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## Radio Equipment Directive 2014/53EU Risk Assessment Guidance

The Radio Equipment Directive (RED) replaces the R&TTE Directive. As from 13 June 2017, manufacturers need to ensure radio equipment products conform to the RED.

The RED technical documentation shall include an adequate analysis and assessment of the risks to the essential requirements. This risk assessment is a fundamental part of the technical file as it is required in order to demonstrate compliance with the essential requirements.

A risk assessment is required in the technical file in all cases, including when the manufacturer is self-declaring conformity.

### **Risk Assessment** **What is it?**

All radio equipment present risks that they may not adequately comply with the essential requirements, which would negatively affect users, radio spectrum use, or the EMC performance of other electronic equipment for example.

The risk assessment analyses the risks and demonstrates how the risks are reduced in such a way that the equipment is deemed to comply with the essential requirements. The risk assessment provides an emphasis for a more lateral compliance strategy which may consider more than what is specified in harmonised standards.

### **What form should it take?**

Manufacturers should present the risk assessments in a format that is suitable to them. Reducing complexity in risk assessments is very important as not to remove focus from showing how the equipment is compliant. A tabulated or spreadsheet format may promote easier risk assessment writing and reading however, a risk assessment can be presented on any format.

There is a minimum amount of information that should be expected before a risk assessment may be considered adequate. Further below is an example outline of principles that if followed may lead to an adequate risk assessment.

## Intended and Foreseeable Use

The risk assessment should primarily consider the intended use for the radio equipment with respect to all essential requirements. However, for article 3.1a health and safety compliance, the risk assessment should also consider reasonably foreseen use.

Foreseen is a potentially unlimited term given that it is not possible to foresee all health and safety risks however, a reasonable consideration should be made given the product type, environment and users for example. Please note that a risk assessment will only be considered adequate if it also considers foreseen use.

## Minimum Risk Assessment Content

An adequate risk assessment should cover these items as a minimum and the risk assessment process should generally follow the order shown below.



### Product Identification

Identify product functions and features, comprising of both radio and non-radio functions and features. Associated accessories or components of, including key safety critical components should also be identified – this may include items such as batteries, AC/DC adaptors, power supplies, LED, earphones/speakers or antennas for example.

### Risk Identification

With respect to the product functions, features and accessories – identify the hazards and subjects at risk. Subjects may be persons, equipment or networks for example, which may be affected by the hazards.

### Risk Analysis

With respect to the previously identified hazards – identify how the hazard may foreseeably harm another subject i.e. harm mechanism.

### Uncontrolled Risk Evaluation

With respect to the previously identified harm mechanisms – identify the uncontrolled risk level. This could be based a methodology that evaluates risk levels based on a combination of risk severity and probability.

### Risk Reduction / Mitigation

With respect to the previously identified risk evaluations – demonstrate how the individual risks are controlled through risk reduction or mitigation.

### Controlled Risk Evaluation

Once risks have been reduced, re-evaluate the risk level. To demonstrate compliance the aim is to reduce the risk as far as practicably possible.

### Compliance Statement

The main purpose of reducing the risks and re-evaluating the final risk level is to demonstrate that the radio equipment presents a low risk to compliance with the essential requirements. Therefore, the risk assessment should have a conclusive statement that confirms the radio equipment's overall compliance as a result of the risk assessment.

### Risk Management

Compliance risk management is an on-going endeavour. It is the manufacturer's responsibility to re-assess the risks to compliance with every modification and where compliance are affected, the subsequent risk controls should be established and documented in the technical file before updating the declaration of conformity and/or EU-type examination certification as appropriate.