Legal Metrology's Experience and Achievements In the Field of Shandong Medical Metrology

Shandong province has established a perfect measurement technology institutions at all levels of networks, and vigorously promote the construction of measurement system. Each metrology institution carried out and implemented the Law on Metrology, and relevant laws and regulations, propagated the metrology laws and regulations in order to enhance the masses' understanding. The medical measuring instruments are periodically verified to guarantee quantity value transfer and traceability, and to safeguard people's health and medical safety.

We still need to establish and improve the measurement regulations and technical specifications, to draft a number of verification regulations, standards and pattern evaluation programs. The verification methods should be researched further at the aspects of medical measurement instruments which have not the national metrology verification regulations and standards. We should formulate the corresponding local verification regulations or calibration specifications on the basis of national and international standards and a great amount of experiment data, which will guarantee the accuracy of measurement value of this type of measurement instruments and continuously meet the needs of verification and calibration.

We participated actively in the cooperation and communication with national metrological institutions, producing enterprises, medical institutions, and have set up collaborative relationships in the aspects of standard setting, research methods, research projects and personnel training, which has formed the better system of production, learning and research. We changed the traditional concepts about the cooperation with medical institutions. In the past, we provided verification and

calibration services unilaterally. But now we pay attention to the combination of service and cooperation, carry out research collaboration with medical units, to promote technological ability jointly, make the conversion of advanced scientific and technological achievements, and to serve the masses better.

We learned advanced experience, explored new fields actively, and enhanced the level of technology and service consciousness. At present, Shandong Institute of Metrology is building the detection laboratory of ionizing radiation dose instruments, which is to establish measurement standards of radiation protection, radiotherapy, and the level of environment monitoring X、 γ ray air kerma and the measurement device of diagnostic X ray instruments; we will establish the standard radiation field which meets the requirements of the international standard, and adopt the international advanced standard dosimeter. After the construction of the laboratory, we can carry on measurement calibrations of dosimeters used in medical diagnosis and treatment, of radiation protection instruments and environmental radiation monitoring instrument, complete the quantity transfer and traceability system of ionizing radiation transfer in Shandong, and provide a calibration service for medical institutions, health environmental protection, industrial and mining enterprises, the nuclear power industry, etc..

With the application of new physical technology, electronic technology and computer technology in the field of medical equipment, medical equipment is continuously developing in the direction of multi parameter, intelligent and dynamic detection, which put forward new challenges and requirements for the development of medical metrology. Metrology institutions should be starting with needs, grasp the direction of the development of medical metrology, increase equipment investment, strengthen the construction of talent teams, pay attention to research, enhance the technology capability, escort for the medical and health undertakings.

3. Conclusion

Above is an brief introduction of the application of legal metrology in medical equipment inspection work in Shandong Province. We, as a provincial metrology institution, feel much honored to introduce to APLMF the work of medical metrology in the region.

Hopefully, the work experience presented in this report will be helpful to the APLMF members. The members of APLMF are welcome to Shandong Institute of Metrology for communications and on-the-spot investigation. We also hope that we can get mutual promotion and development through communication.

Table1 The calibration and distribution of large medical measurement equipment in Shandong in 2013

Region	Num of detecting large equipment	Num of classified machines			
		Medical CT machine	Medical accelerator	Nuclear magnetic resonance machine	⁶⁰ Co therapeutic machine
Jinan	97	56	18	23	0
Qingdao	99	68	12	18	1
Linyi	48	36	6	14	0
Weifang	87	55	6	26	0
Yantai	71	45	6	20	0
Jining	86	49	13	24	0
Dezhou	48	32	7	9	0
Taian	42	22	9	10	1
Heze	42	29	3	9	1
Zibo	52	32	5	15	0
Binzhou	35	17	6	12	0
Liaocheng	61	42	7	12	0
Zaozhuang	34	24	4	6	0
Weihai	33	22	1	10	0
Rizhao	20	12	3	5	0
Dongying	28	18	3	7	0
Laiwu	14	7	2	4	1
Total	897	566	220	109	4

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Henan Area)

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1. The Basic Situation of Henan Region

1.1 Overview

Henan is located in eastern China, the Yellow River, east Anhui, Shandong, bounded on the north Hebei, Shanxi, Shaanxi, west, south, Hubei, was looking north to south, east and west trend.

Henan is the largest province of the country's population, by the end of 2012 the total population of 10,543 people. The province's population density is 628 people per square kilometer. The province has three ethnic areas, 21 townships (towns), 863 villages inhabited by ethnic minorities million or more counties (cities, districts) 50.

Henan Province is a major agricultural province, three industrial structure of the three industries was 12.6: 55.4: 32.0, the proportion of tertiary industry reached 87%.

1.2 Introduction of Henan Medical Condition

Henan Province disease TB disease, cardiovascular disease, cancer and AIDS. The total number of domestic medical institutions Henan is 69,774, including 1,325 hospitals, 67,712 primary health care institutions, professional and public health agencies 598, other institutions 139 (as of November 2013). Of which more than three average number of beds in medical institutions in 2000, the average number of pieces of equipment 6,936 pieces of ionizing radiation diagnostic level hospitals configuration, the number of treatment, protective equipment was about 1,500 pieces.

1.3 Measurement of Henan Province

Metering management is the basis of product quality inspection, is the first quantitative analysis of the quality of judgment, let the data to illustrate the quality of particular products. Measurement and Management is one of the vital work of the technical supervision, it is not only the measurement traceability and calibration needs, but also directly affect the accuracy and validity of test data.

Henan Province is mainly responsible for research measurement institutions to establish and preserve public standards of measurement, according to the law of value transfer, perform other tasks compulsory verification test and the law; drafting metering technical specifications, providing technical guarantee for measurement supervision assume involve trade settlement, health, safety and environmental monitoring compulsory verification of measuring instruments and the amount of

supervision and inspection of goods, to provide technical support for the measurement of law enforcement; bear pattern evaluation commissioned by the Government, the assessment of production conditions and product quality supervision; carry out measurement engineering, online measurement and smart metering study; carry out measurement calibration, technical advice and staff training.

Relying on the measurement of Henan Academy of Sciences, the province has a "National Product Quality Supervision and Inspection Center meter", "National City Energy Center (Henan)," Measurement Engineering Technology Research Center of Henan Province, Henan Province Key Laboratory of Quality and Technical Supervision measurement, Henan Province, computer products and networking systems engineering quality supervision and inspection, measuring instruments, Henan Province product Quality supervision and Inspection Center Station. The establishment of a power meter, water meter, gas meter, heat meter, weighing National Type Evaluation authorized laboratory, with environmental conditions, testing, electromagnetic compatibility testing capacity. Has a length, thermal, mechanical, electromagnetic, radio, time and frequency, acoustic, optical, chemical and ionizing radiation such as X class 204 public standards of measurement, is a measurement test, calibration testing, product quality as one of the professional and technical institutions.

Henan Province Institute of Metrology employees 249 people, including senior engineer, engineer and engineers accounted for 50% of the total. Existing metering member of the National Technical Committee 15, the National voltage and current rating Standardization Technical Committee 1, the national electrical instrumentation Standardization Technical Committee 2; measurement standards assessor national level 9, a national registered metering division 75; enjoy special allowance 3, AQSIQ expert an outstanding young man, AQSIQ technical backbone of an academic person, provincial quality inspection system academic technology leaders 4 people.

2 The Situation in Henan Medical Examination

Mainly in the field of metrology of ionizing radiation in several ways radionuclide activity measurement, radiation dose, radiation processing, measurement, and other research neutron measurement methods; study criteria, the establishment, preservation, maintenance and improvement; whole of society to provide relevant detection calibration services; responsible for the province of ionizing radiation aspects of money transfer and unified task; development organizations undertake ionizing radiation measurement science research and application of technology, products.

2.1 Measurement Test Conditions

In terms of medical measurement, metering project in Henan Institute of Medicine conducted the main source of radiation for medical treatment, medical diagnostic test calibration of measuring instruments and other medical radiation.

Henan Province Institute of Metrology has nine people in the accreditation of medical measuring instruments, with four provincial public standards of measurement and the corresponding standard device.

Medical diagnosis of Henan Institute of Metrology has, therapy equipment Legal Metrology file.

2.2 Medical Inspection Work

2.2.1 Using the Unit with Ionizing Radiation Equipment

Name	Several pieces	Mainstream Model	Manufacturers
X-ray machine CR, DR	2353	CG0-2100, SZ-5	Wandong
		Allura, Essenta DR, Digital Diagnost	Philips
		CR35-X, CR360CR120	AGFA
		Mindray560	Mindray
		VX, Artis zee	Siemens
CT	610	Brightspeed, Prospeed, LightSpeed, Hispeed Dual	GE
		SOMATOM Emotion, SOMATOM Spirit, SOMATOM Definition	Siemens
		Brilliance16, Brilliance64, Brilliance iCT256	Philips
PET-CT	20	InfiniaVcHawkeye4, Discovery STE, Discovery CT590	GE
Accelerator	100	XHA600, XHA600C, XHA600D	Shandong Xinhua
		BJ-6B, BJ-4	Elekta
		2300C / D, 600C / D, Varian CX	VARIAN
		Primus E, Primus Plus	Siemens
		Precise	ELEKTA

2.2.2 The Main Measurement Procedures Ionizing Radiation Equipment

The main parameters of ionizing radiation measuring equipment is: dose index, the air kerma rate, low-contrast resolution and high contrast resolution, spatial resolution, the tube voltage. Ionizing radiation measurement equipment according to daily, monthly and annual statistical use. Statistics radiation dose of ionizing radiation equipment, the device automatically control the dose, hand-tune control the amount of radiation. Ionizing radiation equipment manufacturers in each one, by metrological verification or calibration verification in accordance with the appropriate procedures in accordance with standard calibration once. Calibration/test cycle ionizing radiation equipment is generally for one year, the provincial hospital for test measurement, calibration and issue appropriate certificates. Ionizing radiation equipment traceability of Henan Institute of Metrology conducted by traceability to the highest standards in accordance with traceability annual figure. Strict environmental ionizing radiation device for use in the apparatus according to the required temperature and humidity environment, the radiation protection device is detected by the corresponding units per year. Radiation protection of patients to establish patient radiation file. The operator of radiation protection has its own protective equipment, protective file creation, personal vacations and maintenance, economic subsidies. Protection due to

ionizing radiation leaks or improper medical malpractice occurs, it will be promptly reported to the local authorities and cooperates to make a deal.

2.3 Henan Legal Metrology Experience

Medical measurement is supporting the rapid development of medical technology, is the mutual recognition of medical tests to check the information needs support. In Henan Province, measuring the size of the hospital staff each year for diagnosis and treatment equipment for checking and money transfer, to ensure the accuracy and reliability of the various measuring instruments. Hospitals with the metrology sector research work on the part of measuring instruments in the measurement of identification methods, parameters, etc..

Metrology medical measurement is extended in the medical field, the aim is to achieve the unity of the medical field values related to the diagnosis is accurate, reliable treatment for individuals is life and death, is the harmony and stability of the country. Therefore, to ensure traceability of medical measuring instruments, accurate and reliable, is the basis for the diagnosis and treatment can effectively reduce the rate of misdiagnosis. Improve the level of treatment, control medical risk, is their job each metering staff.

With the development of medical science and technology, a large number of new modern medical equipment appear to require medical measurement technology quickly to keep up. Metrologists we should do: First, to ensure reliable and accurate measurement of existing standards and traceability system, followed by still constantly learning new knowledge, research new measurement standards and traceability system.

According to medical testing situation Henan Province, on how to carry out medical measurement work well in the region, made the following summary.

1, the strict implementation of medical measurement system is to regulate the conduct of internal audit work in medical measurement quality assurance. Medical measurement is for all internal audit procedures involve medical Fluxes activities conducted its own review, the strict implementation of medical measurement of internal audit system is to regulate medical measurement work to improve the basic medical equipment to ensure quality control, should improve the measurement of internal medicine from a legal perspective emphasis audits.

2, establish and improve mechanisms for measuring management organization to develop workable management system, measures and methods. Our hospital has formed a metering management leadership team in charge of the Presidency headed by department supplemented by measurement management backbone network, and the establishment of medical measurement committee to various cities of testing personnel as members. Sound management mechanism enables the measurement of work goals, examine the contents, to punish basis. Meanwhile, we must continue to organize relevant personnel to learn the national measurement regulations, sufficient to make the measurement work toward standardization, institutionalization.

3, further standardized and legal management of measuring instruments, according to "People's Republic of China according to the management of measuring instruments catalog" will be in the area of medical device registration measuring

instruments, and the preparation of test plans. Make test work to be conducted in an orderly, effectively improve the rate of compulsory verification and self-calibration of measuring instruments from the school rate. While ensuring the measurement interval data accuracy, reliability and safety of use, to improve health care quality look to play an active role.

Hospital medical measuring instruments is a key quality of life, and do a good job of medical measurement management, it is necessary to grasp the mandatory verification of medical measuring instruments. Metrology departments to strictly implement the national measurement laws and regulations, learning and advocacy measuring knowledge, promotion of legal units of measurement, while in the health units established in the color green compulsory medical test, and the establishment of measuring instruments accounting, unified arrangement periodic verification plans, and health units work together to improve health care compulsory verification of measuring instruments.

3 Conclusion

As a metering mechanism province of China, to APLMF organizations working in the region carry introduce some legal metrology, said he was very honored. I hope some work experience and understanding proposed in this report can be helpful to APLMF States. Welcome to APLMF member of this organization to work exchanges, field trips. And hope that through communication, mutual promotion and common development.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Jiangsu Area)

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1. Medical Device Industry Status of Jiangsu Province

Jiangsu, referred to as “Su”, with its capital in Nanjing, located in the central eastern coast of China's territory, an area of 102,600 square kilometer saccounting for 1.06 percent of the country, the resident population of 79.2 million, ranking first five in china. Jiangsu, Shanghai and Zhejiang, together constitute the Yangtze River Delta city group which has become one of six World-class city groups. Per capita GDP, overall competitiveness, regional development and people's livelihood index (DLI) of Jiangsu rank the provinces first. Jiangsu has become the highest overall level of development of China's provinces, has entered the "upper-middle" level of developed countries.

Yangtze River Delta is one of three medical device industry gathering area in China. In terms of the industrial scale and economic benefits, the medical device industry in Jiangsu at the forefront of the country, has become an important economic growth pole of pharmaceutical industry. The development of medical devices industry in Jiangsu Province presents four characteristics: the industrial scale continues to expand; products gradually move towards high-end and intelligent; favorable investment environment and market order to attract domestic and foreign companies have come to invest; industrial concentration increase, the industrial clusters manifest.

Jiangsu has 2340medical equipment manufacturing enterprises, 14,061 business enterprises, more than 12,000 copies of Class I and Class II medical device product registration card. The province's medical equipment, sales revenue, etc, major economic indicators to maintain double-digit growth rates for many years: industry production of medical devices firstly broke10 billion yuan in 2006; in 2008 soared to 200 billion yuan; in 2013 close to 500 billion yuan. Recently, many medical device companies in Jiangsu consolidate and upgrade the market share of their ophthalmic surgical instruments, disposable medical supplies, orthopedic implants, electrocardiograph, B-model ultrasonic diagnostic equipment, etc, traditional advantage products, at the same time, independently research and produce high-tech, high value-added devices, such as positron emission tomography (PET) instrument, laser treatment instrument, Color Doppler Ultrasonic Diagnosis Apparatus, gamma knife etc.

From a regional perspective, medical equipment industrial output value of Suzhou, Wuxi and Changzhou, accounted for 60% of the province's total. Main types of medical device in Suzhou have been transformed and upgraded from low-tech

products, for example polymer products and general surgical instruments, to high-tech products, such as CT, MRI, hearing aids, rehabilitation devices and in vitro diagnostic reagents, etc. Medical device industry of Wuxi cover multiple areas from large medical electronic diagnostic equipment to in vitro diagnostic reagents, including a representative of the high-end products are B-model ultrasonic diagnostic equipment, anesthesia machine, bone densitometer, CT tube, etc. More than 80% of the high-end varieties export to European and American. Many international brands of medical devices have built base in Wuxi, such as GE healthcare, Siemens medical, nutricia, sysmex, etc. In recent years, Changzhou rely on the medical industrial park, guide and encourage medical device research institutions and production enterprises to the park, and gradually formed a distinctive competitive advantage, have six industrial clusters mainly with single-use sterile medical instruments, orthopedic implants, disposable surgical instruments, medical dressing, medical electronic products and rehabilitation equipment.

2. In-use Medical Device Status of Jiangsu Province

Over the years, the economic aggregate of Jiangsu province has been in the forefront of china, the development of health care and other social services has been the leading level, has a relatively rich resources for health, and the health care level developed. By the end of 2013, there were 31,005 health institutions in Jiangsu, including 2556hospitals, 172 epidemic prevention and control mechanism, 110 maternal and child health hospitals. New Rural Cooperative Medical System (NCMS) covers more than 98%population.

The feature of modern medicine is to diagnose complex disease with the aid of reliable medical equipment, with detailed data as a basis for clinical treatment. According to incomplete statistics, there are 129 categories of medical equipment totaling more than 1000 kinds, including 60 class and nearly 430 kinds with metrological characteristics. It is necessary to metrology and quality control these medical devices, with a very clear practical significance and social benefits.

Currently there are 86third-grade class-A hospitals in Jiangsu Province, and 445 second-grade hospitals. With the advancement of technology and the development of medical and health services, various medical institutions have increased their investment in hardware, holding volume of PET, MRI, electron linear accelerator and other large medical equipment increased year by year, which greatly promoted the development of medical clinic level.

Taking CT, MRI, DSA, LA (medical linear accelerator), SPECT (single photon emission computed tomography imaging system) as example, from 454 pieces in 2005 to 1409 pieces in 2013, increasing nearly 1,000 pieces. Details are as follows:

Equipment Name	2005/pcs	2007/pcs	2010/pcs	2013/pcs
CT	284	508	571	724
MRI	54	108	161	286
DSA	52	108	132	198
LA	53	88	95	147
SPECT	11	33	38	54

CT, MRI, DSA and LA are almost configured in third-grade hospital. Its configuration number significantly more than second-grade hospital and first-grade hospital, specifically as follows:

Grade of hospital	CT /pcs	MRI /pcs	DSA/pcs	LA/pcs
Third-grade	164	136	133	76
Second-grade	368	141	64	71
First-grade	187	3	1	0
Others	5	6	0	0
Total	724	286	198	147

According to the relevant provisions of the health sector, the technical staff of large medical equipment must be certified. Doctors, operators, and engineers must receive job training, and obtain the appropriate qualifications for employment. The number of employees of medical imaging in Jiangsu province is of domestic leading position. But the contradictions of adding reserve forces is prominent, and qualified personnel issues of first-grade hospital is more prominent.

There are imbalances for usage of large medical equipment. It's annual workload difference in different levels and size hospitals. Taking CT and MRI as example, capacity utilization more than 95%, the diagnostic yield greater than 75%; municipal and most county-level medical institutions are operating at full capacity, basically for more than 12 hours; the workload of township hospitals less than normal, (10-20) person/day more common. Boot time and average daily exposure of medical linear accelerators are also regional difference, specifically in the following table.

Investigation of Accelerator's Boot Time in 2007

Region	Grade of Hospital	Min (hour)	Max (hour)	Average (hour/pcs)	Average (hour/hospital)
Northern Jiangsu	Municipal	5	12	7.2	9.8
	County	3	10	6.2	-
Middle Jiangsu	Municipal	4	16	10.2	14
	County	3	10	5.7	6.2
Southern Jiangsu	Municipal	3	14	8	9.8
	County	3	9	6.1	-
Average	Municipal	4	14	8.3	11
	County	3	9.7	6	6.2

Investigation of Accelerator's Daily Exposure in 2007

Region	Grade of Hospital	Min(practice)	Max(practice)	Average(practice/pcs)	Average(practice/hospital)
Northern Jiangsu	Municipal	30	360	137.7	187.7
	County	15	100	56.7	-
Middle Jiangsu	Municipal	25	400	181.8	250
	County	20	180	73.3	80

Southern Jiangsu	Municipal	70	300	173.6	212.2
	County	20	200	77.5	-
Average	Municipal	41.7	353.3	161.5	213.4
	County	18.3	160	68.5	70.8

3. Management Status of Medical Metrology Instruments in Jiangsu

Medical metrology is an important part of social metrology. Under the unified leadership of the provincial bureau, every quality and technical supervision bureau of the province implement legal management with all medical metering equipment. The active cooperation of the provincial health department, the province has made medical measurement excellent results and improves the quality of medical devices using the application, maintain the vital interests of people, gets community praise.

At present, the province has 66 provincial, municipal and county levels institutes of metrology, has a total of more than 300 medical metrology personnel, verificate and calibrate 64 kinds of medical measuring instruments, such as medical linear accelerators, CT, MRI, ventilators, infusion pumps, according to the principles of hierarchical management.

3.1 Key breakthrough, comprehensively promote the technical work of medical ionizing radiation

Based on "three medical sources", it is to raise public awareness of medical measurement. "Three medical sources" is laser source, ultrasonic source and radiation source, as an important part of medical measurement work. "Three medical sources" applications in medicine have a common characteristic, that is commonly used in the diagnosis of low-energy, high energy is generally used for the treatment. The exact magnitude of these devices or not directly affect the effectiveness of disease diagnosis and treatment. At the same time, taking into account the "three medical sources" on the human body injury, but also in medical applications follow "ALARA (As Low As Reasonably Achievable, as low as reasonably possible) principle". It hopes that lower energy (or dose) through technological progress to obtain better clinical treatment effect.

To further improve the applications of ionizing radiation metrology in medicine, Our institute began to build ionizing radiation metrology laboratory in 2007. Two years later, the laboratory got formal adoption of the laboratory examination AQSIQ. At present, the laboratory can carry out the calibration and verification of protection level dosimeter, diagnostic level dosimeter and treatment level dosimeter, also carry out the calibration and verification of radiation imaging device, nuclear medical imaging device, contamination instrument, radioactivity meter, thermoluminescent dosimeter. In addition, the laboratory also conducted research related to dissemination of the value of quantity and measurement traceability.

Taking medical measuring instruments with high level risk as a breakthrough, strengthen medical metrology. In medical measuring instruments, there are some

devices which measured accurately or not directly affect the treatment effect, the larger error even endanger the patient's life. Similar to infant incubators, ventilators, dialysis machines, high-frequency electric knife, medical linear accelerators, these medical measuring instruments with high level of risk, should be strengthened management, to prevent medical accidents, maintaining a harmonious doctor-patient relationship.

In 2009, the Jiangsu issued Quality Supervision [2009] No. 219, "Notice on a Clear Division of Tasks about Checking the Province's Medical Measuring Instruments". In order to integrate the province's medical measuring resources, and promote the improvement of technical level of the province's medical measurement technology agency, highlight the leading role of "Medical Instrument Measurement Center of Jiangsu Province", help the county establishing a basic test items, the measurement tasks of the province's medical measuring instruments is clearly divided. This hierarchical management model not only improves work efficiency and application quality of equipment, but also to avoid undue competition within the industry.

3.2 Advocating the Concept of Transformation from Technical Supervision to Technical Services

Medical measurement is a multi-disciplinary, involving clinical medicine, nuclear physics, chemistry, electrical, mechanical and other disciplines, such as the most widely used multi-parameter monitors, which monitor the patient's vital signs including ECG waveform, heart rate (including respiratory frequency), blood pressure, oxygen saturation, body temperature, etc. According to the traditional classification, it is corresponding to electronic measurement, time and frequency measurement, mechanical measurement, stoichiometry, temperature measurement and so on. To complete the verification of such a measurement apparatus, at least four or more laboratory should to be completed. It is obviously not conducive to the development of medical measurement. This requires to reclassify medical measuring instruments in accordance with the requirements of clinical diagnosis and treatment of medical institutions, to improve the detection efficiency and ease the effective management of medical measuring instruments. In 2004, after our institute's medical measurement re-integration, work efficiency is greatly improved.

With the changes in social management mode, medical measurement has not only limited to the scope of legal metrology. Over the years, in addition to periodic verification, arbitration verification and initial verification of imported measuring instruments, we also carry out calibration services of medical measuring instruments, type evaluation business of new products, while also help medical institutions to complete the equipment acceptance inspection and clinical data collection, accept stereotypes consulting from hospital before equipment purchased, and joint association of metered to carry out technical training and certification forgauers from medical institutions .

3.3 Strengthen the coordination with health administrative departments and industry associations

Verification and calibration of measuring instruments for medical institutions, it is

mainly ensuring the effectiveness and safety of the equipment. The work of measurement departments should firstly meet the actual needs of the hospital, be recognized by health administrative departments. July in 2006, Jiangsu Province Health Department issued "Evaluation Criteria and Rules of Jiangsu Province Hospital " (comprehensive review of third-grade hospitals in Jiangsu province and evaluation of basic modern hospital conditions), to attention and support medical metrology.

In 2008, Jiangsu provincial quality and technical supervision bureau and the Jiangsu provincial health department jointly issued *thenotice on carrying out special checks of medical measuring instruments of Jiangsu province*. The contents checked include: whether to establish a measurement management system; measuring instruments of mandatory verification whether or not tested; whether there is not tested, the test failed behavior equipment for diagnosis and treatment, and so on. Referring to parameter and directory of mandatory verification, the ventilator, hemodialysis machines, baby incubators and other 65 medical measuring instruments were taken into the scope of supervision and inspection.

Each year, quality inspection departments pooled analysis of the test data, timely information to the health sector, and the health sector to guide medical institutions to do the replacement work of equipment based on these data, and provincial financial allocation to purchase a large number of medical equipment distributed to the primary hospital.

With the platform of professional committee for medical measurement, let the health sector to fully understand the importance of medical measured. In April 2004, with the support of the provincial bureau, Jiangsu province institute of metrology prepared to build medical measurement professional committee, and the secretariat is located in Jiangsu province institute of metrology. After a year or so, 10 prefecture-level cities in the province establish liaison working group to develop more than 600 registered members. Various academic conferences were held several times a year, and promotional activities were carried out in turn in the province. Professional committee of medical measurement truly become a good communication platform for metrology department and health department.

3.4 Following social hot spots, Doing social metrology better

Do the free verification work better for primary hospital. For a long time, primary health care institutions have problem of low measuring instruments and qualified rate. There is a big risk in primary health care quality facing to the peasants. In early 2009, Jiangsu provincial bureau of quality supervision decided to freely measure in-use instruments for village clinics of all the province ,township hospitals and community service centerin Northern Jiangsu (Xuzhou, Huaian, Lianyungang, Yancheng and Suqian). In 2009, pass rate of first test less than 50%, local quality supervision bureau joint with health administrative departments to urge health care institutions rectification, to replace a batch medical devices with poor quality. In 2010, more than 90% passing rate of test. Measurement institute throughout the province free repair sphygmomanometers, praised by the primary health institutions, has also been praised by provincial health department, and get government recognition.

Social emergencies, give full play to the advantages of medical measurement technology. In 2003, SARS outbreak, and later H7N9 avian flu, medical measurement practitioners positive response, fighting in the front line of the fight against the epidemic, withstood the test of emergencies again and again, free test in-use ventilators and thermometer again in the shortest time, and actively cooperate with the diagnosis and treatment of the hospital, get government awards and society praise.

3.5 Efforts to improve the level of business and scientific research capacity to ensure sustainable development of medical measurement

Medical instruments measuring training assessment base of Jiangsu province have solved the human resource needs of medical measurement of sustainable development. After several rounds of negotiations and fully prepared, approved by quality and technical supervision bureau of Jiangsu province, the Jiangsu provincial people's hospital and metrology institute of Jiangsu province jointly plan to set up medical instruments measuring training assessment base, is responsible for medical staff training and assessment of measurement techniques. Training base was established to further enhance the level of business and the overall quality of medical measurement personnel, to promote medical measurement science and technology popularization and promotion.

Since 2007, every year train more than 200 people for the province's medical measurement technician, has trained more than 1000 people from all cities and counties in Jiangsu province measurement medically relevant technical personnel, greatly enhance the skills of medical measurement technician, improved quality of medical metrology, quality assurance province's medical equipment.

Medical research studies adhere to the measurement-based detection methods, supplement the development direction of basic research. Metering technology research direction of provincial agencies adhere to the detection methods research, to develop standards-based. Up to now, our institute presided over the drafting of *Verification Regulation of Medical Digital Radiography System*, *Verification Regulation of Digital Subtraction Angiography System*, *Calibration Specification for Color Doppler Ultrasound Diagnostic Equipment*, etc. national Metrology technical specifications; presided over the drafting of *The Safety and Quality Control of Radiotherapy*, *Specification for testing of apply safe and quality control in Single photon emission computed tomography System* and other local standards; presided over the drafting of the *Verification Regulation of Lung Ventilator*, *Verification Regulation of Infusion pump*, *Verification Regulation of Haemodialyze*, *Verification Regulation of Extracorporeal Lithotripsy* ",and other 12 local regulations; various research projects knot question 20 items, including research detection methods of color Doppler imaging system project won science and technology progress award of provincial bureau; medical ultrasonic scalpel test device and method for the development of projects such as the development of provincial Science and Technology Progress Award.

To meet the industry brought about the development of biotechnology and new medicine huge demand measurement test, medical measurement has always attached importance to work with the province's universities, research institutes and business

contacts. In recent years, research projects cooperative with the Nanjing Military Region General Hospital, Southeast University, Nanjing University of Technology and Engineering have been approved. Annual research investment in research projects on medical measurement over 2 million yuan.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Fujian Area)

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1. The Basic Situation of Fujian Province

Fujian province, the short name of "min", its capital city is Fuzhou. It is located in the southeast coast of China, the northeast is adjacent to Zhejiang province, the west and the northwest are juncted in Jiangxi province, the southwest is connected to the Guangdong province, and the east is on the other side of the Taiwan strait. The land area of Fujian province is 12.4 square kilometers. It controls one deputy provincial city and eight cities.

The resident population of Fujian province is 37.48 million. The reliminary estimated province's GDP in the year of 2013 is totaled 2.191 trillion yuan. The public fiscal revenue of Fujian province in 2013 is 342.876 billion yuan.

Health development Situation in Fujian province: The number of health agency in Fujian province is totaled 7584 (excluding village clinics). Among them, The number of hospitals of various levels is 519 (first-class Level hospital is 40); 532 is community health service institutions (community health service center accounts 217, community health service station accounts 315); Township hospital accounts 880 (central hospitals' is 223, general hospitals' is 657); Clinic and clinics accounts 5270; Health supervision institution accounts 82, maternal and child health care institution accounts 87 , specialized disease prevention institution accounts 25, disease prevention and control institution accounts 96 (see table 1).

Table 1: Health institution table in Fujian province in 2013 Units: Institute

	The year of 2013
Total	7584
1. Hospital	519
General hospital	328
Chinese medicine hospital	75
Combine traditional Chinese and western medicine hospital	8
National hospital	2
Specialized subject hospital	106
Nursing home	0
2. Nursing home	12

3. Community health service center(station)	532
Community health service center	217
Community health service station	315
4. Institutes of health	880
Central hospital	223
Township hospital	657
5. Outpatient department	462
6. Clinic, Health clinic, Infirmary	4808
7. First-aid center (station)	7
8. Blood service	9
9. Maternal and child health care	87
10. Specialized subject hospital for disease control and prevention	25
11. Center for disease control and prevention	96
12. Health supervision situation	82
13. Medical scientific research institute	7
14. Medical on-the-job training institution	25
15. Health education institution	1
16. Other health institution	32

Note: data in this table is not including village clinics

Main cause of Residents death in Fujian province: According to the monitoring statistics of cause of death from part of the county (city, area), the top ten sequence of cause of death in urban are: malignant tumor, heart disease, cerebrovascular disease, respiratory disease, endocrine nutrition metabolic disease, injury poisoning, digestive disease, nervous system disease, genitourinary system disease, mental disorders, the top ten death cause total accounted for 92.6% of all death causes. The top ten sequence of death cause among rural residents are: malignant tumor, cerebrovascular disease, heart disease, respiratory disease, injury poisoning, digestive disease, endocrine nutrition metabolic disease, mental disorders, genitourinary system disease, nervous system disease, the top ten death cause total accounted for 91.7% of all death causes. It showed that malignant tumor is still the leading death cause among urban and rural residents in Fujian province.

2. The Basic Situation of the Region's Measurement Technology Institution

Founded in 1960, Fujian Metrology Institute(FMI) is subordinated to Fujian Provincial Bureau of Quality and Technical Supervision(FBQTS), and authorized by China General Administration of Quality Supervision, Inspection and Quarantine(AQSIQ). It is the center of quantity traceability in Fujian province. Fujian Metrology Institute Medical metrology laboratory and Fujian province medical

measurement test center (in preparation) is authorized by FBQTS and specialized responsible for medical metrological verification and calibration. It performs Compulsory verification and other verification, calibration and testing tasks regulated by measurement laws and regulation, and provide technical guarantee for promoting and improving the accuracy and reliability of medical measuring instruments and its value, safety and quality control. The laboratory has 12 engineering personnel, and has domestic and worldwide advanced measurement instruments from China Metrology Institute, China Institute of technology, United States FLUKE company, Norway METRON company and Germany PTW company, Tec. The fixed assets are more than 4 million yuan.

The verification and calibration programs conducted by the laboratory (center) currently for the medical measuring instruments are:

1) Radiotherapy categories: Medical linear accelerator (electron beam, X-ray), Cobalt 60 therapy apparatus, After installed (cavity therapy apparatus), Deep X-ray apparatus, DSA (digital subtraction angiography vascular), CR, DR digital imaging system, Mammary gland machine, Medical diagnostic X-ray radiation source and Bone mineral density instrument, etc..

2) Imaging diagnostic categories: MRI (Medical magnetic resonance imaging system), Color ultrasound (Color Doppler flow imaging), Ultrasonic doppler, CT machine, Type A heart monitor/M/B type ultrasonic diagnosis instrument and X-ray machine (Perspective, filming, dental machine), etc..

3) Electrophysiological categories: Electrocardiogram machine (meter), electroencephalogram (meter), ECG monitor, Multi-parameter monitor, Blood pressure monitor, Blood oxygen monitor, Defibrillation pulse monitor and audio, etc..

4) Clinical trial categories: Enzyme standard instrument, Spectrophotometer, Acidity meter, Automatic biochemical analyzer, Semi-automatic biochemical analyzer, and urine analyzer, etc..

5) Optical and other categories: Laser therapy apparatus, Meter, optometry, Optometry glasses boxes, Blood pressure, Blood pressure, Electronic sphygmomanometer, Infant incubator, Biochemical incubator, Constant temperature and humidity box, Pipetting, Infusion pumps, Volumetric glass, Blood dialysis machine, Breathing machine, Anesthesia machine, Pulmonary function, Blood cell analyzer, Blood gas analyzer, Blood coagulation analyzer and electrolyte analyzer etc..

3. The Medical Check-Ups of Ionizing Radiation Categories in This Region

X-ray diagnosis, clinical nuclear medicine and radiation oncology proposed to the guideline of several major medical ionizing radiation equipment CT, PET - CT and electron accelerator is roughly:

X-ray diagnostic: The situation of CT machine distribution in our province , there is a total of 132 sets CT machine in our province (including140 in the force), of which 32 is the second-hand (24.2%). According to the CT measurement test results all around the province, the new machines except domestic Alpine are all qualified, the

percent of pass is 98%. The intern pass percent of the second-hand is 90.7%. One is ordered to eliminate as it is still unqualified after rectification. Among 132 CT machines, the machine produced by SIMENS and GE Company accounted for more than 60%, the rest are from island ferry, Hitachi, Toshiba, respectively Picker, Elslint, Technicare and alpine company.

Clinical nuclear medicine and radiation oncology: The institute which has radiation therapy equipment has been developed from 4 in the beginning of 1960's to 27 at present in Fujian province. Basically all over the province has the radiation therapy institute. The radiation therapy staff from just a few doctors and technicians to a clear division of responsibilities and equipped with complete radiotherapy group at present. Among them, 194 are physicians, 34 are radiation physics teachers; 140 are radiation technicians, one is the radiation biological laboratory. The radiation therapy equipment has developed from 4 deep X-ray machines to 21 sets medical accelerator and 21 sets C060, 23 sets simulation positioning machines, 16 sets installed after, 21 sets treatment planning system and 23 sets dosimeter. In 2001, the first radiotherapy professional organization, the Fujian province anti-cancer association of tumor radiation therapy professional committee was established in Quanzhou city. In 2005, the Fujian province anti-cancer association of tumor radiation therapy branch professional committee was also founded. Later, the tumor radiotherapy quality control center of Fujian province has been established. From then, the radiation career in Fujian province is on the development road of unified specification.

The Main Problems of Ionizing Radiation Equipment Metrology:

1) Insufficient Standard Quality Assurance System, Lack of Professionals

The final result of ionizing radiation diagnosis treatment is depends on the personnel quality of physical dose radiotherapy doctors and radiotherapy technicians, it also depends on the comprehensive level of hospital's management level and the ionizing radiation equipment technology performances. In order to obtain satisfactory curative effect and ensure the safety of both doctors and patients, it must have perfect quality control system to guarantee. China has specific laws and regulations on the radiotherapy department about its staffed qualified personnel, equipment, and metrology management. According to the survey by provincial medical administration in radiotherapy quality assurance center, the radiation physics teacher equipment probability in the radiotherapy unit all around the Fujian province is only 62%, the qualified rate of clinicians, radiation physics and radiation technician training was 58%, 80% and 62%. However, the reality is measurement detection rate can't meet the requirements of quality assurance. The verification rate of X-ray machine and CT client is higher, at 95%. But the yearly verification of medical electron accelerator is only 8 sets; it is far less than the actual used number. The detection rate of PET - CT is zero.

2) Hospital Insufficient Understanding of Legal Metrology, Affect the Overall Rate of Tested

From the attitude of hospital leaders, the head of the department (equipment) and the corresponding treating physicians, they are not fully supported and trust about the ionizing radiation verification work. Overall, most of the hospitals lack scientific

medical verification workflow: from the early stage of the overall test plan and the specific to the site, as well as the overall job summary and feedback, did not realize the effective connection. It is to lead that in the eyes of top leaders of medical institutions, the equipment department (medical check-ups counterpart departments) measurement is always a costly hospital treatment and influence work "inefficient" department, which is caused by ionizing radiation (radiotherapy equipment) measurement important reason of lower tested.

4. The Working Experience and Achievements of Medical Legal Metrology in The Region

4.1 Measurement and Medical Mutual Cooperation in This Area

1) Cooperate with local measure technology institution, association for medical equipment inspection. For example, we cooperate with Fujian Nanping city and Quanzhou city, and the regional medical measuring instruments average verification rate has increased 20-30% after cooperation. The medical measuring instruments verification rate of mainly included in the legal metrology has reached 85%. Take Nanping city for example, the medical metrology projects, the institute has upgraded to medical division from the original medical team, and the personnel, equipment and technology have been comprehensively strengthen. Meanwhile, Quanzhou city took "the infant incubator event" as an opportunity to strengthen the medical instruments verification of infant incubator, etc. At present, the medical measuring instruments verification cooperation between Fujian Metrology Institute and metrology institutes in Fujian province is steadily forward.

2) Jointly carrying out the "the provincial medical institutions for medical measuring instruments special supervision and inspection" with FBQTS and Fujian provincial health department. From the end of 2013 to the first quarter of 2014, with an emphasis on the provincial level 2 and above hospitals of various levels, including general hospital, hospital, specialized subject hospital, rehabilitation and health care of women and children's hospital. Key checking whether medical institutions to establish metrological management organization and management system, and whether it is equipped with specialized professional (part-time) measurement management, whether a medical gage list and carries on the metrological verification in accordance with the law, whether to use the provisions of the state to abolish the non-legal measurement units, whether there is are not checked or using verification is unqualified medical measuring instruments, etc., comprehensively promote medical measuring instruments.

From the current situation, the effect is obvious. Take one of the largest hospitals in the province for example: order it to supple totaled 800 sets as the breathing machine, multi-parameter monitor, defibrillation analyzer, infant incubator, electrocardiogram machine, medical magnetic resonance imaging system (MIR) radiation source, medical infusion pump and syringe pump, and take it as an opportunity for the provincial hospital attaches great importance to the medical metrology work, establish the long-term mechanism of medical metrology management

4.2 The Working Experience and Related Suggestions of Carrying Out Medical Testing in This Region

1) To strengthen medical metrology. In the 5.20 world metrology day of the year and the 6.6 world loving eye day both has a special medical measuring instruments propaganda, large public lecture regularly held in the provincial library, and open year-round measurement laboratory, increase public awareness of the medical metrology and understanding.

2) Free community service activities are carried out once a month. Organization "metering convening people" volunteer team, monthly go to a community to carry out the free verification and the maintenance work of medical measuring instruments (such as blood pressure, blood glucose meter, thermometer, human scale), make public trust and support for the work of medical check-ups, gradually form a good brand effect.

3) Invite people's congress, CPPCC member to support medical metrology work. Invite province people's congress, CPPCC member to visit the laboratory, and editorial information report, feedback medical check-ups.

4) Increasing medical metrology communication between Fujian and Taiwan. Rely on "the channel west bank economic zone" geographical advantages, the use of good "first try" preferential policies, signed a long-term cooperation intention to metrology institute of Taiwan, Taiwan industry research institute. Every year we send scholars to do the special subject study there. This year, the scholar we send is to study the rapid detection of glucose meter standard.

5) Other related Suggestions:

(1) New measurement will be rut into world as soon as possible. Strong will be included in the inspection and verification in accordance with the law of medical appliance explicit legalization

(2)Unified ionizing radiation technical specifications. Unified arrange by the state level ionizing radiation medical testing equipment examination/calibration assembly. Effective organize stable cross - at all levels (province, cities and counties, including private, villages and towns) measurement technology institutions and medical institutions.

(3) Public awareness of medical check-ups also needs to be strengthened. Although the province diversity to the propaganda for many times, but have not form a universal, seismic effect, hope to have a big media (such as CCTV, Baidu, Sina home page, etc.), a thorough propaganda the importance of medical metrology, the formation of everybody understand medical check-ups, support medical check-ups.

4.3 The Countermeasures of Development Trend to Ionizing Radiation Medical Testing Equipment

1) Strengthen the frontier technology learning. Metrology personnel (including managers) shall be held at the forefront of ionizing radiation medical testing equipment development trend as soon as possible, to participate in national, international academic conferences and training as much as possible, participate in high-profile laboratory comparison, verification, to improve its detection quality. In a

more open mind lab to conduct academic visits, with well-known institutions across regions.

2) Conditionally introduction of professionals. In addition to its own training talents, develop, and strive for a series of preferential policies, introducing senior professionals to the well-known enterprises and the lab, leading business backbone, promoting professional development.

3) Strengthen the communication with doctors and the medical examiner users. Medical check-ups work is mostly classified to equipment department in hospital, however, actually using the device's physicians and in charge of the leadership is not big concern about it. In fact, achieve the above personnel support and understanding is an important part of the work. To establish effective communication mechanism, make them understand the ionizing radiation medical check-ups, is not only the requirement of legal metrology, also to lengthen the service life of medical equipment to protect the physical and mental health of medical equipment users provides useful help.

4) Establish a medical examiner information feedback team. One task is to collect the national and global industry development trend and feedback to the competent administrative department for development situation; Second is to establish regular communication with suppliers (particularly well-known supplier) mechanism, feedback testing equipment problems, communication measurement inspection technology solutions.

5. Conclusion

As a Chinese provincial metrology, it will be feel very honored to attend APLMF and introduces some legal metrology work in this region. Hoping the experience and understanding presented in this report will be helpful for APLMF member states. Welcome APLMF members come to my institute for communication.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Chengdu Area)

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1. Local Briefing

Chengdu, referred to as "Rong", is located in the western part of China, from Longquan Mountains in her east to Qionglai Mountain in her west. She has a flat topography, complicated rivers network, abundant natural resource and livable climate, so she is called "Land of Paradise" since 1800 years ago. And Chengdu has a history dated back to 611 BC and hasn't changed her town site for the longest time in China. As the capital of Shu, she was famous for developed textile dyeing and other handicrafts in ancient days. But now, Chengdu, the most important western city determined by the State Council, has developed to the capital of Sichuan Province, the politics, science, technology, trading, traffic, education and communication center in western China. Additionally, Chengdu is one of the two national economic and social development planning cities.

Chengdu's total area is about 12,400 square kilometers and her city center area is about 598 square kilometers. Now, Chengdu has 9 districts, 4 prefecture-level cities and 6 counties. In 2013, the city's GDP is 910.89 billion CNY and the first, second and third industry's proportion is 3.9: 45.9: 50.2. By the end of 2013, the Chengdu's resident population was 14.3 million, minority population accounted for 0.9%, the natural population growth rate was 2.71 ‰, and the fertility rate in line with policy was 93.3%.

2. The Conditions of Local Medical Treatment and Public Health

According to the statistics of Chengdu's public health bureau, the healthcare and fitness conditions of local residents improves year by year. Meanwhile, the morbidities of plague, Aids, rubella and other national notifiable diseases decrease but chronic diseases and occupational diseases increase recently years. Now, the top ten of deadly diseases are malignant tumors, diseases of circulatory, diseases of respiratory, injury and poisoning, diseases of digestive system, endocrinal, nutrient, and other metabolic diseases, infection and parasitic diseases, diseases of the genitourinary system, nervous system diseases, and mental disorders.

By the end of 2013, Chengdu has 7976 medical treatment and health organizations. Among them, there are 19 Grade 3-Class 1 hospitals, 16 Grade 3-Class 2 hospitals, 328 township hospitals, 22 Centers for Disease Control and Prevention, 21 Maternal and Child Care Service Centers, 16 Family Planning Service Stations, 134

Community Health Service Centers. These organizations have about 101,000 sickbeds, and there are nearly 94,000 ones in hospitals and health service centers. Additionally, Chengdu has 120,000 medical workers, and there are about 46,000 certified doctors and 51,000 certified nurses. 101.48 million total diagnosis and treatment has been completed all year round.

Recently years, Chengdu government significantly increases the investment on medical treatment and public health. For example, the policy that the annual verification fees of statutory measuring instruments are for free, reduces the public township hospitals' and Community Health Service Centers' financial stress and promotes their medical facilities' updating and help them improve the technical level. Additionally, the total fixed assets of Chengdu's medical treatment and health organizations amounted to 6.53 billion CNY by the end of 2012, and during the national "Eleventh Five-year Plan", Chengdu's total fiscal expenditure on medical treatment and public health amounted to 12.7 billion CNY, which increased 2.61 times than during previous five-year plan. The growth rate of government's investment on medical treatment and public health was 34% higher than the rate of other fiscal spending in 2013. With Chengdu's economic development, increasing of local residents and aging population, the reformation of medical insurance system, and the growing awareness of residents in health care, Chengdu's medical treatment and public health development will maintain a fast and stable pace in future.

Tab.1 The Holdings of Common Medical Equipments in Chengdu(Incomplete Statistics)

No.	Medical Metrological Instruments	Amount
1	Computed Tomography Diagnosis Equipments	130
2	X-ray Diagnosis Equipments	995
3	Medical Ultrasonic Source Diagnosis Equipments	1364
4	Medical Magnetic Resonance Imaging Systems	52
5	Sphygmomanometers	12782
6	Electrocardiographs	1512
7	Oxygen Inhalation Apparatus	35968
8	Medical Syringe Pumps, Volumetric Infusion Pumps	1063
9	Medical Ventilators	95
10	Multi-parameter Monitors	14526
11	Baby Incubators	123
12	Medical Lasers	85
13	Biochemical Analyzers	603
14	Urine Analyzers	712
15	Blood Cell Analyzers	850
16	Electrolyte Analyzers	437
17	ELISA Analytical Instruments	355

18	Trace Element Analyzers	49
19	Time-resolved Fluorescence Immunoassay Analyzers	68
20	Chemical Luminescence Immunity Analyzers	91
21	Fetal Monitors	493

3. The Conditions of Metrological Supervision on Local Medical Metrological Test

3.1 The Condition of Local Technical Institution of Metrology

Chengdu Institute of Metrological Supervision and Verification(CIMSV) is one of the first national certified, public welfare, and general metrological testing institutions. It is also the National Urban Energy Metering Center approved by General Administration of Quality Supervision (AQSIQ) and the metrological calibration and testing laboratory approved and authorized by China National Approval Committee (CNAS). During the past 60 years, its technology on metrological testing improves and equipments updates continually benefited from Chengdu's industrialization, science development and government's financial allocation increasing. Meanwhile, CIMSV carried out many significant revisions of national technical standards, explored and finished many scientific research projects, participated in many important engineering items, and built over 400 social public metrological standards. Because of local medical treatment and public health's rapid development, CIMSV established Department of Medical Testing(DMT) which specialized in medical metrological verification and calibration, to ensure the performances of statutory detecting instruments are under control and to provide relevant technical supports. Now, DMT has 22 laboratory technicians, including a Senior Engineer, and has advanced testing equipments imported from oversea corporations, such as The Phantom Laboratory, Fluke, RTI Electronics, METRON and so on. The fixed assets of DMT amounted to more than 3 million CNY.

Tab.2 The Projects of Verification and Calibration Partly Launched by DMT

Projects	Test Criteria
Ultrasonic Source for Medical Ultrasonic Source Diagnosis Equipments	JJG 639-1998
Ultrasonic Source for Ultrasonic Doppler Fetal Monitor	JJG 394—1997
Electrocardiograph	JJG 543-2008
Sphygmomanometer	JJG 270-2008
Multi-parameter Monitor	JJG 692-2010
	JJG 760-2003
	JJG(Chuan)93-2006
Automatic Electronic Sphygmomanometer	JJG692-2010
Dynamic Electronic Sphygmomanometer	
Sleeve-type Electronic Sphygmomanometer	JJF(Rong)037-2009
Wrist-type Electronic Sphygmomanometer	

Laser for Medicine	JJG 581—1999
Analogue Weight Scale	JJG 13—1997
Electronic Weight Scale	JJG 539—1997
Medical Syringe Pump, Volumetric Infusion Pump	JJF(Rong) 036-2009
Lung Ventilator	JJF 1234-2010
Medical Diagnostical X-ray Radiation Source for Computer Tomography	JJG 961-2001
Medical Diagnostic X-ray Radiation Source	JJG744-2004
Buoy Type Oxygen Inhalator	JJG 913—96
Elastic Element Pressure Gauge, Pressure-vacuum Gauge, and Vacuum Gauge	JJG52-2013
Blood Cell Analyzer	JJG714-2012
Focimeter	JJG580-2005
Trial Case Lense	JJG579-2010
Automatic Refractor	JJG892-2011
Pupil Distance Meter	JJG 952-2000
Urine Analyzer	JJF1129-2005
Biochemical Analyzer	JJF(Rong)051-2013
ELISA Analytical Instrument	JJG861-2007
Electrolyte Analyzer	JJG 1051-2009
Five Trace Elements Analyzer	JJF((Rong)052-2013
Two Trace Elements Analyzer	JJF((Rong)053-2013
Time-resolved Fluorescence Immunoassay Analyzer	JJF((Rong)055-2013

Tab.3 The Public Metrological Standards on Ionizing Radiation of Chengdu Institute of Metrological Supervision and Verification

No.	The Public Metrological Standard Names	Grade
1	Calibrating Apparatus of Medical Diagnostic X-ray Radiation Source	City-level
2	Calibrating Apparatus of Medical Diagnostical X-ray Radiation Source for Computer Tomography	City-level
3	Calibrating Apparatus of Medical Diagnostical X-ray Radiation Source for Spiral Computer Tomography	City-level
4	Calibrating Apparatus of Medical Diagnostic X-ray Radiation Source(CR/DR)	City-level

3.2 The Condition of Local Medical Metrological Test

It is an important people's livelihood that the accuracy of medical metrological instruments which are used for clinical diagnosis and treatment fits the laws' requirements, so Chengdu's government attaches great importance to local medical metrological verification and calibration. Since the "People's Republic of China Metrology Law" was promulgated and carried out in 1986, legal metrology has been initiatively implemented in public medical system with local Bureau of Technical Supervision and Health Bureau's efforts. According to metrology law and regulations, CIMS SV carries out verification and calibration of NMI systems and other over 30 kinds of metrological instruments in all local medical organizations. Local medical

organizations abide by the Metrology Law strictly, build/consummate their metrological systems according to "The Metrological System's Evaluation Criteria of Medical Treatment and Public Health in Chengdu" and equip the instruments conforming to the national metrological regulations. And all the metrological instruments needing mandatory verified are registered in list and strictly execute the periodical verifications.

From 2013, Chengdu government introduced the policy that all the ultrasonic sources, color Doppler ultrasonic sources, sphygmomanometers and weight scales in Community Health Service Centers(Stations) and township hospitals executed the verifications for free, according to AQSIQ's "Plan of Twelfth Five-year Metrology Development ". Meanwhile, it allocated 1.08 million CNY of specialized funds to the policy. Now, 14,600 medical metrological instruments are verified for free annually, the examination rate is 99% and first time yield reaches 96%.

In the aspect of ionizing radiation diagnosis instrument, there were 130 CT diagnosis apparatuses and 126 of them were verified. The examination rate was 97% and first time yield reached 95%. Qualified devices were granted certificates and allowed to be used, but unqualified ones were required to be repaired and the institution were need to be abarbeitunged. The corrective measures included that hospitals could contact the manufacture to repair and maintain the instruments and then applied for verification again until the qualified rate reached 100%; there were 995 X-ray diagnosis apparatus, and 960 of them were verified. The examination rate was 96% and second-pass yield reached 98%. The main reasons of CT which cannot pass the verification are usually that resolution was too low, smearghost was unacceptable, scanning thickness was unqualified and so on. And the main reasons of X-ray devices failed to be verified were that devices were slightly out of focus, tube voltage/current were immoderate, the linearity was unacceptable and so on. Generally, the imported devices had good quality but the domestics always had electrical and mechanical failures.

Tab. 4 Mainstream Diagnosis Apparatuses Types of Ionizing Radiation and Their Manufacturers

Projects	Main Types	Manufacturer	Local Market Share
X-ray Apparatus(Including Ordinary X-ray Apparatus, Digital X-ray Apparatus, Mobile X-ray Apparatus, C-arm Fluoroscope and others)	Definium 6000、DR-F、TXIII	GE	8.0%
	DigitalDiagnost、 BV Libra、 ALLURA XPER FD20	PHILIPS	5.4%
	RAD SPEED M series、 MUX-100DJ Series、 Mobile DaRt Evolution、 0.6/1.2P324DK Series	SHIMAZU	8.2%
	MAMMOMAT Series、 AXIOM Series、 Artis Zee Series	SIEMENS	5.7%
	E7 series	TOSHIBA	3.7%
	XD52 Series、 DX30 Series、 E7 Series	Tianjin Shengbang Ltd.	30.1%

	New Oriental 1000Series、XD52 Series、XD51 Series、HM-32	Beijing Wandong Ltd.	23.9%
	MSD-III	Fujian Meisheng Ltd.	2.0%
	DR200U、KL83 Series	Yuyue Medical Ltd.	1.7%
	XD51 Series XD52 Series	Southwest Medical Apparatus Ltd.	6.8%
	PLX100 Series、PLX112 Series	Nanjing Puai X-ray Imaging equipment Ltd.	1.6%
	XD51 Series、XD52	Shanghai Medical Devices Ltd.	3.1%
CT	Bright Speed、Hispeed、Light Speed、Prospeed Series	GE	25.2%
	Brilliance Series、MX Series	PHILIPS	18.4%
	SOMATOM Series	SIEMENS	37.9%
	Aquilion16、Tsx Series	TOSHIBA	5.8%

According to the surveys, the large and medium hospitals strictly controlled the testing properties of medical metrological instruments and effectively consummated protection measures of radiation dosage. Moreover, technician built profiles to monitor radiation dosage, which can be checked and recorded periodically. Owing to comprehending machine performances deeply, these trained staff were able to accomplish the testing missions well and handle some common faults. However, part of small hospitals, private hospitals and township hospitals selected and purchased instruments of the non-mainstream brands which had poorer qualities, poorer performances and lacked of good after-sales service so that the metrological performances of those instruments were disqualified. The X-ray apparatuses was insufficient in some populous regions, so it would have been not up to standard for instrument performance because regular maintenances of these instruments working all the time were never conducted. Besides, there were more hurdles to overcome in some poorer and backward hospitals and township hospitals where the job training and radiation protection had never been offered to staff, and even compulsory inspection was often evaded.

4. The Experiences and Achievements of Legal Metrology on Medical Tests in Chengdu

The legal managements of local medical metrology have been significantly developed in recent decades. The work's experiences and achievements are below.

1) The execution of medical metrological instruments' mandatory test and supervision has been strengthened according to the legal management system. Meanwhile, all the metrological instrument in medical organizations are registered. And the information network of mandatory management among administrative departments, technical institutions and customers has been established by information

and data sharing to improve the supervision and management of the administrative metrological departments.

2) It's a good way to do adequate publicity and make the citizens to participate in supervision. For example, we did various forms of publicity about the metrology and organized a series of activities on the World Metrology Day every year. On that day we measured blood pressure for free and provided consulting services to public on commercial plazas and populous community. So, the concepts of legal metrology were established and the public awareness of participating in metrology activities were rooted in residents' brains.

3) The CIMS's vice-president, undersecretary of CIMS's Business Department and DMT's superintendent organized training sessions for hospitals' presidents, metrological managers of medical organizations, heads of clinical departments and chief nurses to help them understand the meaning of legal metrology, make them cooperate with our technicians to finish the mandatory test and co-build the metrology system.

4) The members of National People's Congress, Chinese People's Political Consultative Conference and supervisors of legal metrology were invited into medical laboratories to exhibit the effects that metrological work can improve people's living standard and keep the economical order and accelerate and industrial development.

5) Bringing other necessary services during medical metrological test can also help customers to build and consummate metrological management system, such as that technicians can list and register the medical instruments in hospital's online office automation system and label the clinical department' name onto the verification certificates. Additionally, technicians can also provide some suggestion, answer the doctors' relevant questions in use, debug parameters and make some simple and feasible maintenances.

5. Conclusion

As a metrological institutes of the centre city in western China, it is an honor to have this opportunity to introduce local conditions of legal medical metrology and present the surveys of ionizing radiation on human health and safety in our area to APLMF. We hope that all the information in this report could be helpful for other member states.

Welcome to Chengdu and welcome to our institute for further communications and inspections.

Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Suzhou area)

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With the development of modern science and technology, more and more medical measuring instruments are applied in the medical scientific research, clinical diagnosis and treatment in medical field. The reliability of measured value and safety of performance of medical measuring instruments have a direct influence on the diagnosis and treatment effect and direct relation with the human health and life safety. Medical metrology is the guarantee of scientific diagnosis and scientific treatment.

The legal system management of medical metrology has been well put into practice in Suzhou region, and the situation of medical detection work carried out is outlined as follows:

1. Basic Information

Suzhou is located at the southeast of Jiangsu Province, to the south of Yangtze River, at east coast of Tai Lake, at the center of Yangtze River Delta, belonging to the one of megalopolises in Eastern China.

The whole city covers an area of 8488.42 square kilometers, and the urban area is 2742.62 square kilometers. The whole city had a total population of about 13 million by the end of 2013, of which the total registered population was about 6.5 million, and the total registered floating population was 6.5 million. Four county-level cities are under the jurisdiction of Suzhou that was approved as "major city" by the State Council in 1993.

GDP of Suzhou is RMB 1,300 billion (in 2013), GNPP is USD 18,853 (in 2013). GDP of Suzhou ranks the sixth in the whole country, and ranks the first among prefecture-level cities in the whole country.

2. Situation of Quality Supervision

2.1 Situation of administrative management over technical supervision

The Bureau of Quality and Technical Supervision of Suzhou is the governmental department in charge of safety supervision work for quality, certification and accreditation of standard measuring special equipment and supervision work of food production, and performs the supervision function, consisting of five technical organizations.

2.2 Situation of measurement technical institution

There are five statutory measuring verification technical organizations established

according to law in Suzhou region, including one municipal verification institute and 4 county level institutes.

2.3 Brief introduction to the situation of Suzhou measurement institution

Suzhou Institute of Measurement and Testing Technology is the statutory measuring verification technical organization established by the Bureau of Quality and Technical Supervision of Suzhou according to law, whose statutory duties are to provide technical assurance for the implementation of Metrology Law of the People's Republic of China, Method for the Metrological Supervision and Administration of Suzhou, etc. , unify the measured value of Suzhou (including four county level cities), study and establish the highest measuring standard and social public measuring standard, and carry out the measured value transfer; To perform mandatory verification and carry out other measuring verification, calibration and detection work; To undertake the type evaluation on new measuring products issued by the governmental metrological administrative department; To undertake the quality supervision and inspection and measuring arbitral verification on measuring instruments entrusted by the governmental metrological administrative department; To undertake the detection and verification on scientific results entrusted by the relevant department or unit.

Now there are 283 employees and 168 professionals (including 61 senior and intermediate technical personnel) in Suzhou Institute of Measurement and Testing Technology. Initial asset value of measuring instruments is more than RMB 82 million and building area is 24,000 square metres. There are fifteen municipal social public measuring standards and the corresponding regulator for X-ray radiation source of computer tomography (CT) device for medical diagnosis, X-ray radiation of spiral computed tomography (CT) device for medical diagnosis, medical ventilator, electrocardiograph, hematology analyzer, etc., and ten professionals are engaged in the verification on medical measuring instruments.

3. Situation of Medical Verification

3.1 Situation of medical institutions

There are more than 400 medical institutions at all levels in Suzhou, including 16 tertiary hospitals, 48 second-class hospitals, and more than 300 various types of clinics, nursing homes and community health service stations. There are about 40,000 units of measuring instruments which can be verified / calibrated according to the measuring verification procedure or calibration specification, of which the urban area has about 14,000 units.

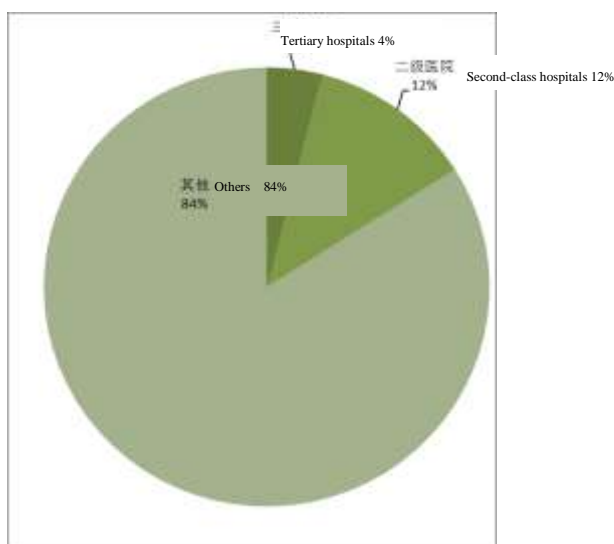


Figure 1 Classification of local medical institutions

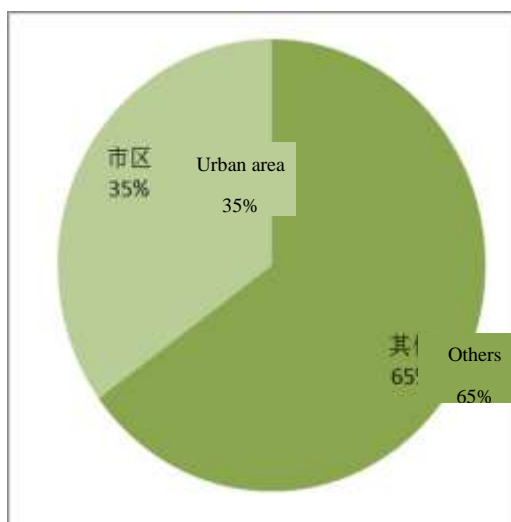


Figure 2 Geographical distribution of measuring instruments verified

3.2 Work situation of medical measurement

The medical verification mode in Suzhou area is coordinated by the three levels of province, municipality and county, which is collaboratively completed by their respective strengths.

1) Provincial technical organization mainly takes charge of coordinating the provincial relevant competent administrative department, drafting the local verification / calibration technical regulations, training the city and county level testing personnel, and completing the verification / calibration work related to the medical measuring instruments for which this institute has no medical testing capacity in this region. Such as: Linear accelerator, DSA, etc..

2) As prefecture-level municipal technical organization, the Suzhou Institute of Measurement and Testing Technology takes charge of the medical testing work in this region and coordinating the medical testing work among the relevant competent administrative department, provincial technical organization and county level technical organization in this region, training county level testing personnel, and completing the verification / calibration work related to the medical measuring

instruments for which county level technical organization has no medical testing capacity. Such as: X-ray radiation of spiral computed tomography (CT) device for medical diagnosis, medical ventilator, hemodialysis machine, etc..

3) Routine medical verification work within the jurisdiction area is taken charged by the county institute. Such as: "Medical radiation source, ultrasonic source, and laser source", ECG monitor, sphygmomanometer and others, and taking charge of coordination work among all relevant competent administrative departments under its jurisdictions. For the items unable to be verified, shall be reported to the upper level technical organization (municipal verification institute) for verification. In the event that municipal verification institute has no capacity to verify items, it shall report to provincial institution and do a good job of coordination.

4) Provincial, municipal and county level medical verification items of Suzhou are shown in Table 1 to 3

Projects Carried Out by Provincial Hospital in the Local Region (Table 1)

Serial No.	Items of medical verification	Serial No.	Items of medical verification
1	Accelerator	15	Meter for bone mineral density (ultrasonic method)
2	Therapeutic machine of cobalt-60	16	Activity meter
3	Afterloading unit (intracavity therapeutic machine)	17	α , β , and γ surface contamination meter
4	X knife, r knife (stereotactic radiotherapy)	18	γ RIA counter
5	Deep X-ray therapeutic apparatus	19	Medical magnetic resonance imaging
6	Positron emission CT	20	x and γ radiation dose equivalent (rate) instrument and monitor for radiation protection
7	Single photon emission CT	21	Direct reading electroscope type personal dosimeter
8	Digital subtraction angiography	22	Measurement devices of χ , γ radiation thermoluminescence dose for personal monitoring
9	CR, DR digital imaging system	23	χ , γ radiation personal alarm apparatus
10	Mammography	24	Therapeutic levels ionization chamber dosimeter
11	Digital gastrointestinal machine	25	Standard dosimeter for γ -ray water absorption dose
12	Simulate gastrointestinal machine	26	Dosimeter for electron beam radiation

			processing
13	Meter for bone mineral density	27	Aurometer
14	Ultrasonic source of ultrasonic therapeutic equipment for medical use		

Projects Carried Out For Medical Verification by SIMT in the Local Region (Table 2)

Serial No.	Items of medical verification	Serial No.	Items of medical verification
1	X-ray radiation source of computer tomography device (CT) for medical diagnosis	22	Hematology analyzer
2	Diagnosing X-ray radiation source (ordinary X-ray machine)	23	Electronic blood cell counter
3	Ultrasonic source of ultrasonic Doppler fetal monitor	24	Hemoglobin meter
4	Ultrasonic source of diasonograph for medical use	25	Electrical conductivity meter
5	Ultrasonic source of ultrasonic therapeutic equipment for medical use	26	Oxygen inhalator
6	Ultrasonic source of ultrasonic Doppler fetus-voice meter	27	Dioptometer and refractometer
7	Ultrasonic source of color Doppler diagnostic apparatus for medical use	28	Optometry lens group
8	Laser therapeutic system for medical use	29	Medical infusion pump and medical injection pump
9	Blood pressure meter (gauge)	30	Spirometer
10	Digital electronic sphygmomanometer	31	Infant incubator
11	Blood pressure monitor	32	Poly-parameter supervisor
12	ECG machine	33	Safety pressure gauge
13	EEG machine	34	Body scale
14	BEAM machine	35	Scale
15	ECG monitor	36	Infrared thermometer
16	Blood gas acid-base analyzer	37	Indentation tonometer
17	Electrolyte analyzer	38	Hemodialysis machine

18	Spectrophotometer	39	Medical ventilator
19	Biochemical analyzer	40	Anesthesia machine
10	Urine analyzer	41	Defibrillation Monitor
21	Microplate reader		

Projects carried out for medical verification with the jurisdiction area of the county (Table 3)

Serial No.	Items of medical verification	Serial No.	Items of medical verification
1	Diagnosing X-ray radiation source(Ordinary X-ray machine)	11	Electronic blood cell counter
2	Ultrasonic source of diasonograph for medical use (black and white B-ultrasonic)	12	Hemoglobin meter
3	Blood pressure meter (gauge)	13	Electrical conductivity meter
4	ECG machine	14	Oxygen inhalator
5	ECG monitor	15	Dioptometer and refractometer
6	Electrolyte analyzer	16	Optometry lens group
7	Spectrophotometer	17	Medical infusion pump and medical injection pump
8	Biochemical analyzer	18	Safety pressure gauge
9	Urine analyzer	19	Body scale
10	Blood cell analyzer	20	Scale

3.3 Situation of medical verification verified

There are more than 400 medical institutions approved by Department of Health to provide external services, with the examination rate reaching 99%, and the examination rate for measuring instruments compulsively verified in various medical institutions reaches 100%; the examination rate for measuring instruments which can be verified / calibrated by the relevant technical regulations reaches 95%, thus ensuring that percent of pass of medical measuring instruments in use after being verified / calibrated reaches 100%.

3.4 Main working methods to carry out medical verification

1) Reinforce publicity to strengthen legal awareness of measurement in the whole society

Metrology law and the relevant regulations are comprehensively propandized to strengthen the awareness of metrological legislation in the whole society by playing the role of news media and through television, broadcast, newspaper, distribution of measuring publicity materials, etc..

Carrying out the "People-benefit Measurement" activities for people's livelihood, of which including free verification and repair of household hematomometer for citizens all year round (it was listed in the practical project for people's livelihood of Suzhou in 2013, there are more than 14,000 citizens received whose household

hematomanometers are submitted for testing, more than 15,000 pieces of hematomanometers repaired, and more than 8,000 pieces of riva-rocci sphygmomanometers in one year. Currently, RMB 0.5 million for people-benefit project has been listed into the annual local government budgets), free verification on measuring instruments in health service stations at village level (there are 190 village-level health service stations and 1,100 pieces of measuring instruments), community quality classroom, 520 World Metrology Day activities, employment of volunteer measurement inspectors, etc., letting the general public be convinced that it is a great event that may cause harm to their health and safety if the measuring instruments are used without verification, particularly for the measuring instrument related to medical safety, and only measuring instruments passing the measuring verification can be safe. So as to build a healthy social environment under which whole society pays close attention to measurement and supports measurement, establishing a pattern favorable for the implementation of quality supervision system promoted by the government, cooperated by hospitals, and focused by ordinary people.

2) Take "Strong Inspection" as emphasis to boost the overall medical verification work

Medical institution is the main body to put medical testing work into practice, to organize the relevant personnel of medical institutions to learn Metrology Law of the People's Republic of China, Method for the Metrological Supervision and Administration of Suzhou and other metrology law and regulations, and to enhance the legal consciousness on metrology of medical institutions.

In the course of implementing medical testing work, the notice of verification shall be issued to the unit using the measuring instruments being subject to mandatory verification a week in advance according to the entrusted requirements of metrological administrative department, so as to make it carry out punctual and fixed point verification on the measuring instruments being subject to mandatory verification; the qualification label is pasted and the corresponding certificate is issued after being qualified; for the measuring instruments below the verification standard, the verified unit shall be notified and receive a result notice, and the mandatory verification work shall be periodically reported to metrological administrative department. For individual units that have incoordination in mandatory verification work, these shall be put it into practice by law enforcement on inspection and administrative supervision.

By comprehensively carrying out the mandatory inspection, using units are be convinced of the importance and necessity of mandatory verification on measuring instruments and verification / calibration on medical measuring instruments, driving the verification / calibration work of other medical measuring instruments. For some units having insufficient understanding of measurement work meaning, they also give positive coordination in verification / calibration of medical measuring instruments in use through the mandatory verification and publicity.

3) Strengthen cooperation of all involved department and measurement supervision
Medical verification work is a complex systems engineering, with its unique

characteristics, and its successful implementation can not be separated from the support and help of leaders at all level in different departments. In order to carry out the better and effective supervision and management, Municipal Bureau of Quality Supervision and Municipal Health Bureau jointly issued the Notice on Further Enhancement of Measuring Instrument Management in Use by Medical Institutions. Main contents include three aspects: Firstly, it is required that the measuring instruments in use being subject to mandatory verification and medical measuring instruments in use of all medical institutions shall be reported to the local quality and technology supervision department for reference after register in detailed lists; Secondly, it is required to make a good job of periodic verification (calibration) work for the measuring instruments in use of medical institutions; Thirdly, it is required to continue to promote the construction of the integrity measurement system in medical institution.

Over the years, Quality Inspection Department and Health Authority of Suzhou have kept a close cooperation and mutual support, laying a solid foundation for medical verification work in this region.

4) Establish management platform of information network to improve the effort on supervision and management

Management information network platform for measuring instrument being subject to mandatory verification and medical measuring instrument in use established by Suzhou Institute of Measurement and Testing Technology is responsible for organizing training on the metrological management personnel at all level of medical institutions, helping to establish and perfect metrological management network, and helping to carry out the complete accounting and registration of measuring instruments. Through this network supervision platform, all medical measuring instrument models and other basic information, qualification status, delayed use condition, the time for verification applied by use unit, completion time for verification work by testing institution and other information are completely opened by network, and the administrative department, technical organization and users can share these information and data, increasing the effort on supervision and management of metrological administrative department.

Currently, filing work is only limited in urban area, the filing efficiency of municipal medical institution reaches 85%, and it will be further expanded to the scope of the whole region.

5) Increasing the input and improvement of measuring testing devices, and improving the technical level of personnel

In recent years, Suzhou Institute of Measurement and Testing has accelerated the improvement of technical equipments, established X-ray radiation of spiral computed tomography (CT) device for medical diagnosis, medical ventilator, hemodialysis machine, color Doppler ultrasonic diagnosis apparatus and verification devices in order to meet the technical requirements for verification and continuously increase the recognition degree of medical institutions on the importance of measuring verification, with a total investment amount of more than RMB 2 million, basically meeting the medical verification requirements in this region.

In personnel aspect, the most of medical verification personnel have the bachelor of medicine. Medical verification personnel are required to continuously improve their individual comprehensive quality, learn and grasp the knowledge and technology in the relevant medical fields as far as possible on the basis of learning, understanding, and grasping the professional measurement technical knowledge, so as to adapt the requirements for its own work and future medical metrology work.

6) Ensure quality of medical verification, introduce service contents

Medical verification personnel shall understand the importance of verification work and comply with the statutory requirements for measuring verification; the measuring verification shall strictly comply with verification procedure or calibration specifications. Under the premise of continuously improving the technical level of medical verification personnel and ensuring the quality of medical verification, the medical verification behavior is standardized through external review and internal review, so as to improve the capacity of medical verification personnel to perform self-inspection and self-correction on verification work and records at ordinary times, thus ensuring the accuracy and reliability of verification / calibration report issued and the quality of medical verification work.

The service content is introduced into medical verification work to help users to establish and perfect the measurement management system, to establish management accounting book for user measuring instrument, and to note the use department, inpatient area, etc. on verification / calibration certificate, so as to facilitate the management by the verified party. Free repair and part replacement are carried out for the riva-rocci sphygmomanometers below the verification standard, making them reach up the verification standard (50% of riva-rocci sphygmomanometers require to be repaired and replaced with part). After the completion of testing work, the improvement suggestions are put forward for the users' insufficient existed in aspect of metrological management, receiving the acceptance of users.

4. Difficulties and deficiencies in medical verification

Although the medical verification of Suzhou is basically in a good condition, some confusion and difficulties are felt in the medical verification work, and its own deficiencies are known very well.

Firstly, cross management for the administrative department. Take ionizing radiation source as an example: Metrology Law of the People's Republic of China stipulates that ionization radiation resource belongs to the measuring instrument being subject to mandatory verification, user unit shall actively apply for verification to metrological verification institutions designated by the local quality and technology supervision department, and it must be qualified before being used. However, Provisions on Radiological Diagnosis and Radiotherapy Management issued by Ministry of Health is shown as follows: Stability test, calibration and maintenance require to be periodically carried out for radiological diagnosis and radiotherapy device, and the testing organizations with quality certification by provincial Health Administrative Department shall perform the status detection at least one time every year. Measurement technique organization performs verification according to the

national JJG verification procedure, and the testing organizations with quality certification by provincial Health Administrative Department perform detection according to GBZ (recommended), of which the overlap of partial metrological characteristics causes the increase of detection cost, giving rise to the objection of verified party.

Secondly, with the fast change of modern medical equipment, technical regulations for calibration are unable to keep pace with the equipment development, while the original regulations need to be further perfected urgently to meet the demand of medical verification.

Thirdly, medical verification personnel are unable to perform the general repair on other medical measuring instruments in addition to riva-rocci sphygmomanometer or help the verified party to solve repair problem, due to suffering from the limitations of technical capacity, even affecting its authority to some extent. Therefore, the technical skill of repairmen and regulation is to be further improved.

5. Conclusion

As one of prefecture-level municipal measurement technique organization of Jiangsu Province, I feel greatly honored to introduce the situations of legal metrology work and medical verification work carried out in Suzhou region to APLMF Organization. I hope that some medical verification situations, work experience and understanding referred in this report can give the help to member countries of APLMF Organization. Welcome member countries of APLMF Organization to the institution for work exchange and on-the-spot investigation.

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Asia-Pacific Legal Metrology Forum (APLMF)
The Report on China's Medical Equipment Inspection Work
under Legal Metrological System
(Ningbo Area)

Yan Jianjun
(Ningbo institute of measurement and testing)

1. The Basic Introduction of Ningbo

Ningbo, Yong for short, is the second largest city of Zhejiang province, deputy provincial municipalities under separate state planning. Ningbo is located in the middle of East China Sea coast and northeast of Zhejiang province, which is in the southeast of Yangtze River delta, eastern end of the Ningshao plain. Ningbo coordinates at east longitude 120°55' to 122°16' and north latitude 28°51' to 30°33' with a total area of 9365 square kilometers. Ningbo is the economic center of south Yangtze River delta and Zhejiang province.

Ningbo residents are mainly Han, and the city is consisted of six districts, two counties, three county-level cities, 77 towns, 11 townships, 64 subdistricts, 663 residents' committees and 2556 village committees. By the end of 2013, the city has a population of 5.801 million registered people, including 2.276 million people in the city and 3.525 million agricultural people.

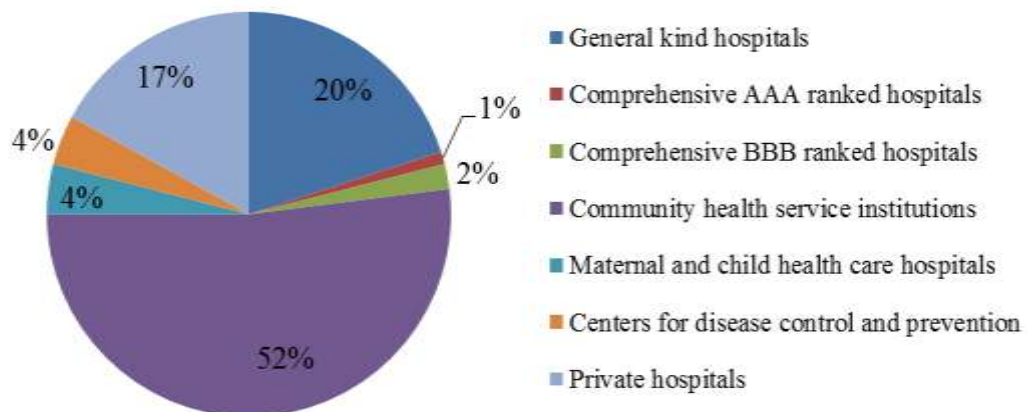
In 2013, Ningbo has a gross domestic product (GDP) of 712.89 billion Yuan, with per-capita production value (GDP) of 93322.42 Yuan (\$15068.53), which is higher than the national average value. From the point of each prefectural level city, Ningbo city's GDP and per-capita production value are in front of Yangtze River delta and ranked in the second of Zhejiang province.

2. Introduction of the Medical Condition in Ningbo City

According to the death monitoring statistics of Ningbo's urban and rural residents, the front ten deadly diseases were: malignant tumor, cerebrovascular disease, respiratory diseases, heart diseases, injury and poisoning (damage), digestive system diseases, in camp metabolism, nervous system diseases, infectious diseases and mental disorders. Malignant tumor has long been on the first rank. The city's CDC statistics show that the crude mortality rate was 644.01/10 million with the number of 37163 deaths in 2012. The front five causes of death are malignant tumors (mortality rate of 204.57/10 million), cerebrovascular disease (the mortality rate of 113.47/10 million), respiratory diseases (the mortality rate of 110.91/10 million), heart disease (the mortality rate of 59.06/10 million, injuries and poisoning mortality (58.49/10 million), which accounted for 84.86% of the total deaths. In addition, heart disease rises from the fifth cause of death to fourth in 2012. From 2006 onwards, cerebrovascular disease had replaced respiratory diseases as the second large number

cause of death, and the situation has not been changed until last year. Currently there are 310 hospitals in Ningbo city (excluding the village health room), where there are 63 general kinds, 3 comprehensive AAA ranked ones, 6 comprehensive BBB ranked hospitals, 162 community health service institutions, 12 maternal and child health care hospitals, 12 centers for disease control and prevention and 52 private hospitals (shown in the figure below).

The distribution of different types of hospitals in Ningbo



According to incomplete statistics, there are 329 ionizing radiation treatment instruments equipped in the first and second grade hospitals in the city, and 259 ionization instruments are being used in township health centers, street community health service center, private hospitals and dental clinic medical. All levels of hospitals in county administrative level are equipped with medical diagnostic X-ray and CT machine, and part of the developed township health centers have also purchased such equipment. The availability of ionizing radiation equipment for the majority of patients in the city has a great effect for disease diagnosis and treatment.

3. Instruction of Ningbo Institute of Measurement and Testing

Ningbo institute of measurement and testing was founded in 1984. It is a non-profit institution with balance allocation. In 1986 Ningbo institute of metrological instrument management was established and the two institutions were run with two brands but one set of management. Following the agreement of the City Hall in 2006, the public technology service platform of measurement was constructed by Ningbo institute of measurement and testing (Ningbo institute of metrological instrument management). The platform is one of the ten big public technology service platforms in Ningbo City (hereinafter referred to as the "metrological platform"). It is located in High-tech Zone with a construction area of about 13000 square meters, in addition to a 1500 square meters underground laboratory with constant temperature and humidity. At the same time, the supervision and inspection Center (Ningbo) of water meter quality as well as the measurement and testing administration of Ningbo bureau of quality and technical supervision also belongs to our institute.

Ningbo institute of measurement and testing (Ningbo institute of metrological

instrument management) is a legal metrological verification institution, which is responsible for the implementation of unified value in all kinds of area. The main responsibility also includes the calibration, inspection and repair work for public standard apparatus, instruments with highest standards used in enterprises, trade settlement, safety protection, medical, health, environmental monitoring, verification of administrative monitoring, judicial identification, verification of measuring instruments and other area with demand.

Currently the total number of employees is 183 in our institute, where there are 154 holding higher than junior college degree, 24 holding master's degree, 3 doctors, 17 with senior titles, 68 with intermediate title, 34 first class Certified Metrology Engineer, 16 second class Certified Metrology Engineer. The institute is constituted by six functional departments (internal supervision, administration, technical quality, business management, legal metrology management, information management) and five professional groups (physical and chemical quality, mechanics, thermal electrical and flow (water meter center). The five professional departments are mainly responsible for the preparation, maintenance of the public standards of measurement in physical and chemical quality, temperature, pressure, electromagnetic, radio and time frequency; length, mechanics, optics, acoustics and other aspects. They are also engaged in the metrological measurement control, metrological verification, calibration and testing method research and standard (rules) preparation, amendment of medicine, environment, chemicals, thermal, electrical, mechanical measurement; length measurement; water meter, gas meter, gas refueling, flow meter, metering tank measurement apparatus. The research department in our institute is mainly for our college business development, introduction and cultivation of talents and the purchase of equipment. They are also responsible for scientific planning in key research fields, the superior scientific research project and the relevant product electromagnetic compatibility testing and inspection tasks.

Our institute holds 12 categories of 198 public measurement standards in length, mechanics, acoustics, vibration speed, temperature, electromagnetic, radio, time frequency, ionizing radiation, chemical, optical, weather and others. We have processed 600 verification/calibration items that have passed the inspection of quality and technical supervision bureau of Zhejiang province, and 571 items that have passed China National Accreditation (CNAS) accreditation of calibration.

Since 2006, we have been authorized 4 projects from Administration of Quality Supervision (AQSIQ), 2 projects from Science and Technology of Zhejiang Quality Supervision, 3 projects of science and technology from Ningbo Science and Technology Bureau. 3 national invention patent and utility model patents have been obtained, and we have participated in the formation (Amendment) of 17 standards and regulations, more than 53 related papers have been published.

4. Instruction of medical investigation in the local area

4.1 Current Situation of Medical Metrology in Ningbo City

In recent years, the city's quality supervision departments at all levels keep the mission of service people's livelihood, which strengthens greatly the supervision of

instruments measurement and management in medical institutions, and ensures that the measuring apparatus is accurate, reliable, and earnestly safeguard the people's health and life safety. Medical metrology has become an important part of legal metrology. As one of Ningbo's municipal legal metrological verification institution, we are specifically responsible to carry out compulsory verification work for the region's medical institutions using medical measuring instrument. According to the verification work of 13646 medical instruments in 310 medical units in the city every year, the examination rate and qualified rate were 96.5% and 93.1% separately. However for a variety of reasons, there is still a gap between the metrological work we provides and its market needs. Consequently, omission and extended use of medical instruments still occur, which have brought great harm to the development of medical institutions and the patients. Therefore, it is urgent to improve the medical metrology awareness of medical units and ensure the inspection rate of measuring equipment. We have already taken steps such as the cooperation with administrative department of quality control, the implementation of strong inspection record and strengthen supervision and management measures quality supervision. As a result of these arrangements, the examination and pass rate of medical and health care measurement instruments increased year by year, the legal consciousness of medical institutions have been strengthened, and the supervision of medical measurement apparatus has shown good development trend.

4.2 The Number of Personnel Engaged in Medical Check-ups and Related Apparatus

At present, there are 5 persons in our Physical and Chemical Quality Institute engaged in medical metrological and verification. We have established 18 municipal public standards of measurement ,including: medical diagnostic X-ray radiation sources , ultrasonic source of medical ultrasound diagnostic instrument , buoy type oxygen inhalator, eeg and ecg machine, electrocardiogram monitor, blood pressure monitor, Medical diagnostic equipment for computed tomography (CT) and X ray radiation source, Portable ECG machine, defibrillators and cardiac defibrillation monitor, medical laser source, audiometer, medical diagnosis device spiral computer tomography (CT) X-ray radiation, ultrasonic source of ultrasonic Doppler fetal meters, ultrasound source of the ultrasonic Doppler fetus monitor, infant incubator, radio knife, noninvasive automatic measuring blood pressure monitor, medical digital photography X-ray radiation source (CR, DR) system, medical magnetic resonance imaging (MRI) system. We also obtain the National Laboratory Accreditation qualification 24 calibration including: semi-automatic biochemical analyzer, multi-parameter monitor, ventilator, infusion pump, injection pump, urine analyzer, blood cell analyzer, etc. Most of the measurement instruments are from Ole, Fluke or National institute of measurement and testing technology, which can meet the testing requirements of the corresponding codes and specifications.

4.3 The Development of the Instruments and Apparatus for Measuring or Detecting Ionizing Radiations in Medical Application Area

Until now, we have established several standards of measurement for large medical measuring instruments. The medical measuring instrument includes: Medical X-ray machine CR, DR system, medical CT machine etc. We carry out verification of measuring instruments in our city; the ultimate standard of measurement of each kind will be checked and found to be qualified by China institute of metrology periodically. Ionizing radiation based medical diagnostic equipment Legal Metrology file as follows:

No.	Procedure name	Procedure No.	Classification
1	Medical Diagnostic X-ray radiation test procedures	JJG744-2004	Municipal public standards of measurement
2	X-ray radiation test procedures for medical diagnostic computed tomography device (CT)	JJG961-2001	Municipal public standards of measurement
3	X-ray radiation for medical diagnostic test procedures spiral computed tomography apparatus (CT)	JJG1026-2007	Municipal public standards of measurement
4	Medical digital photography (CR, DR) system for X-ray radiation test procedures	JJG1078-2012	Municipal public standards of measurement

In 2013, there are 462 X-ray machines, 76 medical CT machines, 2 PET - CT machines, 4 medical electron accelerators in all in Ningbo. Most of the equipments are made by PHILIPS, SIEMENS, GE, TOSHIBA, Shimadzu, Beijing wandong medical equipment Co. Shanghai Medical Equipment factory, etc.

Apparatus Name	amount	Main model	Manufacturer
Medical CT	27	Brilliance 16、Brilliance 64、Brilliance iCT	PHILIPS
	19	SOMATOM Emotion、SOMATOM Spirit、SOMATOM Definition	SIEMENS
	16	BrightSpeed、Prospect、LightSpeed、Hispeed Dual	GE
	14	Aquilion ONE TSX-301A、TSX-101A、TSX-031A	TOSHIBA
Medical CR,	76	Digital Diagnost	PHILIPS

DR system of X machine	53	AXIOM Aristos MX、 Multix Select DR	SIEMENS
	52	RAD SPEED M、VISION PLUS 50	Shimadzu
	56	1000B、HF50-RA	Beijing wandong medical equipment Co..
	25	XG500、XG502	Shanghai Medical Equipment factory
medical of electron accelerator	2	Clinac 23EX	Agilent Technologies
	2	ARTISTE ART、 PRIMUSM_TH_S1205	SIEMENS
PET-CT	1	Discovery ST16	GE
	1	biograph 40	SIEMENS

The main measurement parameters for ionizing radiation equipment includes: dose index, kerma, kerma rate and quality of radiation output, etc. Here, we can take one county-level (3 b level) hospital as example: ionizing radiation equipment works for 8 hours a day, 70 persons can be checked by one set in a day; In a month the equipment can work for 240 hours,1900 persons can be checked by each set. There are 12 sets in the hospital, each set can works for 2800 hours, there will be 250000 persons can be checked. Similarly, in township hospital ionizing radiation equipment works for 3 hours a day on average, 20 persons can be checked/a day by one set on average, mean monthly use 60 hours, the average monthly 400 / set, annual average 680 hours, 3600 people can be checked.

Now in most second-level hospital the dose can be controlled automatically by ionizing radiation equipment, in township hospitals half of the devices should be controlled manually. In accordance with the standards regulation of all the ionizing radiation equipment must take place by the manufacturers every year; however most of the manufacturer fails to carry out relevant standards.

In accordance with the corresponding verification code the region ionizing radiation instrument verified by the municipal legal metrological verification institutions once a year.

Medical institutions using ionizing radiation should register in the region's bureau of quality and technical supervision measurement units. The local quality supervision departments entrusted City metrological verification institutions for verification. After the success of verification, they would paste the qualified label and issue the corresponding certificate. The period of validity is one year

Ningbo institute of measurement and testing is the legal metrological verification institution in this region. They should carry out compulsory verification on local ionizing radiation measurement equipment, authorized by the Provincial Bureau of

quality supervision. The value of ionizing radiation equipment can be traced to the national standard. In most public medical units, the temperature, humidity, radiation protection equipment can meet the requirements during the measurement of the ionizing radiation, most of the units are built with protective archives, have their own protective equipment maintenance and personal leave maintenance, economic subsidies, A small part of the private hospital has not strict on the environment, the protective equipment is not perfect, the file is not on file protection etc. There is no malpractice in the region because of ionizing radiation leaks or improper protection in recent years.

4.4 The Working Experience and Achievements of the Legal Metrology in the Field of Medical Check-ups in the Region

4.4.1 The cooperation between the field of metrology and medical service in this area

In recent years, with the reform of medical and health services, medical measuring instruments, as a science and technology content of modern medical equipment is widely used in clinical diagnosis and treatment. Medical measuring instruments accurate or not, is directly related to people's health and safety. Most medical institutions can apply for verification on schedule.

In every hospital, they would arrange one staff to be responsible for medical measurement instruments, verification and registration, measurement management and so on. But due to various reasons, the metrological work of medical institutions and the measurement requirements in the legal system that still has certain gap, medical problem such as leak and super cycle use instruments still occur.

Firstly, some medical institutions especially the township hospitals do not pay attention to measurement management. In some medical units, the staff and the leaders did not treat measure management as “permanent” measures which ensure the people’s quality of medical and health.

Some are completely take the metrological verification as a way to upgrade the hospital, after the examination the verification is neglected. In practical work, the medical staff use the measuring instruments that without the metrological verification or exceed verification period, they does not think it is illegal, even the unit leadership and related technical personnel shall not hold any doubt. Even worse, some units often try to escape the metrological supervision and inspection just in order to save costs. Lack of understanding the measurement laws and regulations and on the deviation of understanding meterage management work lead to the aversion to verification work.

Secondly, in the villages and towns the medical institutions is so separated, for some people it is just their part-time job. All of these factors directly affect the Measuring instruments examination rate. The county township medical institutions personnel is relatively small, the medical staff part-time situation is relatively common, some are distributed in Rural Clinic. During medical measuring instruments in calibration, it is hard to find the responsible person, which is a big obstacle to carry out verification work.

Thirdly, some rural medical institutions meet financial difficulty. As a result, when outdated equipment, they can't change in time, it is difficult to ensure that equipment in test cycle has been in good working condition. On the other hand, because of the metrological verification cost is a little high, which also affects the rural medical instruments measuring rate. These factors give a high risk to the development of medical treatment of medical institutions and the majority of patients. Therefore, the improvement of measurement awareness, ensure the use rate of medical metrology testing equipment tested, is the current measurement management the urgent task to be solved.

4.4.2 Service awareness of measurement in the medical field

a) Enhancing service awareness, improving service ability. We enhanced further service awareness and overcome the fear of hardship in our work, performing check and verification, as well as maintenance. In the public measurements sponsored by quality supervision agencies in Ningbo, the main reasons why several apparatuses in rural clinics worked 'unhealthy' were found out, including that doctors had lots of house calls, and apparatuses were difficultly maintained. For this situation, we actively purchased some attachments, play a full roll of our technical power to maintain apparatuses for rural doctors as we could, and explained how to use and maintain to users. These are all based on our principle of being responsible for peoples healthy. To problems we cannot solve, we would contact competent organizations for them, recovering the apparatuses as early as possible. Therefore, we obtained trust and recognition from medical institutions.

b) In order to improve the metrology legal awareness of the heads in charge of medical institutions, and to overcome limitations of cognition, we organized several trainings about metrology law and regulations, and relative measurement knowledge. Organization of measuring equipment in medical institutions is useful to the legal management and the development of medical institutions. Furthermore, it also reflects the responsibility to realize 'quality-assurance project' and do practical things for people. Accordingly, practitioner in medical and health institutions improved their metrology awareness.

c) On 20th May every year which is named 'World Metrology Day', we go to communities and old-age universities regularly, vigorously publicizing medical measuring knowledge, teaching citizens to improve self-protection awareness. Meanwhile, we also instruct patients how to use metrology knowledge as seeking medical care, such as asking the hospital that did all the used equipments validated by statutory measuring and verification institutes, recognizing tags and marks correctly, remembering that only the medical measuring instruments with verification certificates awarded by statutory measuring and verification institutes are qualified; to avoid hurt caused by inaccurate measurements of the medical instruments and effectively protect general consumers' legal rights and interests, patients have rights to reject examinations if the medical instruments are out of their verification period.

4.4.3 Developing trends of ionizing radiation medical equipments confronting metrology personals

As more and more new technologies applied in ionizing radiation medical test equipments, such as physics, electronics, computers and sensors, complex technologies with multi-parameter interdisciplinary are utilized in the same medical measurement equipment. And the development of metrology is faced with new challenge. In the future, the medical metrology will develop in the direction of research on hybrid parameters' automatic tests, consisting of performing automatic measurements and hybrid parameters' tests. On the other hand, test software will developed more rapidly than hardware. At present, the most of internal test equipments cannot meet the hybrid parameters' measuring requirements of advanced medical equipments. Therefore the specification for measurement of ionizing radiation must be established quickly, led by national or provincial institutes, composed by some technology or research organizations with high theory level and strong testing ability, including some municipal metrology institutes. The upgrade and development of medical and healthy equipments is so rapid with more and more advanced level and complex structures, that the quality and inspection institutions and their test equipments and personals must be improved simultaneously to keep up with the developing trends. Only in this way can we do effective managements, and the testing quality be guaranteed.

4.4.4 Experience of local medical test and measurement

a) *Exerting the role of social supervising, reforming the supervision and management.* The management of medical and healthy measurement instruments should be based on the metrology law and concentrate on the management catalogue of compulsory verified measurement instruments, facilitating the implementation of metrology laws and regulations by administration management while the legality mean is used. To change the backward situation of compulsory verification management, the modern computer management system is used in our institute, and the legal management software of measurement instruments for compulsory verification measurements management system in Ningbo is built. Metrological technology institutions can release verification database of hospitals to the public through network. The verification and qualified status of measurement instruments in every unit can be queried and supervised by the public. This is a fundamental method to solve the difficult problem of measurements in medical and healthy field.

b) *Improving social supervision system, enhancing metrological supervision.* As the competent supervision and administration authority of local metrological work, Ningbo quality and technical supervision department should usually inspect compulsory verification instruments in medical and health units, and generally inspect these units' measurements with health departments, in accordance with the Metrology Law of the People's Republic of China and the Regulations of Zhejiang Province Metrological Management. Based on the characters of medical and health measurements, it is useful to design and display posters in hospitals, measurement departments and other places, making medical and health measurements known more wildly and popular. Behaviors such as serious violation of metrological laws and regulations because of light legal awareness should be notified and exposure by medias. The news media is also effective in the supervision by the public. After

periodic verification every year, the results should be released to the public, propagating units with better managements, and espousing those units which eschew verifications from statutory metrological institutions or still use unqualified measurement instruments.

c) Guiding hospitals to practice effectively in metrological managements by multi management means. As China integrates with international norms step by step, hospitals gradually value and approve JCI. JCI required clearly that instruments used in quality controlling must be verified or calibrated. For this reason, we must actively guide hospitals to apply for JCI authentication, so that they would be volunteer to do better in testing medical measurement instruments. We should implement measurement management systems as helping hospitals improving their measurement management regime.

d) Strengthening cooperation between departments, improving awareness of service. Some local quality supervision departments actively communicated with medical and health units and strive for their support, taking the measurement managements as one of the comprehensive examinations of hospitals. At the same time, they cooperated with medical and health units, applying for financial support to guarantee funds for compulsory verifications, increasing effectiveness of their measurement management and establishing the long-effect mechanism.

5. Conclusion

As a municipal metrology technical institution in Zhejiang province, we are honored to introduce our work in local legal metrology and ionizing radiation measurements to APLMF. It is my wish that our experience mentioned in this report is useful to APLMF members. Welcome to visit our institute and communicate.