

**IEEE PSES San Diego Chapter
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**TÜV SÜD RED Transition and
Implementation**

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**Solutions that ensure that ensure
safety, reliability and compliance.**





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Radio Equipment Directive (RED) Introduction & Summary of Key Changes

- The new [Radio Equipment Directive \(RED\)](#) 2014/53/EU, replacing the Radio Equipment and Telecommunications Terminal Equipment (R&TTE) Directive 1999/5/EC, has been published in the Official Journal of the European Union on 22 May 2014
- All items of equipment within its scope placed on the European Market for the first time must follow one of the RED Conformity Assessment Procedures
- In order to be legally used in the European market equipment must comply with the requirements of the Directive when first used
- The new Radio Equipment Directive cannot be used until it has been transposed into National Law.

- The directive enters into force 20 days after publication and shall be transposed and become applicable from 13 June 2016:-
 - The obligation is on Member States to adopt and publish in national law by 12 June 2016; and apply the RED from 13 June 2016
 - The R&TTE Directive 1999/5/EC is repealed from 13 June 2016
 - Products previously assessed and with a Declaration of Conformity against R&TTE Directive 99/5/EC issued before 13 June 2016 may continue to be placed on the market until 13 June 2017
 - a “making available on the market” and “putting into service” provision means that products that comply with the R&TTE Directive before 13 June 2016 and are placed on the market before 13 June 2017 may be sold and brought into service later (Article 48)

- General principles for product compliance in the RED are very similar to the R&TTE Directive:
 - **Compliance with a set of essential requirements (no changes here)!**
 - Article 3.1(a) Health and Safety
 - Article 3.1(b) EMC
 - Article 3.2 Radio
 - Article 3.3 additional requirements when invoked by the European Commission
 - Harmonised standards provide a presumption of conformity with the essential requirements
 - Conformity assessment procedures:
 - Internal Production Control
 - Assessment of technical documentation by a Notified Body (Type Examination)
 - Full Quality Assurance Approval
 - Use of Notified Body where no radio or Article 3.3 Harmonised Standard exists
- However **there are some major changes for manufacturers, auth. Reps, imports & distributors, NBs and MSAs!** (*details are available from TUV SUD America*)

- Radio receivers must achieve a minimum level of performance to contribute to an efficient use of radio spectrum (includes broadcast radio and TV receivers)
- Fixed line terminal equipment is outside the scope of the RED
- Clear obligations for manufacturers, importers and distributors
- Strengthened market surveillance, e.g., the traceability obligations of manufacturers, importers and distributors
- Notified Body Opinion of Annex IV of R&TTE Directive replaced by Type Examination procedure where modifications to products which affect compliance must be agreed by the Notified Body
- Product registration scheme for types of radio equipment within categories affected by low levels of compliance (determined by European Commission)
- Notified Body Report - to accompany the Notified Body Type Examination Certificate, the Notified Body will be required to supply a report to explain and justify the issuing of the certificate

- Deletion of notification procedure for radio equipment using non-harmonised frequency bands
- Deletion of “alert” mark
- No requirement for CE marking in user documentation
- Deletion of the R&TTE Directive Annex III procedure
- Explicit requirements for combinations of radio equipment and software
- Technical documentation includes confirmation of operation in at least one Member State without infringing requirements on the use of radio spectrum
- Cannot use the EMC Directive or LVD conformity assessment procedures, the RED only refers to the EMC Directive and LVD to state the essential EMC and Health & Safety requirements

- Interworking with accessories such as common chargers can be invoked under Article 3.3 if decided by the European Commission
- Sample testing of products by manufacturer / importer to protect the health and safety of end users; plus register of complaints and recalls
- Electronic CE marking not permitted but is included for review by Commission
- Notified Body identification number must not be used in the CE marking on products which followed the Type Examination procedure
- CE + NB number product marking only for Annex IV FQA
- NB number must be used in DoC where Type Examination or FQA procedure is followed
- User information for radio transmitters should include:
 - frequency band(s) in which the radio equipment operates;
 - maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates

- Codifies requirements for universal chargers
 - Presently, common/universal chargers are optional under industry MOUs
 - Requirement in the directive for common or universal chargers
 - For example, mobile phones, tablets, cameras, music players, etc.
 - Desire is to reduce impact to the environment and inconvenience to consumers

Scope of RED

- Products which fit within the following definitions (and are not excluded by Article 1 – see later) are subject to the RED:
 - 'radio equipment' means an electrical or electronic product, which intentionally **emits and/or receives** radio waves for the purpose of **radio communication and/or radiodetermination**, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination
 - '**radio communication**' means communication by means of radio waves
 - '**radiodetermination**' means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves
 - 'radio waves' means electromagnetic waves of frequencies **lower than 3000 GHz**, propagated in space without artificial guide

Note: equipment which makes use of radio waves without radio communication or radiodetermination is outside of the scope of the RED, e.g. microwave ovens

Scope of RED

- All radio receivers, including broadcast radio and TV receivers, (apart from those excluded by Article 1) are within the scope of the RED. Justification provided by the European Parliament's Committee on the Internal Market and Consumer Protection:
 - considering that radio spectrum is a finite resource, it is important to guarantee its efficient usage, therefore the equipment capable of receiving radio waves should fall under the scope of proposed Directive.
- Telecommunications Terminal Equipment (TTE), i.e. fixed line terminal equipment, is outside the scope of the RED and, as a result, is within the scope of the EMC Directive and LVD
 - New RED makes the safety requirement for animals more clearer for everyone
 - the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in LV Directive 2014/35/EU (new), but with no voltage limit applying;

- “radio equipment exclusively used for activities concerning public security, defence, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law”
- Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations, unless the equipment is made available on the market.
 - The following shall be regarded as not being made available on the market:
 - (a) radio kits for assembly and use by radio amateurs;
 - (b) radio equipment modified by and for the use of radio amateurs;
 - (c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.
- Marine equipment falling within the scope of Council Directive 96/98/EC
- Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council
- Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes

Examples of Equipment Types included in the RED



Airborne products, parts and appliances not excluded by Annex I.3 of RED	Base Station for Mobile Network
Broadcast radio and TV receivers	Citizens Band radio
Broadcast transmitters	Distress/Position Indicating Beacon
Cordless Telephone	Fixed Wireless Access
Fixed Link	Maritime (for Non-SOLAS vessels)
Industrial, Scientific, and Medical within scope of directive	Paging (Radio Messaging)
Mobile (Cellular) Telephone Handset	Radar
Private/Professional Mobile Radio	Radio Local Area Network
Radio Frequency Identification (RFID)	Short Range Device (SRD)
Satellite Earth Station (Fixed / Mobile)	Ultra Wideband
Wireless Microphone	GPS Receivers

The technical requirement is that equipment within the scope of the Directive must comply with the “Essential Requirements”

Definition of “Essential Requirements” is given in Article 3 of the Directive:

Essential Requirements

3.1(a) Health and safety of persons and of domestic animals and the protection of property , including the <i>objectives</i> with respect to safety requirements set out in LVD, but with no voltage limit applying <i>* Includes all hazards, such as SAR/RF exposure and Acoustic Shock</i>	3.1(b) EMC An adequate level of electromagnetic compatibility as set out in EMC Directive	3.2 Effective use and support the efficient use of radio spectrum in order to avoid harmful interference	3.3 Additional requirements where decided by European Commission:
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Note: TUV SUD would have concerns certifying products that risk the health & safety of any animal, not just domestic animals.



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RED Transition and Implementation

RED

- Agreed 16th April 2014
- Will come into effect 13th June 2016

R&TTE

- Currently in Effect
- Ceases to be valid 13th June 2017

The RED contains the following transitional period (Article 48): 2

Member States shall not impede, for the aspects covered by this Directive, the making available on the market or putting into service of radio equipment covered by this Directive which is in conformity with the relevant Union harmonisation legislation applicable before 13 June 2016 and which was placed on the market before 13 June 2017.

Applicability of Legislation

(extract from European Commission Document dated 19/08/2015)



This Document covers the transition rules:

- R&TTE to RED
- EMC/LVD (old) to EMC/LVD (2014)
- R&TTE to EMC/LVD
- EMC/LVD to RED

- The Following slides address these

R&TTE Transition - Products within scope of R&TTE and will be also within scope of the RED



For example, **mobile phones, non-SOLAS marine radio equipment, radio basestations, GPS receivers**

Where compliance has been established under the R&TTE Directive, products may continue to be placed on the Market (i.e. supplied into the market place) until 13th June 2016.

Where such products fall within the scope of the RED they may continue to be placed on the Market using compliance against the R&TTE until 13th June 2017.

Products placed on market after 12 June 2017 must be compliant with the RED

- Includes Compliance with the RED Essential Requirements , and administrative requirements .

Where such products require modification the compliance may be re-established under the R&TTE until 13th June 2017

New or derived products which fall within the scope of the RED may enter the market under a DOC citing the R&TTE until 13th June 2017

Product currently under the EMC/LVD



This addresses products currently under the EMC Directive (2004/104/EC) and possibly also under the LVD (2006/95/EU)

Where compliance has been established to the relevant Directives (EMC and LVD) they may continue to be placed upon the market until 20 April 2016 under those directives

After 20 April 2016 those products must be compliant to new EMC Directive 2014/30/EU and where relevant the new LVD (2014/35/EU) .

- See also next slide .
- Note While outside this presentation there are a few subtle differences between the 2004 and 2014 EMC Directives. (including labelling, DoC, and User info)

There is No Parallel Transition for the EMC Directive.

Product currently under the EMC/LVD but will be under the RED



This addresses products currently under the EMC Directive (2004/104/EC) and possibly also under the LVD (2006/95/EU) which fall within the scope of the RED, for example, **broadcast radio and television receivers, radio receivers or transmitters operating below 9KHz.**

Where compliance has been established to the relevant Directives (EMC and LVD) they may continue to be placed upon the market until 20 April 2016 under those directives.

After 20 April 2016 until 13th June 2016 those products must be compliant to EMC Directive 2014/30/EU and where relevant the LVD (2014/35/EU).

- Products placed on market between 3 June 2016 and 12 June 2017 must follow either the compliance rules for the RED or the 2014 LVD/EMCD
- Products placed on market after 12 June 2017 must be compliant with the RED
 - Includes Compliance against RED Harmonised Standards.

Product currently under the R&TTE but will be under the 2014 LVD/EMCD



This addresses products currently under the R&TTE which fall outside the scope of the RED and therefore are within the scope of the 2014 LVD/EMCD, for example, **telecommunications terminal equipment such as wireline PSTN telephones and ADSL modems.**

Where compliance has been established to the R&TTE Directive they may continue to be placed upon the market until 13th June 2016

After 13th June 2016 those products must be compliant to EMC Directive 2014/30/EU and where relevant the LVD (2014/35/EU)

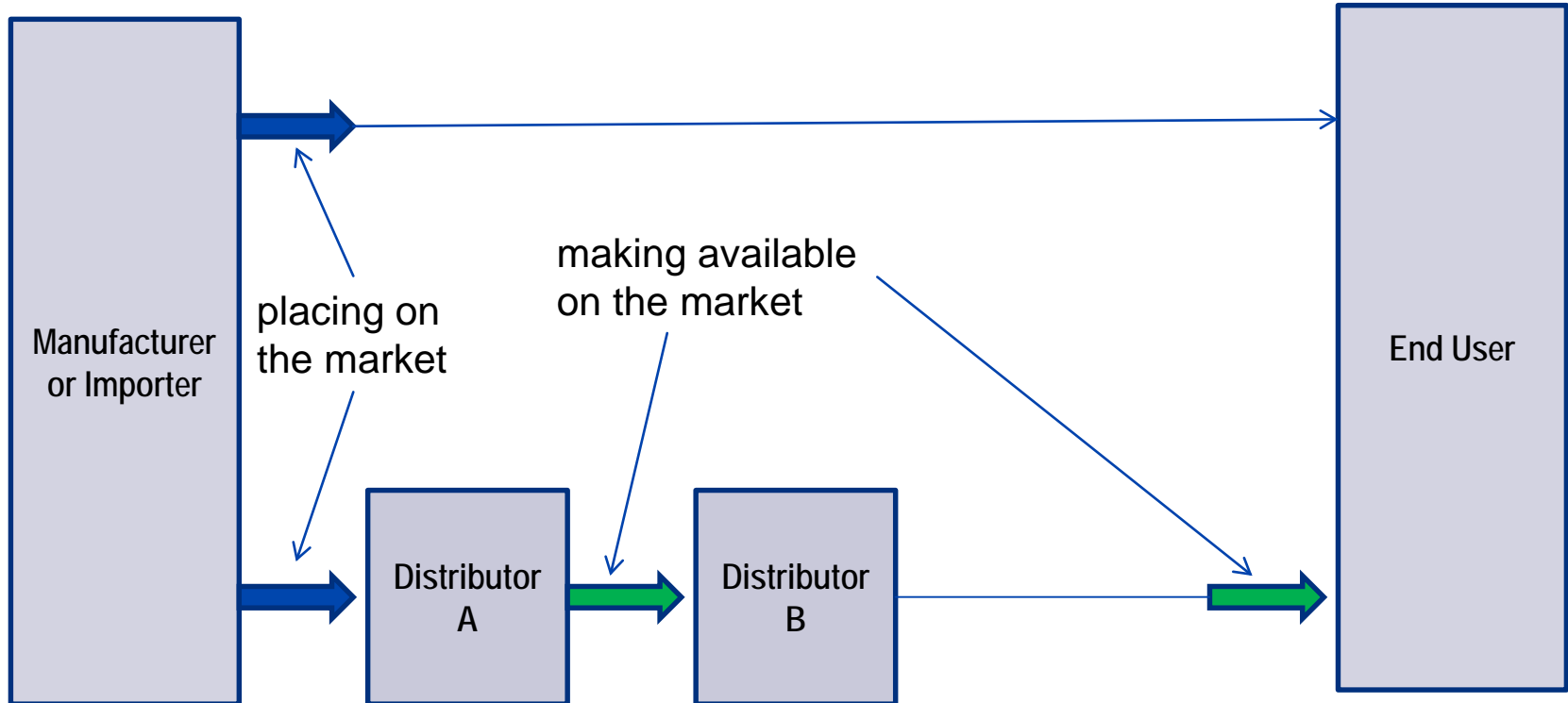
- if the equipment is outside the voltage range specified in LVD, the LVD is not applicable, but the General Product Safety Directive could be applicable provided that the equipment is a consumer product

- A product is placed on the market when it is made available for the first time on the Union market.
 - Placing onto the Market is reserved either for a manufacturer or an importer i.e. the manufacturer and the importer are the only economic operators who place products on the market. When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, the operation is always labelled in legal terms as “placing on the market”.
- Products made available on the market must comply with the applicable Union harmonisation legislation at the moment of placing on the market.

- Making available onto the market
 - Any subsequent operation after placing on the Market, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.
 - As for “making available”, the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.
- Consequently, even though a product model or type has been supplied before new Union harmonisation legislation laying down new mandatory requirements entered into force, individual units of the same model or type, which are placed on the market after the new requirements have become applicable, must comply with these new requirements.

“making available on the market” and “placing on the market”

The definition of “placing on the market” includes “first making available on the market”



Each individual radio equipment made available on the market must comply with the Radio Equipment Directive at the moment of placing on the market

This means that Products may establish compliance with the RED and be supplied with a DOC citing the RED on and after 13 June 2016

After 13 June 2017 ALL Radio Equipment must be compliant with the RED and may no longer be placed on the Market using the R&TTE.

Any product design originally compliant to the R&TTE must be re-assessed under the RED to continue in supply after 13 June 2017.

Each EU member must enact National legislation to bring the RED into their Legal framework.

The Target for this is prior to 13 June 2016.

- DBIS (responsible UK Government Department) normally only enacts Directives close to the final date.

- The Scope of the RED differs from the R&TTE which means additional standards are required; and existing standards require additional requirements.
- The Essential requirements have been changed which means that many standards require review and amendment
- Standards already cited under RTTE Directive 1999/5/EC (228 in June 2015) are being reviewed & will be published under RED
- ETSI have stated that it is not possible to complete all standards in the time requested (by 13 June 2016)
- Likewise some Standards produced by CEN/CENELEC will require amendment.
- The Commission has mandated some new Harmonised Standards for the RED from the Standardisation bodies (ETSI and CEN/CENELEC)

- Standardisation request M/536 issued 4 August 2015:
 - A request to draft RED Article 3 harmonised standards for radio equipment
 - 1st joint annual report to European Commission by 31 January 2016
 - First list of the HS titles to European Commission by 15 March 2016
 - 15 March 2016 publication deadline for standards for:
 - Sound and TV Broadcast Receivers and receiver characteristics of non-receive-only equipment
 - Radio equipment operating below 9 kHz
 - Radio-determination equipment
 - Health & Safety standards to include reasonably foreseeable conditions of use
 - Effective and efficient use of radio spectrum in addition to tightening transmitter requirements has introduced requirements on receiver performance (see recitals 10 and 11 of the RED)
 - This will be a key requirement for mobile terminal antenna performance, and for communication equipment used in safety of life applications.
 - The development of sharing mechanisms and mitigation techniques are a priority to achieve the efficient use of radio spectrum to increase spectrum sharing capabilities of equipment.

- The Harmonised Standards list for the R&TTE will continue in effect until replaced by another R&TTE HS list or 13 June 2017
- The Commission will publish a HS list for the RED prior to 13 June 2016 and update as necessary.
- ETSI have stated: Harmonised standards listed in the OJ under the Low-Voltage and EMC Directives cannot be used to show conformity with Articles 3.1a and 3.1b of the RED
 - Only harmonised standards listed in the OJ under the RED can be used to show conformity with this Directive.
 - Standards which do not appear in the RED list no longer give presumption of conformity
 - This means that former EMC Directive “product” specific EMC Standards will no longer provide full conformity where the product includes a transmitter or receiver, for example, a consumer product which incorporates a radio module – a refrigerator.

- Unless specific advice has been issued by the Commission, or the RED-CA, Harmonised Standards represent the “State of the Art”.
- Conformity with Harmonised Standards (HS) in full gives the presumption of Conformity [in full = meeting all the relevant requirements related to the product functions]
- However for any Article a mix of Harmonised and Non-harmonised Standards, or just non-harmonised standards may be used to establish conformity.
- Where this occurs there is no Presumption of Conformity related to that article. The Technical file must include a justification why compliance with the used standard is equivalent or better than the “State of the Art” as specified in the HS.
- Where Non-Harmonised Standards have been use (or an HS is not used in full) for Article 3.2 or 3.3 then an NB must review the Technical File;
- Where Non-Harmonised Standards have been use (or an HS is not used in full) for Article 3.1a or 3.1b then the Client may either self declare, or use an NB.

- The definition of radio equipment does not allow treating inbuilt radio functionality separately from the main equipment.
- The product cannot be separated into parts to which different Directives apply.
- The presence of an inbuilt radio module or component makes the whole product radio equipment. **Combined equipment is radio equipment.**
- ETSI committee ERM EMC proposes developing a new set of harmonised standards for combined equipment intended to be listed in the OJ under the RED.
- Such new standards would:
 - Refer to existing radio EMC standards for radio related requirements.
 - Refer to existing non-radio EMC standards for the other relevant requirements.
 - Solve the problem where different requirements are in the radio and non-radio standards by specifying which requirements apply.
- This proposal has the following advantages:
 - There is no need to revise existing radio and non-radio standards.
 - Requirements are stated by dated references to other standards.

- Notified Bodies listed under the R&TTE may continue to operate until 13 June 2017 .
- Member states must designate Notified Bodies under the RED prior to them operating.
 - In UK, DBIS will only designate bodies with UKAS accreditation for the RED
 - UKAS will only Accredit Notified Bodies when the UK Legal Instrument (Statutory Instrument) is in place
 - UKAS has assessed TUV SUD B A B T (our certification body) and is satisfied with our RED implementation.
- REDCA (formerly R&TTE CA) have been informed of the ETSI Guide, which provides guidance Notified Bodies on assessment of radio equipment for which the Harmonised Standards have not yet been completed
 - EG 203 336 is intended to provide guidance on typical parameters for EMC and radio Harmonised Standards

- The RED requires that where a manufacturer does not make use of Harmonised Standards in their entirety under Articles 3.2 and 3.3 then a Notified Body must be involved with the compliance.
- Where a manufacturer does not make use of Harmonised Standards in their entirety under Articles 3.1a, or and 3.1b then they may still self declare (if they wish) but must include a justification why the Standards used meet the state of the art.
- Consequence of late production of ETSI RED standards is that many Manufacturers wishing for an early implementation of the RED will have to apply for an NB Type Examination Certificate (TEC) (Module B), and follow that path afterwards.

TUV SUD BABT will accept applications for RED TECs from 1 March 2016 subject to following details:

- the TCF must include all the required documentation
- The Standards used to establish compliance must either :
 - have been issued by their standardisation body
 - ETSI will issue RED Standards in advance of formal listing in a HS list. BABT will review for compliance using the issued standards as representing “the state of the Art”.

Or

- May be the “best Fit” standard with a justification for their relevance using following the ETSI Guide, which provides guidance Notified Bodies on assessment of radio equipment for which the Harmonised Standards have not yet been completed
 - Best Fit may either be early/final draft ETSI standards prepared for the RED; or R&TTE Standards supplemented with additional tests (e.g. Receiver tests).

- TUV SUD BABT will accept testing to the final draft of a standard but will only assess against the published version
- Until end of 2016 TUV SUD BABT will accept unaccredited test reports supporting the RED from test Laboratories who retain accreditation for the equivalent standard under the R&TTE.
 - This allows Test Labs time to gain accreditation for these new standards.

- When a RED HS list appears TUV SUD BABT will review all completed RED jobs to ensure that compliance is still valid
- Any TUV SUD BABT TEC issued prior to 13 June 2016 will have a validity date of 13 June 2016.
 - TUV SUD BABT will reserve the right to rescind any certificate which fails to meet the requirements on that date.

- TUV SUD BABT will NOT transition R&TTE Notified Body Opinions into the RED. Clients will have to apply for New Certification.
- Why?
 - Clients may apply any Modification after an R&TTE NB opinion which means current NB opinion may NOT represent the latest build and TCF state
 - The RED has additional and some different requirements.
- However:
 - Clients may re-use still valid test data with justifications
 - Much of the Supporting documentation will not change.
 - Some Changes are not difficult to implement.

- TUV SUD BABT will permit Parallel applications for R&TTE and RED in the same application
- Why:
 - Some Clients may wish to supply product prior to 13 June 2016 but know their distributors will look/demand RED compliance after that date.
- However:
 - The Primary TCF must show compliance with the RED and use RED Harmonised Standards
 - The product is within the scope of both Directives
 - A Delta file contains a limited number documents supporting the R&TTE (e.g. Doc, Product Labelling)

TUV SUD BABT will accept applications for RED FQA transfers from immediate effect:

The Transfers are based on our “Cloning” policy which leaves the existing Certification intact.

- R&TTE FQAs may continue until 13th June 2017.

A new Version of the Audit Standard (BABT 940) has been produced to cover the RED requirements

- This will co-exist with the R&TTE version until 13th June 2017.
- This is based upon Deltas from ISO9001:2008
- A “de-coupled” version will be developed in due course as we will not align BABT 940 with ISO9001:2015

Any TUV SUD BABT FQA Approval issued prior to 13 June 2016 will have a validity date of 13 June 2016



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