

# **Quality Control Methods and Risk Assessment of Inspection and Testing Institutions**

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Abstract: The function of the inspection and testing institution is to test specific objects and analyze whether they meet the relevant national regulations. But at present, the risk assessment and quality control methods of inspection and testing institutions have certain defects, and they need to be improved in practice. This paper takes the food and drug inspection and testing organization as an example, analyzes the inspection status of the food and drug inspection and testing organization, and puts forward some improvement measures.

Keywords: Quality Control; Risk Assessment; Food and Drug; Inspection and Testing Institution

### **Foreword**

With the soaring development of the economy, people's quality of life has been unprecedentedly improved. They pay more and more attention to physical health, and the safety of diet as well as drug, pursuing higher requirements for the quality of food and drug. In addition, safety problems of China's food and drug have occurred frequently. The body damages caused by low-quality foods and drugs have emerged one after another. This has alerted the people to pay more attention to the safety of foods and drugs. At present, the production enterprises in the food and drug industries are large in scale and mixed with dragons and fishes jumbled together. It is inevitable that there will be criminals producing low-quality food and drug in order to earn huge profits. Therefore, the relevant inspection and testing institutions need to do daily inspections strictly in accordance with the food and drug testing standards to ensure that the food and drugs entering to the market

with high quality and proved safety, and provide a basic guarantee for people's health of diet and drug.

# 1. Inspection status of inspection and testing institutions

# 1.1 Irregular inspection standards

If the quality of foods and drugs entering to the market with high quality and proved safety, advanced quality control standards and inspection standards are required<sup>[1-2]</sup>. But in the actual testing process, most of them are carried out in accordance with the inspection standards that have been issued many years ago and completely deviate from the latest inspection standards. The reason is caused by the defects of the testing equipment. The inspection and testing institutions in some areas do not have advanced testing equipment, or the testing performance of the testing equipment is low. As a result, some of the foods and drugs entering to the market with low quality and low safety. The inspection

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functions of food and drug have changed, but the laws and regulations on food and drug have not been changed accordingly, which has led to differences in the result of actual inspection and the standard. In addition, China's food and drug inspection standards are relatively backward compared to developed countries, and the monitoring of raw materials for food and drugs is not strong enough.

#### 1.2 Equipment and technical defects

With development and of modernization, in the production of food and drug, the added chemical elements are complex and diverse, and the factors affecting food and drug are emerging in an endless stream. Therefore, it is difficult for the old testing equipment to comprehensively inspect the food and drug. That's why advanced high-tech testing equipment and more complete testing technology are needed<sup>[3]</sup>. However, in some areas, especially the relatively poor areas, the inspection and testing institutions have little funds to purchase high-tech testing equipment, in these backward areas, the testing technology has not been updated in time to reach the inspection standard of national food and drug. It is worth mentioning that, in economically backward areas, there may be certain inspection ability for food, but have more defects in the inspection of drugs, so that it is difficult to ensure the safety of drugs.

# 1.3 Complex inspection process

In the process of testing food and drugs, the procedures are too complicated and there are too many invalid steps. It is precisely because of the complexity of the test content that caused problems such as weak supervision or negligence in the test process. It is impossible to guarantee whether the test process is carried out in accordance with the test standards. The testing effectiveness is greatly reduced and the test results of foods and drugs often have huge differences, which leads to the unqualified foods and drugs entering to the market, causing great threat to people's health.

# 1.4 Low professional ability of staff

The quality and safety of food and drug directly affect people's lives and health, so the high inspection standards for food and drug are a huge challenge to the professional and technical capabilities of staff. However, due to various factors, the staff recruited by the inspection and testing institutions are also mixed with low-profession staff. In addition, the inspection and testing institutions have fixed numbers of inspection jobs, which also leads to the shortage of staff in heavy food and drug inspection work, accompanying with the limited technical level, thus the efficiency of the food and drug inspection process is low.

# 2. Risk assessment of inspection and testing institutions

#### 2.1 Risk identification

In the daily work of inspection and testing institutions, it is necessary to discover potential risk sources, such as customer complaints, sample testing, information management and other steps<sup>[5]</sup>. Not only to strictly control the existing risks, but also to collect new risk information from the practice process and the safety reports on food and drugs, and update the safety risks that affecting food and drugs in a timely manner to comprehensively identify the risks.

#### 2.2 Risk assessment

Conduct a risk assessment of the hazards caused by various risk factors, and classify the degree of hazards into different levels<sup>[6-7]</sup>. Among all the risk factors, if the risk factors have no effect on the inspection results, they can be regarded as low risks, such as forgot to back up data. If the risk factors have a small influence on the inspection results, and can be remedied in time before the food and drugs enter the market, it can be regarded as a medium risk, such as the incorrect data found in the review of inspection report. If the risk factor can directly cause the error of the inspection result, it can be regarded as the highest level of risk factor, which needs to be focused on, such as forging test reports.

#### 2.3 Risk management

In risk management, there are generally three contents. First, eliminate risks, summarize the risk points found in the inspection of drugs and foods, analyze the causes and take preventive measures, and make up for the work loopholes in the inspection process in time to achieve the purpose of eliminating risks. Second, transfer

risk. If it is found that drugs and foods do not fully meet the inspection standards, you can purchase some products from another manufacturer to replace some unqualified products and achieve the purpose of transferring risks. Third, reduce risk, first of all, it is necessary to formulate a standardized inspection step, and then for the inspection staff, regular assessment and technical training need to be carried out to improve their work ability<sup>[8]</sup>. In addition, staff need to be taught to have risk awareness, equip them with full understanding of risk factors in food and drug inspections, and take preventive measures against these risk factors to achieve the purpose of reducing risks.

### 2.4 Risk monitoring

The monitoring of risk factors is a dynamic process. To ensure the effectiveness of risk monitoring, taking the risk level as an example that if the risk level of food and drug is divided, the risk level of each risk factor has been clarified and completed and the corresponding preventive control measures were took, and in the next test, it is still found that the risk factor occurs and is not effectively controlled, then the risk level of the risk factor needs to be further increased. If the risk factor has not appeared in the subsequent tests, its risk level can be reduced. In this way, the dynamic monitoring of risk factors can adjust the risk level in time, which is helpful for risk assessment and identification.

# 3. Quality control of inspection and testing institutions

# 3.1 Increase the intensity of joint law enforcement

For inspection and testing institutions that inspect food and drugs, the workload is often very large and the process is relatively complicated. If only rely on the inspection and testing institutions alone, comprehensive inspection work cannot be done. Therefore, local inspection and testing institutions should increase joint enforcement efforts, cooperate with local industrial and commercial bureaus, tax bureaus and other government bureaus for joint enforcement, information sharing, etc., and cooperate with each other in work communication through timely and information transmission. The supervision and management of major

shopping malls and pharmacies should be real-time and effective, and strict monitoring should be conducted on the purchase channels of food and drug in shopping malls and pharmacies.

### 3.2 Improve the accountability system

In order to ensure the high efficiency of drug and food inspection, the working attitude and professional qualities of the staff of inspection and testing institutions are very important. The staff who is perfunctory and lazy, and does not strictly implement the food and drug inspection regulations need to be disciplined by superior leaders. This requires careful implementation of the accountability system. If the accountability is unreasonable and the punishment is too heavy, it will cause the staff to be panic and if the punishment is too light, then the staff who do not work seriously will continue to be perfunctory on inspection work, which may lead to more staff work with perfunctory attitudes and other negative phenomena, and the accountability system is becoming like the water off a duck's back. Of course, if the staff is active and responsible with a correct attitude, and can efficiently complete the inspection of food and drugs, he should be rewarded generously and publicized to set an example for other staff and mobilize their work enthusiasm. In addition, the accountability of the staff should not be limited to perfunctory work, but should also improve the accountability system for violations. In order to enable the production of drugs or foods to smoothly pass the inspection, some enterprises bribe the inspection staff to change the inspection results. Therefore, inspection and testing institutions should severely crack down on such illegal acts, add the legal responsibilities of the staff involved, and eliminate the source of bribery in the inspection of drugs and food.

### 3.3 Improve inspection standards

In the inspection of food and drug, first of all, scientific inspection standards are needed to ensure the effective conduct of inspection. For the backward areas, the inspection standards for food and drugs should be gradually aligned with developed areas to ensure the actual unification of China's inspection standards for food and drugs. In the inspection process of food and drug, some error-prone steps should be improved in time

to reduce errors made by staff. With time passing by, risk factors affecting foods and drugs are emerging one after another. For these new risk factors, the corresponding inspection standards should be updated and improved in time to ensure the scientific and comprehensive inspection of foods and drugs. In addition, it is also necessary to improve the inspection standards of China in combination with that of in developed countries, and to use the inspection technology of developed countries to ensure the high efficiency of inspections on food and drugs. It is possible to create an information exchange platform on food and drug inspection, collect various emerging risk factors from all over the country, and share innovative inspection technologies help relatively backward areas.

# 3.4 Increase capital investment

China's current defects in food and drug inspection work are partly due to the backwardness of inspection equipment. Especially in the underdeveloped areas of inspection and testing institutions, the equipment performance is insufficient, so that the relevant food and drug inspection requirements cannot be met. Therefore, the state should increase investment in food and drug inspection institutions to purchase advanced equipment, which can update the aging equipment in a timely manner, including the use of tools, equipment, etc. Only with advanced equipment can the requirements of food and drug inspection be increased. In addition, the office environment of the inspection institution can be appropriately improved, and the comfortable office environment enables the staff to better complete the inspection work.

# 3.5 Improve the inspection process

Since the inspection procedures for food and drug are relatively complicated, to ensure that the inspection work is carried out in an orderly manner, the inspection process should be improved. During the random inspection of food and drugs, the samples and relevant descriptions of the samples should be personally delivered to the inspection and testing institution by the staff of the inspection and testing institution. Before the inspection, the protection and collection of samples

should be done. In the inspection, the operation specifications should be done, the inspection steps should be reasonable, and avoid mistakes. After the inspection, the inspection data should be backed up in a timely manner, and the inspection data should be reviewed that whether there is a recording error, and the perform mark identification of the corresponding sample.

# 4. Conclusion

In the inspection and testing institution, risk assessment and quality control are very important parts of the inspection work, which affects the entire inspection process and is an important guarantee for the effectiveness of the inspection work. Therefore, inspection and testing institutions need to constantly improve the quality control and risk assessment system to reduce the risk in the inspection process and improve the accuracy of the inspection results.

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