



REGULATORY APPROVALS THE RADIO EQUIPMENT GOAL

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INTRODUCTION

Many manufacturers think of product testing as the significant step to market access, but most of that testing is performed to get the equipment authorized for use in the intended country, for regulatory approval.

It's important to develop a good product that works correctly and will please the end-user, but making an exciting product is pointless if you are unable to put it in the hands of your customers.

At Element, we perform a wide range of equipment testing including [radio performance](#), [electromagnetic compatibility \(EMC\)](#), [RF exposure SAR](#), [over the air \(OTA\)](#) performance, and [product safety](#). Some of our testing is for product development, at the R&D stage, and some tests are for the final evaluation, but generally, the goal

for a manufacturer is to place a product on the market. The topic of regulatory approval is often seen as secondary to testing, a final hurdle at the end of the important part because the approval process is typically cheap and quick in comparison to the testing stage. But for most companies, the time and money spent testing is for one purpose; to gain regulatory approval, sell the product to customers, and turn the innovation into reality.

To place a piece of equipment onto the market, regulatory approval for the country or region is required. There are many reasons why we have regulatory approval. Country authorities typically need to consider the safety of users, the protection of their property and data, the reduction of interference between electronic devices in their radio spectrum, and confidence that their citizens and businesses have access to good quality products. There is also protection of national interest in the face of international trade.

Regulatory approvals take many names and procedures. There are certifications, declarations of conformity, supplier declarations, and type approvals. All of these are forms of equipment authorization for regulatory approval.

THE AUTHOR

Michael Derby is a Technical Director at Element Materials in the Connected Technologies group, supporting manufacturers and colleagues in the test and approval of radio enabled equipment.



He has more than 30 years' experience in the industry, with testing and approvals roles, including EMC, Radio performance, and RF Exposure SAR.

Michael also provides training and technical support to the industry through advisory projects

and seminar courses. Within Element, Michael is a Certification Body for the USA and Canada; an EU Notified Body for the RED and a UK Approved Body for the RER.

Michael is an active member of the REDCA (RED Compliance Association) and TCB Council; acting as the liaison between the two organizations and author of many technical guidance documents within the industry.

Michael is the technical secretary of the EMC Test Lab Association. His past experience includes product development, testing and certification for manufacturers and test laboratories. He provides worldwide services to customers and colleagues from his office in the Hampshire area of the UK.

THE USA AND THE FCC

Radio equipment to be placed onto the market in the USA must meet and be authorized to the FCC rules. There are two routes to equipment authorization with the FCC:

1. Certification
2. Supplier's declaration of conformity (sDoC).

As a broad generalization, radio transmitters require certification, whereas receivers and other electronic equipment require either certification or sDoC. However, this applies to each operation within a product, and not always to the whole product itself. The important thing to remember with FCC authorization is that multiple authorizations can apply to a single product, if that product has multiple operations or functions.

If we consider a typical laptop, it is a digital device computer, it is a WLAN transmitter and it is a Bluetooth transmitter. Therefore, to authorize this laptop for use in the USA, there will be two types of transmitter certifications; and one other authorization, either certification or sDoC, for the digital electronics operations of the laptop itself. A typical smartphone has multiple types of transmitter certifications, sDoC or certification for several receivers, and an sDoC or certification as a digital device and computer peripheral.

The manufacturer of any radio equipment must ensure that all the authorizations are in place and valid before placing the final product on the market.

FCC CERTIFICATION

Radio equipment for the USA is certified to the FCC rules, based on testing performed to published standards and other FCC guidance documents. Once a piece of equipment is certified, it remains certified even if the test standards or procedures change as the equipment is certified to the rules themselves. If the FCC rules change, which is rare, the FCC decides if the existing certifications must be updated or not.

If radio equipment is changed or modified by the manufacturer after the certification is complete, it may be necessary to perform a new FCC certification on that equipment or it may be possible to update the existing certification, depending on the type of changes.

At Element, we have three TCB designations in the USA and UK, and we have TCB engineers operating across the USA, in Europe, and in Asia to cater to our global customer base.

SDOC FOR THE FCC

The sDoC for the FCC is a process handled by the manufacturer, but also relies on a correctly created test report to the correct test standard and the correct set of rules. The sDoC is a procedure or process, and not an actual document. The manufacturer does not need to create a sDoC document, but the manufacturer's sDoC authorization is valid only when the manufacturer has completed the correct testing and regulatory process. A device containing digital electronics and radio receivers may have followed the sDoC procedure for multiple modes of operation, to complete all authorizations.

If the equipment has many parts to it, such as the laptop with Bluetooth, WLAN, and digital electronics; the final equipment can be marketed in the USA when all applicable authorizations have been completed.

There are many TCB companies designated by the FCC around the world but not all have full certification capabilities. In addition to the official listing of the TCB, it is important to understand the capability and competence of the TCB you work with. The TCBs at Element have in-depth knowledge and experience with the FCC rules, having certified a wide range of equipment. Element TCBs have certified some of the early 5G handsets, the first ever portable WiFi-6E device, and are experienced in working closely with the FCC on new technologies. An Element TCB serves on the TCB Council Board of Directors and chairs committees on important topics such as radio module approval and installation.

TELECOMMUNICATION CERTIFICATION BODY (TCB)

All certifications for the FCC are reviewed and processed by a Telecommunication Certification Body (TCB). The TCB review and certification is a highly technical process, requiring knowledge that is a mixture of radio communications, physics, electronics, and law.

The TCB's role is to carefully review every aspect of the radio equipment, including the test reports, to ascertain if it can be certified to the FCC rules. The FCC rules are very clearly defined and the TCB can only complete the certification if every applicable aspect of the FCC rules has been correctly applied.

Any deviation from the rules or the test standards means that the equipment cannot be certified by the TCB (unless the FCC also becomes involved on a case-by-case basis). This is because deviations from test standards or the FCC rules cannot be accepted, the TCB

must have a technical understanding of the test procedures and a detailed knowledge of the FCC rules.

After the TCB has completed the review, they upload the information to the FCC website and complete the certification. From that moment, the equipment is certified and authorization of that radio transmitter is complete. The TCB captures a screenshot of the FCC Grant and sends this to the manufacturer. In many cases, the FCC is simply not involved in the certification.

Many people assume that the TCB is only interested in the test reports. However, the TCB is reviewing everything from the test reports to technical datasheets, labeling, user instructions, and construction photos. The accuracy and consistency of information in the application forms and paperwork are also carefully considered.

CANADA AND ISEDC

Radio equipment to be placed onto the market in Canada must meet the applicable ISED Canada standard(s). There are two routes to equipment authorization with ISED Canada:

1. Certification
2. Supplier's declaration of conformity (sDoC).

As a generalization, radio transmitters require certification, receivers and non-transmitter electronic equipment require the sDoC authorization procedure.

As with the FCC, the authorizations apply to each operation within a product, and not always to the whole product itself. Multiple authorizations can also apply to a single product. A typical smartphone has multiple types of transmitter certifications to multiple Canadian standards and an sDoC for several receivers and as a digital device.

The manufacturer of any radio equipment must ensure that all the authorizations are in place and valid before placing the final product on the market in Canada.

Certification can be completed by ISED Canada directly, but most certifications for Canada are reviewed and processed by a Certification Body (CB), known as a Foreign Certification Body (FCB) if the CB is outside of Canada. Again, the CB's role is to carefully review every aspect of the radio equipment, including the test reports, to ascertain if they can be certified to each appropriate Canadian standard.

There are a lot of similarities between the Canadian standards and the FCC rules, and so it is quite common for a manufacturer to consider both regions at the same time. The testing is not identical in all cases though, and the regulatory approval process and certification are different, with different application forms, procedures, and labeling. When picking a CB/FCB, it is critical to pick one with a detailed understanding of the differences between the FCC and ISED Canada requirements.

The Canadian standards are clear and the CB/FCB can only complete the certification if every applicable aspect of each Canadian standard

has been correctly applied. Any deviation from the standard cannot be certified by the CB/FCB, unless ISED Canada also becomes involved on a case-by-case basis.

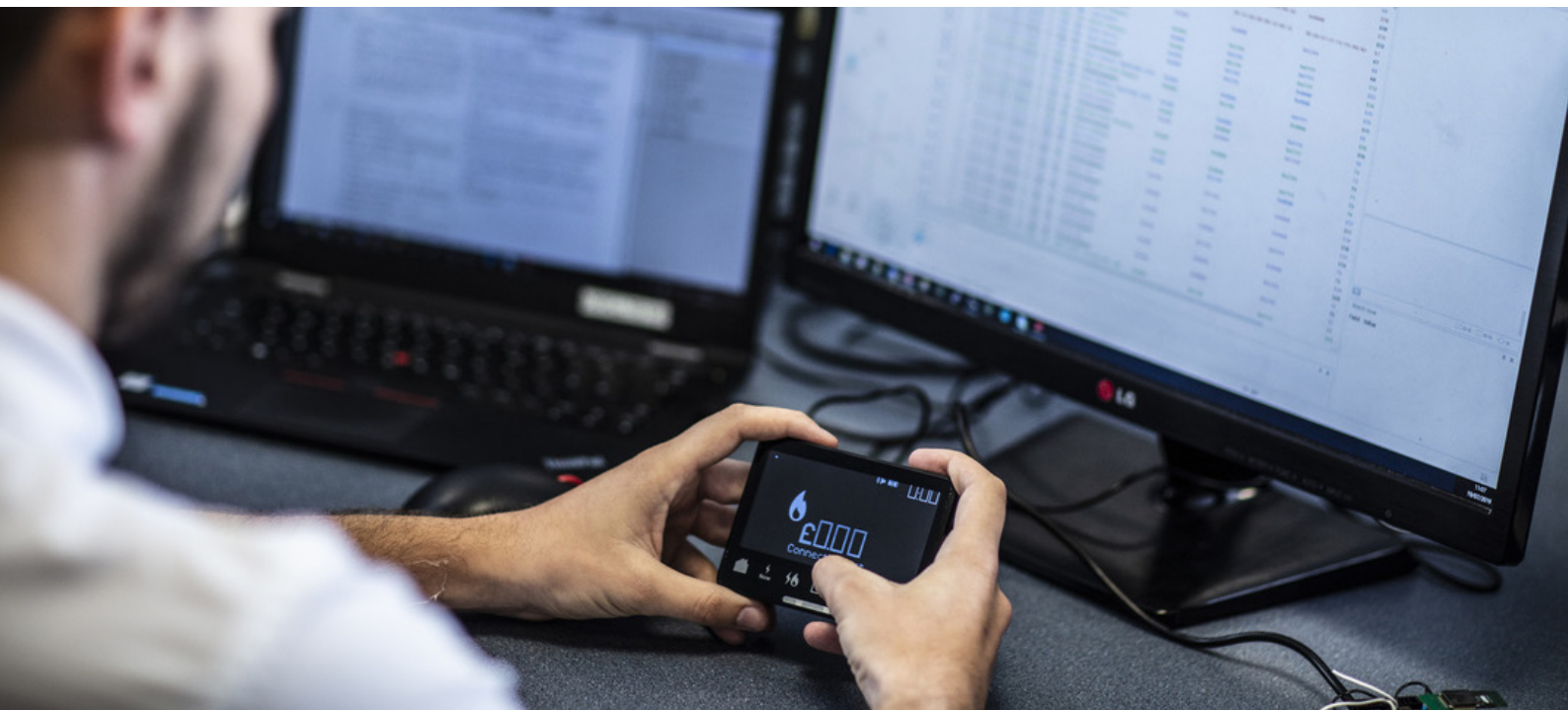
After the CB/FCB has completed the review, they issue their certificate to the manufacturer, and the certification application is then submitted to ISED Canada for review. ISED Canada performs their own review and then completes the certification by listing the product on their Radio Equipment List (REL). The product is certified from the moment that ISED list the product on their REL, not from the date the certificate is issued by the CB/FCB. This two-stage process explains why the date on the CB/FCB's certificate is typically a few days before the actual certification date, which is shown on ISED Canada's REL.

Radio equipment for Canada is certified to a Radio Standard Specification (RSS), including the issue number. If ISED Canada publishes a new issue number of the standard, the new standard supersedes the old one and therefore the manufacturer is expected to review the new standard and ensure that their equipment compliance is up to date with the latest requirements.

In most cases, the update of standards does not invalidate the certification, and a re-certification is typically not necessary, but it is a requirement the manufacturer should be aware of. If the testing requirements have changed in the new issue of the standard, the manufacturer should consider that, and if the manufacturer goes to a CB/FCB for some other process, such as adding a new model number or a change to the equipment, they will be expected to provide evidence that they have been keeping up with all the changes in the standard.

At Element, we have three FCB designations over the USA and UK, and we have FCB engineers operating across the USA, in Europe, and Asia. Our FCB team provides guidance and training to the industry on the unique requirements for Canada.

As with the FCC, the ISED Canada sDoC is a procedure or process, not an actual document.



THE EU AND THE RADIO EQUIPMENT DIRECTIVE (RED)

Radio equipment to be placed onto the market in the EU and other EFTA/EEA member states must comply with all applicable CE Marking Directives. For radio equipment, the Directive of interest here is the Radio Equipment Directive, known as the RED.

All radio equipment in scope of the RED is assessed to the Directive itself, based on assessments of radio performance, EMC, safety and some other specific compliance aspects. All authorizations to the RED are based on Declaration of Conformity (DoC) by the manufacturer.

The RED is a trade Directive, for the purpose of free trade around the EU. There are no technical limits or test methods contained within the RED itself, although the RED does mandate that an assessment is performed to the essential requirements. The recommended solution for demonstrating compliance with the RED is to apply standards, created by independent groups ETSI or CENELEC. Most of these standards include tests that can be performed to show compliance with the standard, and the manufacturer may use those results to justify their compliance with the RED.

CREATING A RISK ASSESSMENT DOCUMENT

The first step for any manufacturer wishing to demonstrate compliance with the RED is to begin creating their risk assessment document. The risk assessment is used by the manufacturer to identify their product, its intended use, and intended environment.

An important early stage for the manufacturer is to check if radio equipment can be used in the EU; and if it can be used in all EU member states or only in some.

Next, based on their risk assessment, the manufacturer identifies which standards to apply to the device, and then applies those standards. The most common solution is to get the testing done at an independent test lab, such as Element.

The EU Commission publish a document known as the Official Journal of Harmonized Standards (OJEU). If a manufacturer fully applies a standard from that document, they have a presumption that the radio is in conformity with that part of the requirements, for that operation of their product. For any standards used which are not on the OJEU, the manufacturer must document their reasons for choosing and applying that standard.

If the radio performance or other specific compliance aspects are not fully assessed using standards listed on the RED OJEU, then a Notified Body will be needed to issue an EU Type Examination Certificate (EU-TEC) to the manufacturer, to enable them to complete their DoC. Even in cases where the Notified Body EU-TEC is not mandatory, it is still available as an option and most Notified Body EU-TEC are issued in cases when they are not mandatory, but are useful to the manufacturer for confidence, marketing or procurement reasons.

When assessment or testing to the standards is complete, the manufacturer must look again at their risk assessment to confirm that all compliance risks associated with their product have been

resolved. If there are any compliance issues associated with their device which were not covered in the standards, the manufacturer must resolve them. This can mean performing additional tests which were not in the standards.

Only one authorization applies to the radio equipment, and that is the DoC by the manufacturer. Each mode or function must be assessed, and the combination of functions must be evaluated in the case of equipment with multiple modes or multiple radios; but only one DoC authorization applies.

An important aspect of EU compliance to the RED is that the DoC is a document, and not just a procedure or process. A DoC document must be completed, signed, and must accompany every radio equipment to be placed on the market; and that relates to each individual unit, not just to a model or range of products. If a manufacturer makes a change to a product line, the new variant will need a re-assessment before it is placed on the market with its DoC. Similarly, if the test standards change, or how the product is being used changes, the manufacturer must reassess for the next units to leave their factory and enter the market in the EU.

The manufacturer of any radio equipment must ensure that all assessments have been performed and their technical documentation is complete before applying the CE Mark to their product and placing it onto the market in the EU.

DIFFERENT ROLE OF A NOTIFIED BODY

The role of the Notified Body is quite different from that of a TCB or FCB. In the case of the FCC or ISCED Canada, the TCB or FCB is performing a certification based on the correct application of published standards, by the manufacturer and an accredited test lab. In the case of the EU, the Notified Body is performing an examination review to the high-level requirements of the Directive, which may or may not be based on published standards and may include deviations from published standards. The Notified Body has the authority to decide if the manufacturer's assessment is at least equivalent to a full test to a standard, and if it demonstrates compliance with the RED. The role of a Notified Body is a very complex process, requiring a detailed understanding of the test methods, the use of the radio spectrum, and the Directive itself. It is not a simple case of checking test reports to a standard.

Element Materials has two EU Notified Body designations in the USA, with Notified Body engineers operating across the USA, in Europe and in Asia. The regulation exists for the EU, but our customer base is world-wide.

The RED Notified Bodies at Element are at the forefront of the industry, providing training and support to manufacturers, consultants, and our own test labs. Many of the official RED guidance documents have been created under the responsibility of Element Notified Bodies, including guidance on radio modules, integration of radio equipment, SAR and RF Exposure, radio into vehicles and many more.

THE UK AND THE RADIO EQUIPMENT REGULATION (RER)

Many people will say that the UK Radio Equipment Regulations (RER) are a replication of the EU's RED, but it is not quite that simple.

There are many similarities and much of the text is identical. Radio equipment placed on the market in Great Britain (GB) of the UK must comply with all applicable regulations, including the UK RER, and compliance is based on a Declaration of Conformity (DoC) by the manufacturer, in the same way as the RED.

Assessments are performed to designated standards for the UK, with a certificate available from a UK Approved Body.

HOWEVER THERE ARE SOME DIFFERENCES

Firstly, it is important to remember that the RED is a trade Directive for the movement of equipment around the EU, and the UK RER is a trade regulation for equipment placed on the market in Great Britain. Just because radio equipment is acceptable for use in the EU, does not mean it can be used in Great Britain and the manufacturer must always check that the technology is permitted in the target region.

The UK has a list of designated standards, in the same way as the EU has a list of harmonized standards. Listing a UK-designated standard requires the authority of only one nation and no external consultant. Listing a standard on the EU OJEU requires the agreement of all EU member states and independent consultants. So, it is easy to see how

the UK and EU standards lists deviated so early into the process. The EU RED and UK RER are both based on an assessment of safety, EMC and radio performance. However, the EU RED contains additional requirements which are enabled through delegated acts.

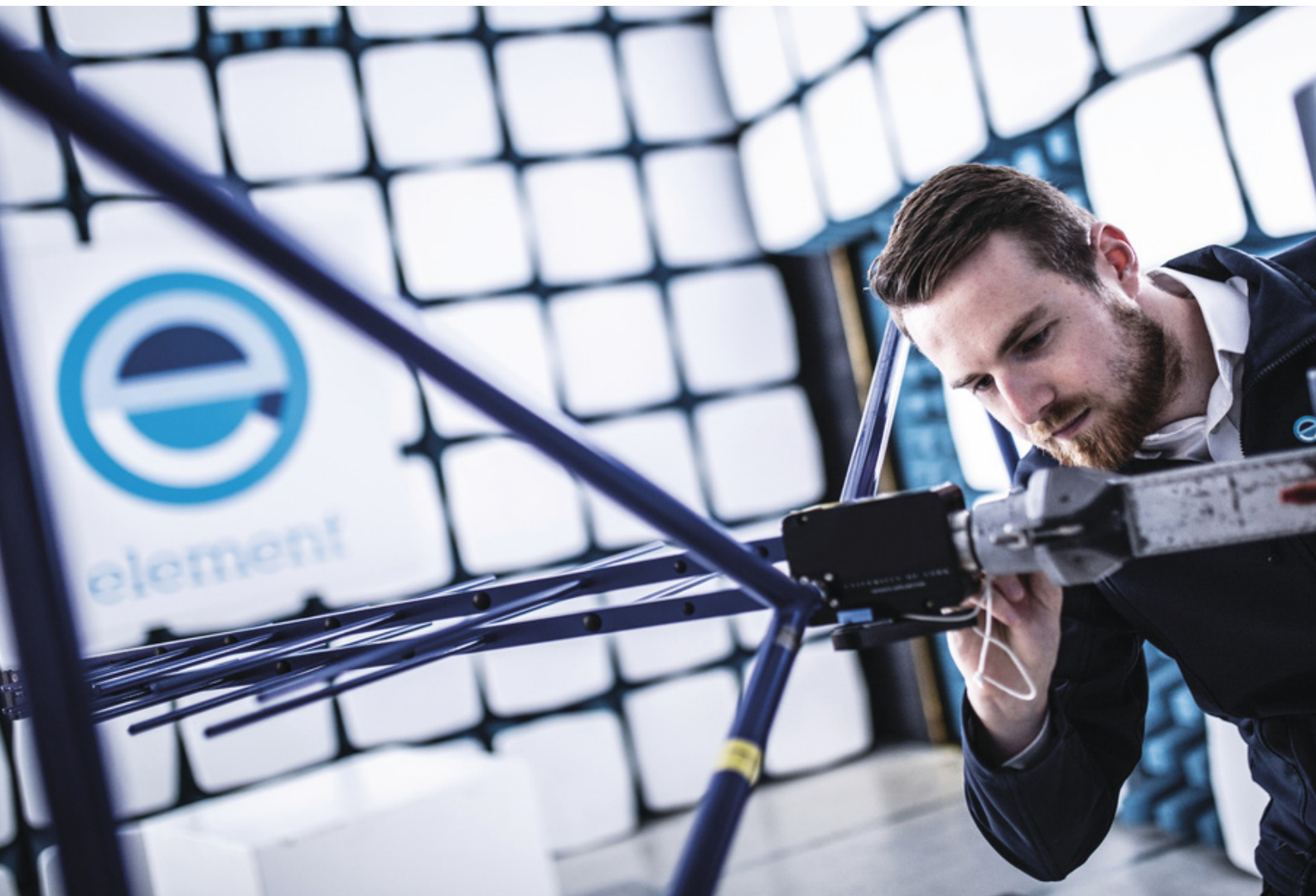
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FCC, ISED, RED, UK - COMMON TOPICS

The introduction of this article explained that testing leads to authorization and regulatory approval, but it is important to remember that testing and authorization are separate things. Testing may lead to authorization if done correctly, and authorization indicates technical compliance when done correctly.

Element understands that Regulatory Approval is the main goal for most of our customers, and that correct authorization is critical for getting to market on time. Our team of TCBs (USA), FCBs (Canada), RCBs (Japan), Notified Bodies (EU), and Approved Bodies (UK) are focused on staying at the cutting edge of technological advances because we know that correct Regulatory Approval is more than just testing.

[Contact our team](#) of experts to connect innovation to solutions, from R&D innovation to reality.





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