

Respirator National Standard Development in China - A Perspective of Past Decade

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ABSTRACT

The China national respirator standardization and respirator approval systems, i.e. Quality Safety (QS) and Labor Safety (LA) certification, are both administrated by the Chinese government. National standard's (GB) development for respiratory protection has been very active in the past decade following the Standardization Administration of the People's Republic of China (SAC) guideline to extensively adopt the International Organization for Standardization (ISO) standards and other advanced standards abroad, aiming to improve the quality of China's respirator products, and to facilitate import and export trade. This paper reviews the introduction of GB/T 18664-2002, GB 2626-2006, GB 19083-2003 and GB 2890-2009 along with some history and background information of the standard development process and current application status. Besides the direct impact on respirator product application in China, the new respirator standards are also having a strong influence both on occupational respiratory protection and domestic respirator industry development. While China is currently an observer member of ISO respirator standard development project, it is suggested that China SAC should take actions to actively participate in this project, so that it eventually will help China's respirator industry to improve and grow. Due to the lack of research work in respiratory protection in China, combined along with less thorough communication and collaboration among the associated administrations during standard development, there are gaps and omissions in many new respirator standards in China. Some of the resulting issues are also discussed in this paper.

Keywords: respirator, standard, occupational protection, PPE, China

INTRODUCTION

The standardization work in China is administrated by the government. The government also takes the responsibility to supervise product quality according to standards. The China Personal Protection Equipment (PPE) Standardization Technical Committee (PPE Committee) is responsible for national standard development for all types of PPE, including respiratory protection. The development of the respiratory protection standard was accelerated in the early 2000s with the establishment of the Standardization Administration of the People's Republic of China (SAC) in 2001. This agency is responsible for undertaking unified management, supervision and overall coordination of standardization works in China.

The PPE Committee is under the supervision of SAC and led by the State Administration of Work Safety of China (SAWS), an agency responsible for occupational safety and health supervision in the workplace. The Ministry of Labor (MOL) and Ministry of Health (MOH) were in charge of this work in the past. The members of the PPE Committee consist of representatives of SAC and SAWS, the National PPE Test Houses, associated researching institutes and PPE manufacturers. Under the guideline from SAC to extensively adopt the International Organization for Standardization (ISO) standards and the other advanced standards, the national respirator standard development work has been remarkably active in the past decade. These new developments are having significant impact on the quality improvement of China's respiratory products and respiratory protection services, as well as import and export trade.

ROLE OF RESPIRATOR NATIONAL STANDARDS IN CHINA

According to China's Standardization Law, national standards coded with "GB" are mandatory, and the standards coded with "GB/T" are recommended. In China, occupational PPE is required to be certified in compliance with national standards, and two PPE certification systems are built for this purpose.

The Industrial Product Production Licensing system is under the Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). This system has over 20 years' history. According to the regulation (AQSIQ, 2005), domestically manufactured respirators that are on the Special PPE List provided by AQSIQ regulation are required to have an Industrial Product Production License. For respiratory products, dust masks and gas and vapor (G&V) respirators are on the list. AQSIQ is responsible for the production process audit, sample collection on site and testing by a PPE Test House authorized by the AQSIQ according to the national standard. After the Quality Safety (QS) mark is granted, the products need to be retested each year by the PPE Test House to maintain the effectiveness of the QS mark. Without the QS mark, the products are not allowed for trade in China.

QS certification is not applicable for imported PPE. Before SAWS issued the regulation of Implementation Measures of Special PPE Labor Safety (LA) Mark Certification in 2005 (SAWS, 2005), imported PPE was not under regulation in China. Now, the LA certification is applicable for all products on a Special PPE List issued by SAWS, which is similar to AQSIQ's Special PPE List. Whether the product is made domestically or imported, it needs the LA mark if the product is or will be used in the workplace for occupational protection in mainland China. For domestically made PPE, the LA certification process is similar to QS: for imported PPE, regardless of the existing approvals, the product needs to be tested and pass the test in a China PPE Test House based on the China national standard. The application process also includes the manufacturing site audit, whether domestic or overseas. LA Mark can facilitate SAWS officials conducting workplace occupational health and safety supervision, as PPE application is one of their focuses. As is similar to the QS certification, LA certified products also have to be retested each year to maintain their certification.

When a mandatory national standard is absent, according to China Standardization Law, a trade standard may be formulated and enforced for QS and LA certification. For example, LD 29-92 Dust Mask (MOL, 1992) was used in QS and LA certification although there have been more than one GB/T standard available in the past (NATS, 1992 and 1997). LD is the code of trade standard developed by MOL.

STANDARD FOR RESPIRATOR SELECTION, USE AND MAINTENANCE

Respirators were widely used for occupational protection in China back in the 1990s, among which the dust masks were the most widely used respirators in all kinds of dusty working environments. The G&V respirators, were applied in a variety of chemical plants, sometimes for emergency handling and clean-up chemical spills or leaks. Non-powered supplied air respirators (long tube breathing apparatus) could be found in use for highly toxic and oxygen-deficient atmosphere, such as confined space entry. Self-contained breathing apparatus (SCBA) have mostly been used in fire fighting and rescue. The application of powered air purifying respirator (PAPR) was rare due to the lack of domestic suppliers and the high cost of imported products at that time.

The available guidance for respirator selection before 2002 was GB11651-1989 Selection Norm of PPE (NATS, 1989). According to this standard, a certain type of respirator was assigned to certain types of industrial operations without respiratory hazard identification and hazard level evaluation. A welder, for example, would be equipped with a dust mask together with welding helmet, safety shoes, etc, in welding, and would be in compliance no matter what air contaminants exist in the welding fume and how high the contaminant concentration was. Besides, no guidance was available for respirator use, replacement, maintenance and user's training.

Early in 2000, the PPE Committee approved a project proposal to work on a new standard development for respirator selection, use and maintenance. A work group was set up with members from 3M China Ltd, the China National PPE Test House (Wuhan City, Hubei Province) and the Research Institute of Chemical Defense. The PPE Test House (Wuhan City) was one of the two National PPE Test Houses for QS certification at that time, having the specialty of dust mask design and evaluation. The Research Institute of Chemical Defense has a military background with a specialty in gas and vapor respirator research and development. The standard was drafted with extensive reference to OSHA 29CFR 1910.134 Respiratory Protection Standard (OSHA, 1998). In order to set up a process for respirator selection, the Assigned Protection Factor (APF) for each type of respirator is generated (Table I) with reference to ANSI Z88.2 (ANSI, 1992), as OSHA's APF Table was not available yet. As per this new standard, a respirator is required to be selected according to respiratory hazard identification and "Hazard Factor" calculation which is obtained by dividing the workplace concentration of the contaminant by its Occupational Exposure Limit, and the APF is required to be larger than the Hazard Factor. In order to prohibit the use of respirators with low APFs from application in highly dangerous environments, the terms of Immediately Dangerous to Life and Health (IDLH) and IDLH concentration, same as OSHA standard (OSHA, 1998), are adopted, and only the most protective respirators could be used for IDLH environment (seen footnotes in Table I). Respirator fit testing is adopted as a tool for mask selection, and associated information is provided in an appendix with both quantitative and qualitative fit testing method instructions. Conducting user face seal checks before entering the workplace, how to determine when a filter should be replaced and the limitation of user's capability to detect smell a function of the G&V filter's end of service life, etc., are all fully addressed. Respirator user training is also highlighted with a clear requirement for setting up a written respiratory protection program at the facility level to make sure the respiratory protection is exercised according to this standard. The new standard GB/T 18664-2002 "Selection, Use and Maintenance of Respiratory Protective Equipment" was announced effective in 2002.

GB/T 18664 is a recommended standard and has not been enforced by any occupational health and safety administration in China until now. However, since its issuance, it has been gradually gaining awareness among the occupational health practitioners in enterprises, research institutes and government agencies, and has been regarded as a practical technical guide when dealing with occupational respiratory protection.

Table I. APF of Each Type of Respirator Defined in GB/T 18664-2002 (SAC, 2002)

Type of Respirator	Type of Facepiece	Positive Pressure	Negative Pressure
Non-powered air-purifying	Half facepiece	N/A	10
	Full facepiece		100
Powered air-purifying	Half facepiece	50	N/A
	Full facepiece	>200 & <1000	
	Loose-fitting facepiece	25	
	Hood	>200 & <1000	
Supplied air	Half facepiece	50	10
	Full facepiece ^a	1000	100
	Loose-fitting facepiece	25	N/A
	Hood ^a	1000	
SCBA	Half facepiece	>1000	10
	Full facepiece ^b		100

a= can be used for IDLH environment only when it is used together with an escape respirator that is appropriate for the nature of the IDLH environment.
b= positive pressure type can be used for IDLH environment.

STANDARD FOR DUST MASKS

The revision of the dust mask standard was pushed forward by the issuance of Occupational Disease Prevention Law (ODPL) in 2002. ODPL is developed by MOH, it sets up the minimum requirements for employers to take effective actions, including using PPE, to protect workers from occupational diseases, which are listed as a total of 115 types according to ODPL and are mostly caused by respiratory hazards. In China, over 80% of the officially reported occupational disease cases are dust lung, a preventable but not curable disease caused by inhalation of respirable dust (Liang and Xiang, 2004). Since then, more and more public attention has been focused on the dust mask certified with LD 29-92.

China had been using talc dust for dust mask filter efficiency test, an old technology that had already been abandoned by standards abroad. The provision regarding particle size distribution was: "over 90% air born dust should be less than 5 μ m in diameter, and over 70% air born dust should be less than 2 μ m at the same time" without any specification of a deviation limit. At the 30L/min test flow rate, an initial filter efficiency not less than 90% had been the minimum requirement. Besides, the mask leakage was not under any control (MOL, 1992). All these helped to secure the Model 301 as an approved dust mask which is also the most representative dust mask in China for a long time (Fig.1).



Figure 1. Front and back view of Model 301 dust mask made in China.

Low filter efficiency and maybe leaking, the dust mask was required to be comfortable by the LD 29-92. The maximum initial inhalation resistance for replaceable masks like Model 301 was 49Pa, which was achieved by loosely fixed paper filters and a leaking face seal made of foam material. This is not much better than gauze mask, as some thick gauze masks may also pass LD 29-92. In 2000, the government made a specific statement to prohibit gauze masks from being regarded as a dust mask, but they are still used widely, even now.

In 2002, the PPE Committee approved the project of revising the dust mask standard. The two major goals of this revision were to abandon the coarse dust test method for filter efficiency and to set up basic provision for respirator leakage control. From a technical perspective, there are two standard models on filter efficiency, EN 149:2001 (CEN, 2001) and US NIOSH 42CFR84 (NIOSH, 1995). After comparison of the two technologies and based on the fact that most of the particle filter materials used on dust masks in China are not oil protective, a consensus was reached that the particle filters should be non-oil and oil-protective specific. Efforts were also made to remove disagreements in LD29-92 and GB2890-1995, a national standard for non-powered air-purifying G&V respirators (NATS, 1995), because a facepiece passing LD 29-92 had a small chance of passing GB 2890, and vice versa.

GB 2626-2006 "Respiratory Protective Equipment – Non-powered air-purifying particle respirator" was officially approved and issued in 2006. The particle filters are divided into two types with three efficiency levels: "KN" for non-oil particles tested by sodium chloride aerosol, and "KP" for non-oil and oil particles tested by oil aerosol. The filter is tested at 85L/min until either the minimum filter efficiency is reached or a particle mass 200 mg is loaded onto the filter (Table II). Although breathing comfort is regarded to be important to Chinese users, without any investigation into the availability of low-resistance and high-efficiency filters in China, 350 Pa is specified as the maximum inhalation resistance for the whole respirator when tested at 85L/min. This is the same as the NIOSH standard. Total inward leakage (TIL) provisions for disposable particle respirators are shown in Table III. The maximum allowable inward leakage (IL) for replaceable half facepiece is less than 2%, and for full facepiece it is less than 0.05%. All TIL and IL tests are run on people wearing the respirator in a test chamber at a similar conditions listed in European standards but without working rate simulation.

Table II. Classification of Filter Elements and Filter Efficiency (SAC, 2006)

Type of Filter Element	Disposable Facepiece	Replacable Half Facepiece	Full Facepiece
Type KN	KN90 (90.0%) KN95 (95.0%) KN100 (99.97%)		KN95 (95.0%) KN100 (99.97%)
Type KP	KP90 (90.0%) KP95 (95.0%) KP100 (99.97%)		KP95 (95.0%) KP100 (99.97%)

Table III. TIL of Disposable Facepiece (SAC, 2006)

Filter Classes	At Least 46 Out of the 50 Individual Exercises TIL Results (i.e. 10 Subjects $\times$ 5 Exercises) Shall not Be Greater Than	At Least 8 Out of the 10 Individual Wearer Arithmetic Means of the TIL Results Shall not Be Greater Than
KN90 or KP90	13%	10%
KN95 or KP95	11%	8%
KN100 or KP100	5%	2%

LD 29-92 was officially abolished soon after GB2626-2006 became effective, however, GB2626-2006 did not replace LD 29-92 for QS and LA certification until late 2009, since it took a long time for China PPE Test Houses to upgrade their testing capabilities. The China product standard update and China National PPE Test House testing capabilities upgrades were performed under different administrations, and therefore, they could not be carried out simultaneously. Before the new GB2626 standard was approved by SAC, none of the China National PPE Test Houses were funded to upgrade their testing capabilities, and no validation testing could be conducted. Late in 2006, 3M China Ltd. invited representatives from the National PPE Test Houses to visit a 3M Korea Ltd. facility to communicate test technology used in NIOSH and European standards, and to learn and practice the test methods of GB2626-2006. Then each test house went through the process of applying for governmental funds, purchasing equipment and setting up test systems and procedures. During this period, China's dust mask manufacturers were facing difficulties in standard communication, product redesign and preparation for re-approval. Therefore, there was chaos among all the parties including the PPE Committee, SAC, the PPE certification administrations, and the manufacturers and users. Regardless of the disconnect between standards development and implementation in that period of time, the progress in technology still pushed forward the improvement of China domestic particle respirator industry and application of proper functioning particle respirators in all dusty industries, such as mining, smelting and machining.

STANDARD FOR MEDICAL RESPIRATORS

The outbreak of SARS early in 2003 stimulated a strong demand to protect China's health care workers (HCWs) nationwide. After finding out that the 14 layer gauze mask recommended by MOH failed, and in response to the World Health Organization's recognition of NIOSH N95 and EN 149 FFP2 for HCWs globally, the State Food and Drug Administration of China (SFDA), the administration responsible for medical device production licensing, needed to approve numerous domestic products claiming N95 performance in a short period of time. Later on, realizing that the available dust masks certified by QS based on LD 29-92 were not comparable to N95 or FFP2,

SFDA started to immediately develop a national standard for medical respirators.

The China Medical Device Standardization Technical Committee under SFDA had no experience or expertise on respirators in the past, therefore, the members of the PPE Committee who were working on the new GB2626 development helped SFDA with their new medical respirator standard development. The medical respirator is defined as both a disposable particle respirator and a surgical mask in GB 19083-2003 "Technical Requirement of Medical Respirator" (SAC, 2003), a mandatory standard announced effective in April 26th 2003. SFDA recognized the NIOSH N95 provisions for medical respirators, and preferred a quantitative fit testing method for leakage control with a minimum fit factor of 50, which is a compromise to resolve the urgency, because the quantitative fit test equipment could be purchased at once, but the setting-up of a total inward leakage test system would take longer time. Six SFDA medical respirator test labs were built in late 2003, and upon SFDA's request, the 3M Company helped arrange for a group of representatives from SFDA visited the US National Personal Protective Technology Laboratory (NPPTL) and a respirator test lab in 3M UK Ltd. to learn particle respirator test technology and to provide specifications for respirator leakage test equipment. A TIL test system in compliance with EN 149:2001(CEN, 2001) was established in two SFDA labs in 2009 with equipment imported from Europe. The respirator leakage test method in GB 19083 is expected to be revised accordingly.

SFDA has been much more knowledgeable and ready for the emergence of H5N1 Avian Flu and the outbreak of 2009 H1N1(A) pandemic. HCWs can use medical respirators when facing high infectious risk, however, MOH regulations have not yet required medical respirators to be applied for HCWs in infection control of respiratory diseases with high risks, such as tuberculosis.

STANDARD FOR GAS AND VAPOR RESPIRATORS

In China, the GB 2890-1995 "General technical requirement for filtering type gas mask" was heavily influenced by China military standard of gas mask, which is used for national defense. Some of the provisions in this standard demonstrate the opposite when compared with those in LD 29-92. For example, a dust mask is not required to be tested for leakage, while a full face G&V respirator is required to have a fit factor of 20,000 when tested by people wearing it in a chamber full of oil mist; the filter efficiency of a dust mask is tested using coarse talc dust, while the combined G&V canister is challenged by 2500 mg/m³ oil fume (NATS, 1995). These requirements in GB2890-1995 have been technical barriers for imported G&V respirators. One apparent defect in this standard is the lack of breakthrough gas concentration for G&V filter's service life. The service life is tested by a chemical reaction method dependent on a reagent's color change upon breakthrough gas amount, while the gas amount is not defined. Furthermore, the G&V filter classification, which is shown in Table IV, is not consistent with other international standards. It should be noted that, a multi-gas canister with organic vapor (OV) protection is not tested with an OV (Type 1 and 2 canister in Table IV), and the canister for ammonia has to be H₂S protective at the same time (Type 4 canister in Table IV). GB 2890-1995 is now enforced in QS and LA certifications.

The PPE Committee decided to revise GB2890-1995 after working on GB2626, which resulted in the formulation of GB2890-2009. Many improvements have been achieved in GB 2890-2009. The filter type classification and color code are defined basically following EN 14387:2004 (CEN, 2004) which is shown in Table V, without any limitation for multi-gas combination; the breakthrough gas concentration is provided (Table V) and instrumental method is recommended. The old chemical reaction methods, known to be incorrect, as the chemical reagent color change was not corresponding to the breaking through gas concentration required in the new standard, are still kept in GB 2890-2009. The efficiency of the combined particle filters are tested with oil fume at lower oil aerosol challenge concentration of 150~200mg/m³. The requirements for initial filter efficiency are 95%, 99% and 99.99% separately, same

as before. The full facepiece IL criterion is changed from 0.005% to 0.05%, which is the same as that specified in GB2626-2006.

Table IV. G&V Canister Classification in GB2890-1995 (NATS, 1995)

Type Code	Gas Example	Challenge Gas
1	Multi-gas, e.g. organic vapor, phosgene, HCN, AsH ₃	HCN
2	Multi-gas, e.g. organic vapor, phosgene, HCN, AsH ₃ , CO	HCN, CO
3	Organic vapor, Cl ₂	Benzene, Cl ₂
4	NH ₃ , H ₂ S	NH ₃ , H ₂ S
5	CO	CO
6	Hg	Hg
7	Acid gas, Cl ₂ , H ₂ S, NOx, phosgene	SO ₂
8	H ₂ S	H ₂ S

Table V. G&V Filter Type Classification in GB2890-2009 (SAC, 2009)

Type of Filter	Color Code on Label	Gas Example	Challenge Gas	Breaking Through Concentration (ppm)
A	Brown	Organic vapor, e.g. Benzene, aniline, CCl ₄ , nitrobenzene, chloropicrin,	Benzene	10
B	Gray	cyanogen chloride, HCN, Cl ₂	HCN	10 ^a
E	Yellow	Acid gas, SO ₂	SO ₂	5
K	Green	NH ₃	NH ₃	25
CO	White	CO	CO	50
HG	Red	Hg	Hg	0.1
HS	Blue	H ₂ S	H ₂ S	10
a= C2N2 may be contained in downstream, (C2N2+HCN) total concentration should not exceed 10 ppm.				

GB 2890-2009 will replace GB2890-1995 in 2011. National PPE Test Houses are working to upgrade their testing capabilities. There is no comparison investigation report available yet to help domestic manufacturers understand the difference of G&V filter service life test method introduced in the new standard, and whether their G&V filter products that approved by GB 2890-1995 may have any issue in compliance to GB 2890-2009 regarding to service life capacity.

DISCUSSION

China's respirator national standard development has been very active in the past 10 years. All the respirator standards over 10 years old have been revised with the major objectives being to improve comparability with the most recognized global respirator standards and correct defects. As shown in Table VI, on average, it took 2 years for a new standard development. It should be noticed that almost all

the new provisions and test methods are finalized before the test capabilities in PPE Test House are established, bringing in apparent risk to manufacturers who may not understand in what a way the new standards will affect their products until the new standards enforced by QS and LA. The reason simply is that the standards were too outdated in technology, suppressing respirator technology development and building trade barriers. The PPE Committee was pushed by SAC to change this as quickly as possible with a fixed development time schedule defined by SAC. The urgency for the change makes a longer step-by-step research and investigation process unfeasible. Following EN or NIOSH respirator standards, or taking those standards as reference, is believed as the only practical strategy to fulfill the task in an expected short time. The experience throughout the development of GB2626-2006 was full of resistance and difficulty, mainly attributable to competition from low-cost respirator technology, the weakness of occupational health and safety supervision in the past, and the lack of research motivation in the China's respirator industry.

Table VI. New China Respirator National Standards Developed in the Past Decade

Development Time Period	Name	Replacement	When Effective
2000~2001	GB/T18664-2002 Selection, use and maintenance of respiratory protective equipment	n/a	2002
2002~2005	GB2626-2006 Respiratory protective equipment - Non-power air-purifying particle respirator	GB/T2626-1992 GB/T6223-1997 GB/T6224-1986	2009~2010
2003 May	GB19083-2003 Technical requirement of Medical respirator	n/a	2003
2005~2006	GB/T 16556-2007 Self-contained open-circuit compressed air breathing apparatus	GB 16556-1996	2008
2007~2008	GB 2890-2009 Respiratory Protection - Non powered air-purifying respirator	GB 2890-1995 GB/T2981-1995 GB/2892-1995	2011
2007~2008	GB 6220-2009 Respiratory protection – Long tube breathing apparatus	GB6220-1986 GB/T6221-1986	2011
2007~2008	GB 23465-2009 Respiratory protective equipment - Practical performance evaluation methods	n/a	2009

The new standards have pushed many domestic respirator manufacturers to pay more attention to new technology progress, however, the lack of research and development capabilities in China has impaired the progress. China is still an "Observer" member in the new ISO respirator standard project, and there has been no plans indicating SAC would join actively. Language is still a big barrier for Chinese professionals and this prevents them from becoming interactive with global technology development. Additionally, most of them are not aware of the ISO respirator standard development status. Professionals in National PPE Test Houses are burdened by the gigantic amount of PPE product retesting each year and the heavy work load of standards development for all types of PPEs at the same time. Although they are experts of product testing, they are not necessarily knowledgeable about product application, use or design. There is not yet a recognized procedure available for an open exchange between manufacturers and administrations on the translation of standard's provision and the test procedure specifics, putting respirator manufacturers in an inferior position. The resultant solution for some of the manufacturers is that they start to seek bypass. For example, GB 2890 requires that each respirator model should be tested for leakage by a group of people without facial size description. If the

respirator is available in more than one size, and each size is identified with a different model number, then each size should be tested separately by a group of people without facial size description. It becomes apparent that the small and large size might be more vulnerable for failure if this procedure is followed. In order to avoid this, some manufacturers will identify their respirators with just one model number for all sizes, and only submit the middle sized facepiece for QS/LA certification to secure a pass result for leakage, while using an internal stock number to differentiate sizes for customer selection.

The lack of effective communication is another issue experienced in respirator standard development. In current practice, a work group will be established after the standard development work is assigned to a leading institution by SAC. The work group members come from research institutes, PPE Test Houses and enterprises, and are made up of mostly volunteers. In most circumstances, only the leader from the leading institution undertakes the standard drafting, while other members are invited to join the discussion on limited occasions. It is apparent that the process could be influenced heavily by individual people or individual institutions rather than by team communication and consensus.

CONCLUSION & PROSPECTS

Significant improvements have been achieved in China's respiratory protection standards in the past 10 years on updating outdated technology and improving product quality. With enforcement by the government, respiratory protection standards are having more influence on the domestic respirator industry and the application of respirators in more areas beyond traditional industries. Lack of systematic investigation and basic research for respiratory protection in China limits the vision of professionals who work on standards development and administrations that enforce the standards. The fast-growing respirator market and the improvement on occupational health awareness in China have been pushing standard development forward to follow global advancements in standards and technology, which is a long-term strategy of the PPE Committee. It is believed that China SAC should take a more active role in ISO respirator standards development work and provide incentives for the China's respirator industry to gain more knowledge about the most advanced respirator science and technology that is being adopted in developing ISO standards which has overwhelming influence on the global respirator industry in the near future.

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