

Conformity Assessment System and Regulations of China

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Outline

- **An overview of the Conformity Assessment system in China**
- **Internationalized infrastructure for conformity assessment**
- **Regulatory conformity assessment programmes**
- **Regulations on conformity assessment activities**
- **Access to China market for foreign CABs**

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Chapter 1

An overview of the CA system in China

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An overview of the CA system in China

- **Standards and Technical regulations**
- **Conformity assessment measures**
- **Standard and Conformity assessment bodies**
- **Laws and Regulatory Bodies**

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Requirements on products :Standards

- **National Standards (approx. 21,000 Pcs)**
 - Voluntary standards (approx.18,100 Pcs)
 - Coded GBT-- XXX
 - Mandatory Standards (approx.2,900Pcs)
 - Human health, safety and environment related
 - Coded GB—XXX
- **Local Standards (approx. 7,000 Pcs)**
 - Voluntary and mandatory
 - Coded DB—xxx
- **Sector Standards (approx. 28,000 Pcs)**
 - Published by Ministries or professional bodies
- **Company Standards (approx. 600,000 Pcs)**
 - Should be registered

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Technical Regulations

- **Usually not directly for product requirement**
- **Always adopt relevant standards (usually mandatory standards)**

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Conformity assessment measures

- **Manufacturers Declaration**
 - For conformity with non-compulsory standards
- **Market surveillance inspection and testing done by regulatory bodies**
- **Product certification**
- **License to Manufacturers or products**

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Conformity Assessment Bodies

- **Product Quality Testing Centers**
 - National level (approx. 300)
 - Provincial or Ministerial level (approx.1000)
- **Regulatory authorities**
 - Commodity Inspection and Quarantine (CIQ)
 - Quality and Technical Supervision Bureau (CSBTS)
- **Third party certifiers**
 - For Voluntary programmes
 - Mostly government owned

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Related laws and Regulations

- Law on Product Quality
- Law of P.R.China on the on the Entry-Exit Animal and Plant Quarantine
- Law of P.R.China on the Import & Export Commodity Inspection
- Law on Metrology
- Food Hygiene Law of P.R.China
- Regulations of P.R.China on Certification and Accreditation

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Regulatory Bodies

- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)
- China National Administration for Certification and Accreditation (CNCA)
- Standardization Administration of China (SAC)
- Ministry of Health (food and medicine etc.)
- Ministry of Information Technology
- Ministry of Public Security (fire proof products and others)
- Other Ministries

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Chapter 2

Internationalized infrastructure for conformity assessment

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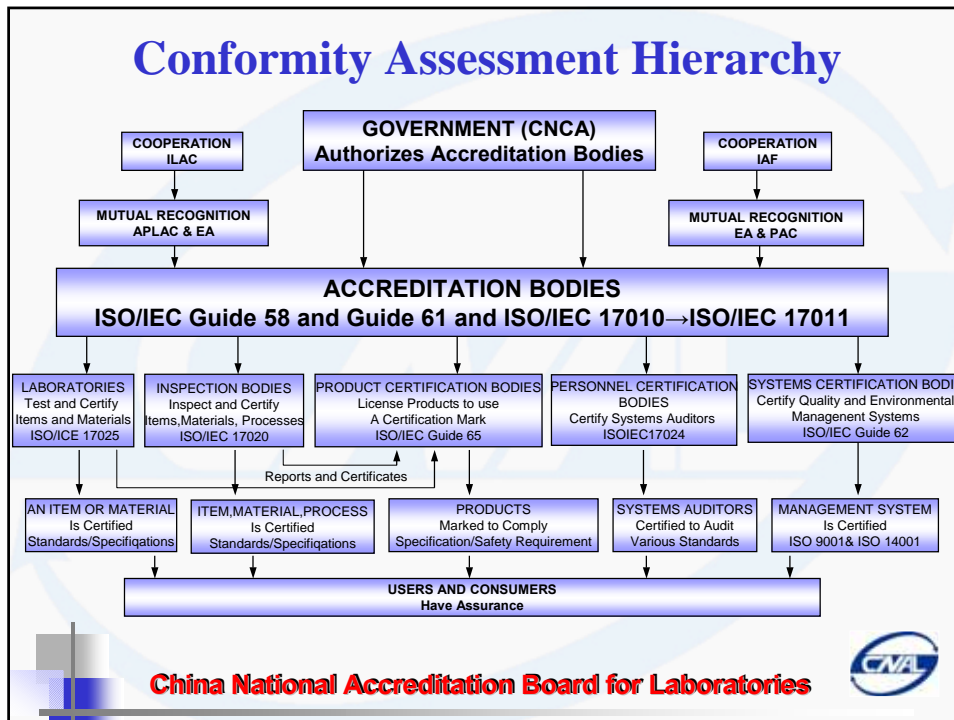
Building up an Internationalized infrastructure

- Since late 1980's ,China has been putting effort to build up an Internationally recognized conformity assessment infrastructure to meet the needs of market oriented economy
- The system is now recognized by the international community and ready to be used by industries and the government
- China began to regulate the conformity assessment activities in order to make a better use of this infrastructure

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Conformity Assessment Hierarchy



Accreditation

“Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks”

(ISO/IEC Guide 2:1996)

Key words: “competent”
“specific tasks”

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Accredited CABs

- **Conformity Assessment Bodies (CAB'S)**
 - **Certification Bodies certifying**
 - **Management Systems**
 - Quality Management System
 - Environment Management System
 - HACCP
 - Occupational Health Management System
 - **Product**
 - **Personnel**
 - **Training Course Providers**
 - **Laboratories**
 - **Inspection Bodies**

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Accreditation Bodies

- Authorized and supervised by CNCA
- Running accreditation system based on international standards or Guides
- Entered into international Mutual Recognition Arrangements

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Accreditation bodies in China

- China National Accreditation Board for Laboratories (CNAL)
- China National Accreditation Board for Certifiers (CNAB)
- China National Auditor and Training Accreditation Board (CNAT)

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CNAS

BOARD
CNAL

BOARD
CNAB

BOARD
CNAT

China National Accreditation Service (CNAS)

Secretariat
CNAL

Secretariat
CNAB

Secretariat
CNAT

Corporate
Department

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CNAB Accredits

- **Management System Certification**
 - Quality Management System
 - Environment Management System
 - HACCP
 - Occupational Health Management System
- **Product Certification**

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CNAB Updates

- **Accredited Management System Certification bodies**(by Sep. 1st, 2004)
- | QMS | EMS | OHSMS | HACCP |
|-----|-----|-------|-------|
| 67 | 53 | 44 | 7 |
- **Accredited Product Certification bodies**(by Sep. 1st, 2004)

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CNAT Accredits?

- **Auditors**
 - QMS, EMS, OHSMS, HACCP
- **Training Course Providers**
 - QMS, EMS, OHSMS

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CNAT Updates

- **Registered auditors (by Sep. 1st, 2004)**

QMS	EMS	OHSMS	HACCP
44874	14308	5624	792

- **Accredited Training Course Providers (by Sep. 1st, 2004)**

QMS	EMS	OHSMS
21	15	10

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CNAL Accredits?

- **Testing Laboratory**
 - Medical Laboratory
 - Bio-safety
- **Calibration Laboratory**
- **Inspection Body**
- **Proficiency Testing Provider**

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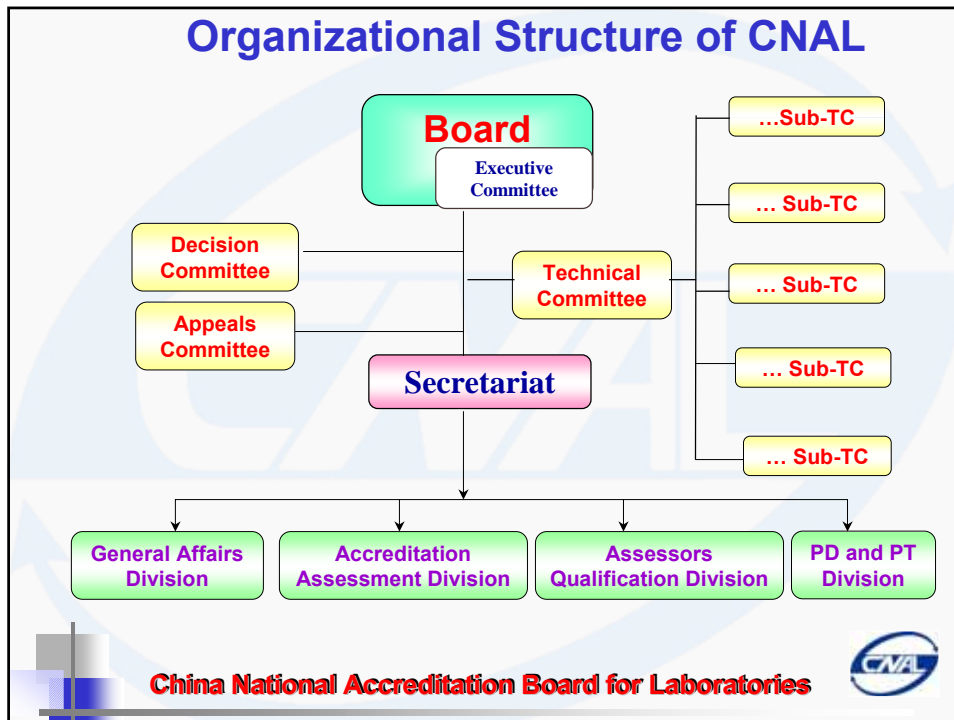
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CNAL

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Organizational Structure of CNAL



Mission of CNAL

- ❖ To raise awareness of and to promote laboratory accreditation in China
- ❖ To set up and implement a national voluntary accreditation scheme on the basis of national or international standards/Guides for :
 - ❖ Laboratories (Calibration and Testing)
 - ❖ Inspection bodies
- ❖ To undertake other mandatory laboratory evaluation works on behalf of relevant government bodies
- ❖ To provide technical support to the government
- ❖ To participate in international cooperation

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Accreditation Scopes of CNAL

Testing

- Biology
- chemistry
- electricity
- mechanics
- non-destructive testing
- optics
- acoustics and vibration
- electromagnetic compatibility
- animal/plant quarantine
- medical quarantine
- light industry products
- textiles-clothing-leather products
- metallurgy, metallic/nonmetallic mineral products and etc.

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Accreditation Scopes of CNAL

Calibration

- Heat calibration thermology
- Mechanical
- Electromagnetic
- Dimensional
- Optical
- Chemical
- Ionizing
- Radio
- Acoustic
- Time frequency calibration

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Updates of CNAL

As of November 12 2004

- accredited laboratories :
 - 1707
- accredited inspection bodies:
 - 26
- increasing rate:
 - about 30% per year
- registered assessors :
 - 2186
- registered technical experts :
 - 2174

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International Cooperation of CNAL

- Funding member of ILAC and APLAC
- Signed MRAs
 - Renewed its MRA Signatory status within APLAC & ILAC in 2003 for testing and calibration areas
 - is going to enter into APLAC MRA for IB shortly (peer evaluation completed)
- Hosted APLAC meetings
- Organized PT Programs for APLAC
- Chair the Training Committee

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Use of Laboratory Accreditation

- **How Chinese government uses lab accreditation:**
 - **3C certification must use CNAL accredited lab**
 - **all national testing center for product quality must be accredited**
 - **all CIQ laboratories will be accredited**
 - **laboratories undertaking testing for defense industry must be accredited**

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Certification

- **Voluntary Sector**
 - **Management system Certification**
 - **Some Product Certification**
 - **Some new programs are developed according to ISO Guides**
 - **Still many programs are not based on internationally accepted standards or practices**
 - **Accreditation is not involved in many cases**

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Voluntary certification

- Product certification
 - Certificates issued **11,629**
 - CB's involved **46**
- Management systems certification
 - QMS Certificates **132,891**
 - EMS Certificates **8849**
 - OHSMS Certificates **3589**

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Certification

- **Regulatory schemes**
 - Mostly on product
 - Complicated situation
 - 3C Certification
 - QS marking for food
 - Animal Feed Approving
 - Quality licensing for some industrial product manufacturers
 - Quality licensing for some exporting enterprises
 -
 - Operated by different Ministries or Provincial Governments
 - Accreditation is not applied in many programs

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Testing laboratories

- **20,000 testing labs providing public services for product testing**
- **Over 30,000 medical testing laboratories**
- **Many other competence assessment programs except accreditation**

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Calibration Labs

- **Approx.3,000 public labs in China**
- **Most of them are legal metrology verification bodies**
- **Only 200 more are accredited**
- **All of them are approved by Metrology regulators**

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Inspection Bodies

- **More than 2,000 Independent Inspection bodies for**
 - Boiler and pressure vessels
 - Commodity inspection
 - Ship inspection
 - Factory inspection
 - Building and construction
- **Mostly in regulated area**

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Chapter 3

Regulatory Conformity Assessment Programmes

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Regulatory programmes

- CCC marking
- CIQ Inspection on import and export commodities
- Licensing to industrial products
- Market surveillance inspection and testing
- others

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China Compulsory Certification --CCC



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Products Subject to Compulsory Certification

- Health and safety of human beings
 - Life safety of animals and plants
- Environmental protection
- Public security
- National security

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Catalogue of Products Subject to Compulsory Certification

- **Total 20 categories (in 9 sectors)**
 - Electric and Electronic appliances
 - Telecommunication equipment
 - Vehicles and motorcycles
 - Safety glass
 - Fire-fighting equipment
 - Fire and burglary detectors
 - Agricultural machinery
 - Rubber products
 - Tires
- **139 product items**

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Compulsory Product Certification

- **Catalogue of products subject to CCC Certification**
 - Formulated and adjusted by CNCA jointly with the relevant departments of the State Council
 - Mostly on consumer products
 - 139 items covered at present and to be expanded
- **For those products also listed in the Catalogue of import-export commodities subject to compulsory inspection, the inspection shall be simplified**

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Kernels for Compulsory Product Certification System

- Products in the Catalogue must be certified by certification bodies designated by CNCA.
- Products must obtain the certificate and be applied the certification mark

- Products made inside China be applied with mark before release from factory
- Imported products be affixed with mark before entry into China.

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Models of Certification

- type test
- testing or inspection of samples taken from the factories
- testing or inspection samples taken from the market
- assessment of manufacturers' quality assurance system
- regular follow up inspection on certified products

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Procedures for Certification

1. Application and acceptance
2. Sampling and testing
3. Initial factory inspection
4. Evaluation and approval on certification results
5. Follow up inspection

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CCC --Statistics

- Certificates issued **152,296**
 - Domestic **140,504**
 - Abroad **11,792**
- Manufactures certified **32,108**
 - Domestic **29,939**
 - Abroad **2169**
- Number of labs used **115**
- Number of CBs designated **12**

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Inspection on import and export Commodities

- **Catalogue of imp. & exp. commodities subject to compulsory inspection by CIQ**
 - Promulgated by General Administration of Quality Supervision, Inspection and Quarantine of P.R.China (AQSIQ)
 - 3339 product items subject to importing inspection
 - 4059 product items subject to exporting inspection
 - Inspection is carried out by local CIQ Authorities

For details: <http://www.aqsiq.gov.cn>

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Registration of food exporters and manufacturers

- **Catalogue of food exporters and manufacturers subject to registration is established by CNCA**
- **Manufacturers of food within the catalogue shall be registered with and supervised by CNCA (11,225 companies registered by now)**
- **For details:**
[http : // www.cnca.gov.cn](http://www.cnca.gov.cn)

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Licensing to Product manufacturers

- **86 categories of product are subject to Manufacture licensing issued by AQSIQ**
 - Equipment for industrial use
 - House holds products
- **Procedures**
 - Products be tested
 - Factories be assessed
- **Overlaps with CCC for some products**

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Market surveillance inspection and testing

- Conducted by local CSBTS under direction of AQSIQ
- No limit for product selection
- Products are sampled from market or manufacturing site
- Designated CABs are used usually accredited labs
- Results are published
- Those who fail the test may be punished

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Other compulsory programmes

- **Compulsory inspection on Special equipment**
 - Boilers, pressure vessels, pipeline
 - Lifts, cranes, outdoor entertainment equipment
 - Etc.
- **Compulsory inspection on medicine and medical apparatus**
- **Compulsory certification and inspection on Metrology instruments**
- **Compulsory inspection on auto vehicles**

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Chapter 4

Regulations on conformity assessment activities

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Regulations on conformity assessment activities

- “*Regulations on Certification and Accreditation*” came into effect in November 2003
- This regulation will help to apply the international requirements to the existing conformity assessment programmes

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Regulations on certification and accreditation

- **The regulations require Certification Bodies**
 - Be approved by CNCA
 - Shall have adequate facilities
 - Shall have effective management system
 - Shall have more than 10 permanent staff
 - Shall have registered capital no less than 100,000 RMB
 - Be accredited if undertake mandatory certification programme

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Regulations on conformity assessment activities

- **The regulations require laboratories and inspection bodies providing data or results for public use**
 - Be verified and approved for its competence
 - Be accredited if undertake testing for mandatory certification programmes

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Regulations on conformity assessment activities

The regulation require

- To formulate a unitary accreditation system so that there is no overlap in accreditation
- Accreditation bodies be authorized by CNCA
- Accreditation bodies implement effective quality system to ensure integrity of the accreditations

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Effects of the new regulations

- To encourage internationally accepted practice in conformity assessment activities especially in regulatory area
- To use more accreditation as a means of competence demonstration
- To enhance the quality and integrity of conformity assessment activities

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Chapter 5

Access to China Market

For Conformity Assessment Bodies & results

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Foreign investment in CBs and Testing Labs in China

- **From December 11 2003 to December 10 2005**
 - Only joint venture is permitted
 - Foreign investors may hold over 51% shares
- **From December 11 2005 onward**
 - Sole foreign investment will be allowed
- **The foreign investors should have more than 3 year's experience in the area concerned**

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Conditions for Foreign-funded CB in China

- **Requirements for CB**
 - Fixed premises and necessary facilities
 - Management system required
 - Registered capital of RMB3,000,000(about USD 360,000)
 - 10 full-time certification personnel in relevant fields
- **Requirements for foreign investor :**
 - is accredited by national or regional AB
 - engaged in certification activities for 3 years minimum
- **Other requirements of law, administrative regulations and provisions on foreign investment apply**

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Acceptance of Accreditation by MRA Signatories

- **Is very limited by regulators**
 - Most of regulatory testing or certification are carried out by designated bodies
 - Accreditation is usually not the only condition for designation
 - In many cases accreditation is not even a condition for designation

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Acceptance of Accreditation by MRA Signatories

- **In the case of CCC marking**
 - **Foreign testing report can be accepted when**
 - The lab is accredited by a MRA member body
 - A bilateral agreement between two governments exists
 - Under the IEC CB scheme
- **In the case of Import Inspection**
 - **Foreign testing report is accepted only based on government to government agreement**

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The way ahead

- **The trend of CA activities in China**
 - **More international standards adopted**
 - **CA procedures become closer to internationally accepted standard**
 - **Accreditation will be more widely used**
 - **Better accessibility to foreign CABs**

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Summary

- **China is aligning its conformity assessment system with international standards and practices**
- **Existing regulatory conformity assessments system needs to be improved or reformed**
- **Voluntary conformity assessment programs are encouraged to be developed and serve in the market**
- **The conformity assessment infrastructure meeting international requirements has been build up and is growing fast and will be better used**
- **The new regulations will speed up the process of reforming**

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Any Questions?

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THANK YOU !

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