

## Quality Control Orders (QCOs)

Region: India

### WHY IS THIS ALERT IMPORTANT?

If your company uses and/or handles products, which may contain certain (hazardous) chemicals identified by the Bureau of Indian Standards (BIS), then this regulatory alert will provide you with the key obligations, possible risk(s) to IAEG members, and revision to the BIS (Conformity Assessment) Regulations for QCOs.

The BIS (Conformity Assessment) Amendment Regulations, 2022, which amends the 2018 version of the Regulations, introduces a conformity assessment scheme for granting licenses to use or apply Standard Mark for goods and articles. Specific requirements are outlined for the scheme in the amendment to the Regulations.

### INTENDED AUDIENCE

This Regulatory Alert is intended for IAEG members in India who are engaged in the manufacture, import, distribution, sale, hire, lease, storage, or exhibition for sale of goods and articles.

### EXECUTIVE SUMMARY

QCOs are gazette orders issued by the Indian government pursuant to the [BIS Act, 2016](#) (Sections 16, 17, and 25). These orders specify the applicable Indian Standards (IS) prescribed by the BIS for a product. The product subject to the QCO must conform to the corresponding IS mentioned in the QCO, and bear the Standard Mark under a License or Certificate of Conformity (CoC) from the BIS as per the relevant [Scheme of BIS \(Conformity Assessment\) Regulations, 2018](#) (as notified in the Order). Therefore, the manufacture, import, distribution, sale, hire, lease, storage, or exhibition for sale of such products are subject to these standards. QCOs specify conformity assessment measures for a variety of consumer products and are enforced by the BIS, including the penal consequences for any violation of the QCO. There are similarities to other global product declaration processes, such as the CE and UKCA markings in Europe and the UK respectively, and the UL certification in the US and Canada.

### BACKGROUND ON REGULATION

The BIS is the National Standards Body of India set under the BIS Act, 2016. This governing body develops and publishes Indian Standards, implements Conformity Assessment Schemes, recognizes and runs laboratories for Conformity Assessment, implements Hallmarking, works for Consumer empowerment, conducts capacity-building programs on quality assurance, and represents the country in the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).

The IS established by BIS provide third-party quality assurance, safety, and reliability for products sold to consumers through Product Certification Schemes. Although the BIS Certification Scheme is generally voluntary, the Central Government has made some product compliance standards mandatory in the interest of human

health and environmental protection, along with the prevention of unfair trade practices and national security. To legally mandate the requirements set by the various standards, regulators across ministries under the Central Government issue QCOs, which mandate the use of Standard Mark under a License or a Certificate of Conformity (CoC) from BIS. The Indian Standards Institution ([ISI Mark](#)), for example, is the most recognized standards-compliance mark for industrial products such as electrical appliances, chemicals, steel and stainless steel products, fertilizers and cement in India. Thus, BIS Standard Marks on products indicate conformity with IS specifications. QCOs are usually issued after consultation with stakeholders and they become effective from the date specified in the respective QCOs.

QCOs stipulate the relevant scheme of conformity to be followed in order to obtain product certification. Conformity assessment schemes of BIS are covered under the [BIS \(Conformity Assessment\) Regulations, 2018](#). There are two schemes: [Scheme I](#) (also known as the ISI Mark Scheme) and [Scheme II](#) (also known as the Compulsory Registration Scheme, CRS). Scheme I is a licensing scheme, which applies to over 380 products, including chemicals, polymers, batteries, cylinders, valves, regulators, cables, electrical motors, capacitors, automotive accessories, safety glass, textiles, and steel and iron products. Under this scheme, a factory audit and licensing of premises are required. Following approval of the product certification under Scheme I, a Standard Mark for ISI is issued by BIS.

Scheme II is a self-conformity scheme, which applies to around 80 products, including chemicals, textiles, photovoltaic systems, and various electronic equipment (accessories). Unlike Scheme I, a factory audit is not required. Approval of the product under Scheme II would result in the issuance of a Standard Mark for CRS.

On 16 March 2022, the latest amendment to the BIS Regulations was published in the official gazette. Schedule II was amended to include [Scheme X](#), which outlines the Conformity Assessment Scheme for the use or application of Standard Marks for goods and articles as per the specified requirements.

[Products under compulsory certification](#) are explicitly listed and can be accessed via the [official website of BIS](#).

## APPLICABILITY

QCOs apply to any person(s) that manufacture, import, distribute, sell, hire, lease, store, or exhibit for sale any products that are covered under the QCO. Whilst all persons involved in these activities must check to ensure compliance of their products with the relevant QCO, the manufacturer holds the main responsibility to manage and maintain compliance of the products.

This applies to manufacturers located in India (domestic manufacturers) and outside India (foreign manufacturers). Foreign manufacturers of products covered by QCOs are required to obtain a license or CoC (Certificate of Conformity) from BIS under the Foreign Manufacturers Certification Scheme (FMCS) of BIS. In order to do so, an Authorized Indian Representative (AIR) based in India must be appointed and testing must be conducted by a BIS-approved laboratory. Domestic manufacturers must also be granted a license or CoC from BIS, provided their products undergo BIS-approved laboratory tests. Further obligations can be found on the 'Regulatory Obligations' section.

The scope for products covered by QCOs depends on which conformity assessment scheme of BIS it falls within, as discussed in the 'Background on Regulation' section of this Alert. Schemes I and II cover around 380 and 80

products respectively, including chemicals and electrical equipment. A full list of products in scope of [Scheme I](#) and [Scheme II](#) can be accessed on the [Products under compulsory certification](#) website.

Recent examples of QCOs that are relevant to the Aerospace and Defense industry include:

- » [1,3-Phenylenediamine](#) [CAS No. 108-45-2; QCO No. S.O. 1960(E), dated 27 April 2022]:
  - must comply with IS 17450 : 2020,
  - used in e.g. adhesives, adhesive removers, polymer additives and dyes in textiles; and
- » [Trimethyl phosphite](#) [CAS No. 121-45-9; QCO No. S.O. 1637(E), dated 5 April 2022]:
  - must comply with IS 17412 : 2020,
  - used flame-retardant textiles and polyurethane foams.

In general, the IS provide requirements on e.g., characteristics, such as appearance, color, and purity; packing; marking; sampling; and testing.

Exemptions for QCOs vary on the specific product(s) in question, and are provided in the respective QCO itself. Examples of exemptions include non-applicability of the QCO on specific product(s), and product(s) meant for export. These exemptions will permit the application/action for the product to take place.

## RELEVANT DATES

- » BIS Act, 2016 published: 22 March 2016
- » BIS Act, 2016 in force: 12 October 2017
- » QCO effective: *varies depending on the product(s)/product categories being regulated*

## REGULATORY OBLIGATIONS

- » Manufacturers and importers of products covered by QCOs must ensure that such products comply with the IS mentioned in the QCO from the commencement date of the QCO, including the labelling and marking requirements specified in Article 6 of the BIS (Conformity Assessment) Amendment Regulations, 2022;
- » After the date of commencement of the QCO, no person shall manufacture, import, distribute, sell, hire, lease, store or exhibit for sale any product(s) covered under the QCO without a Standard Mark except under a valid license or CoC from BIS;
- » Manufacturers and importers must renew licenses and CoC, if necessary (licenses are granted initially for not less than three years and up to six years, and may be renewed for a further period of not less than three years and up to six years);
- » Foreign manufacturers must appoint an AIR (Authorized Indian Representative) based in India who will be responsible for all statutory compliances under the provisions of the BIS Act, 2016 on behalf of the foreign manufacturer;
- » Samples of products must be tested from a BIS-approved laboratory, which is any laboratory in India or abroad recognized by BIS for the purpose of testing conformance of product to the relevant IS, in order to be granted a valid license or CoC from BIS;
- » Any changes or revisions to an Indian Standard covered under the QCO will be deemed to apply to the QCO provisions effective from the notification date by BIS; and
- » Any queries/clarifications related to coverage of any product under IS covered under QCO must be directed to the BIS.

## RISKS TO AEROSPACE AND DEFENSE

Penalties for non-compliance include imprisonment up to 2 years and/or a fine up to ten times the value of the goods or articles being produced or sold without the Standard Mark.

According to Article 12 of the BIS (Conformity Assessment) Amendment Regulations, 2022, the BIS may cancel the license or CoC, or refuse renewal of license if:

- » The manufacturer has misused the license or CoC;
- » False declaration of the certification, falsification of records or unfair trade practices is found;
- » Suspension of license exceeds more than one year;
- » The manufacturer has violated any conditions of the license or CoC; and/or
- » Cancellation or refusal of re-certification under the provisions of Scheme III of the Regulations for management system certification.

## USEFUL LINKS

[BIS Act, Rules & Regulations – includes BIS Act, 2016; BIS \(Conformity Assessment\) Regulations, 2018; and BIS \(Conformity Assessment\) Amendment Regulations, 2022](#)

[Products under Compulsory Certification](#)

[Indian Chemical Regulation – Schemes 1 and 2 information](#)

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