20-1025 (Lead); 20-1138 (Consolidated)

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL HEALTH TRUST; CONSUMERS FOR SAFE CELL PHONES; ELIZABETH BARRIS; THEODORA SCARATO

CHILDREN'S HEALTH DEFENSE; MICHELE HERTZ; PETRA BROKKEN; DR. DAVID O. CARPENTER; DR. PAUL DART; DR. TORIL H. JELTER; DR. ANN LEE; VIRGINIA FARVER, JENNIFER BARAN; PAUL STANLEY, M.Ed.
Petitioners

v.

FEDERAL COMMUNICATIONS COMMISSION;
UNITED STATES OF AMERICA
Respondents

Petition for Review of Order Issued by the
Federal Communications Commission

PETITIONERS' REPLY BRIEF ADDENDUM OF AUTHORITIES

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TABLE OF CONTENTS

Statutes

5 USCS §706

Current through Public Law 116-163, approved October 2, 2020.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title [*5 USCS §§ 556* and *557*] or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

47 USCS §402

Current through Public Law 116-163, approved October 2, 2020.

§ 402. Judicial review of Commission's orders and decisions

(a) Procedure. Any proceeding to enjoin, set aside, annul or suspend any order of the Commission under this Act (except those appealable under subsection (b) of this section) shall be brought as provided by and in the manner prescribed in chapter 158 of title 28, United States Code [*28 USCS §§ 2341* et seq.].

(b) Right to appeal. Appeals may be taken from decisions and orders of the Commission to the United States Court of Appeals for the District of Columbia in any of the following cases:

(1) By any applicant for a construction permit or station license, whose application is denied by the Commission.

(2) By any applicant for the renewal or modification of any such instrument of authorization whose application is denied by the Commission.

(3) By any party to an application for authority to transfer, assign, or dispose of any such instrument of authorization, or any rights thereunder, whose application is denied by the Commission.

(4) By any applicant for the permit required by section 325 of this Act [*47 USCS § 325*] whose application has been denied by the Commission, or by any permittee under said section whose permit has been revoked by the Commission.

(5) By the holder of any construction permit or station license which has been modified or revoked by the Commission.

(6) By any other person who is aggrieved or whose interests are adversely affected by any order of the Commission granting or denying any application described in paragraphs (1), (2), (3), (4), and (9) hereof.

(7) By any person upon whom an order to cease and desist has been served under section 312 of this Act [*47 USCS § 312*].

(8) By any radio operator whose license has been suspended by the Commission.

(9) By any applicant for authority to provide interLATA services under section 271 of this Act [*47 USCS § 271*] whose application is denied by the Commission.

(10) By any person who is aggrieved or whose interests are adversely affected by a determination made by the Commission under section 717(a)(3) [*47 USCS § 618(a)(3)*].

(c) Filing notice of appeal; contents; jurisdiction; temporary orders. Such appeal shall be taken by filing a notice of appeal with the court within thirty days from the date upon which public notice is given of the decision or order complained of. Such notice of appeal shall contain a concise statement of the nature of the proceedings as to which the appeal is taken; a concise statement of the reasons on which the appellant intends to rely, separately stated and numbered; and proof of service of a true copy of said notice and statement upon the Commission. Upon filing of such notice, the court shall have jurisdiction of the proceedings and of the questions determined therein and shall have power, by order, directed to the Commission or any other party to the appeal, to grant such temporary relief as it may deem just and proper. Orders granting temporary relief may be either affirmative or negative in their scope and application so as to permit either the maintenance of the status quo in the matter in which the appeal is taken or the restoration of a position or status terminated or adversely affected by the order appealed from and shall, unless otherwise ordered by the court, be effective pending hearing and determination of said appeal and compliance by the Commission with the final judgment of the court rendered in said appeal.

(d) Notice to interested parties; filing of record. Upon the filing of any such notice of appeal the appellant shall, not later than five days after the filing of such notice, notify each person shown by the records of the Commission to be interested in said appeal of the filing and pendency of the same. The Commission shall file with the court the record upon which the order complained of was entered, as provided in *section 2112 of Title 28, United States Code*.

(e) Intervention. Within thirty days after the filing of any such appeal any interested person may intervene and participate in the proceedings had upon said appeal by filing with the court a notice of intention to intervene and a verified statement showing the nature of the interest of such party, together with proof of service of true copies of said notice and statement, both upon appellant and upon the Commission. Any person who would be aggrieved or

whose interest would be adversely affected by a reversal or modification of the order of the Commission complained of shall be considered an interested party.

(f) Records and briefs. The record and briefs upon which any such appeal shall be heard and determined by the court shall contain such information and material, and shall be prepared within such time and in such manner as the court may by rule prescribe.

(g) Time of hearing; procedure. The court shall hear and determine the appeal upon the record before it in the manner prescribed by *section 706 of title 5, United States Code*.

(h) Remand. In the event that the court shall render a decision and enter an order reversing the order of the Commission, it shall remand the case to the Commission to carry out the judgment of the court and it shall be the duty of the Commission, in the absence of the proceedings to review such judgment, to forthwith give effect thereto, and unless otherwise ordered by the court, to do so upon the basis of the proceedings already had and the record upon which said appeal was heard and determined.

(i) Judgment for costs. The court may, in its discretion, enter judgment for costs in favor of or against an appellant, or other interested parties intervening in said appeal, but not against the Commission, depending upon the nature of the issues involved upon said appeal and the outcome thereof.

(j) Finality of decision; review by Supreme Court. The court's judgment shall be final, subject, however, to review by the Supreme Court of the United States upon writ of certiorari on petition therefor under *section 1254 of title 28 of the United States Code*, by the appellant, by the Commission, or by any interested party intervening in the appeal, or by certification by the court pursuant to the provisions of that section.

Regulations

47 C.F.R. §1.1307

§1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

See FCC Statutory Addendum pp. 12-29.

Other Authorities

Sen. Report 104-140, Department of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Bill, 1996, (Sept. 13, 1995), excerpted p. 91

Calendar No. 185

104TH CONGRESS, 1st Session | SENATE | REPORT 104–140

DEPARTMENTS OF VETERANS AFFAIRS AND HOUSING AND URBAN DEVELOPMENT, AND INDEPENDENT AGENCIES APPROPRIATIONS BILL, 1996

SEPTEMBER 13 (legislative day, SEPTEMBER 5), 1995.—Ordered to be printed

Mr. BOND, from the Committee on Appropriations, submitted the following

REPORT

[To accompany H.R. 2099]

The Committee on Appropriations to which was referred the bill (H.R. 2099) making appropriations for the Departments of Veterans Affairs and Housing and Urban Development, and for sundry independent agencies, boards, commissions, corporations, and offices for the fiscal year ending September 30, 1996, and for other purposes, reports the same to the Senate with amendments and recommends that the bill as amended do pass.

Amount of new budget (obligational) authority

Amount of bill as recommended in House	$79,697,360,000
Amount of change by Committee	+1,286,626,000
Amount of bill as reported to Senate	80,983,986,000
Amount of appropriations to date, 1995	89,920,161,061
Amount of budget estimates, 1996	89,899,762,093
Under estimates for 1996	8,915,776,093
Under appropriations for 1995	8,936,175,061

93–589 cc

The Committee has provided $1,670,000,000 for program administration and management, and has made the following changes to the budget request for abatement, control, and compliance and program and research operations:

- −$81,474,300 for program office laboratory costs (funded in the "Science and technology" account).
- −$140,080,200 for ORD personnel costs (funded in the "Science and technology" account).
- −$683,466,200 from State and tribal capacity grants (these grants are funded in the "Program and infrastructure assistance" account).
- −$40,600,000 from the environmental technology initiative.
- −$90,000,000 from the climate change action plan programs. The amount provided is approximately the same as the fiscal year 1994 level of $40,000,000. Funds for the green programs have been eliminated. The Committee notes that these programs overlap and conflict with statutory authority provided to the Department of Energy in the Energy Policy Act of 1992. For example, the Secretary of Energy was given a mandate to develop labeling and advertising rules for lighting, equipment, and appliances. Therefore, EPA should transfer to DOE those energy efficiency and energy supply programs which DOE, not EPA, is authorized to carry out. Future appropriations for these programs should be requested as part of the DOE budget submission.
- −$24,000,000 from the Montreal Protocol facilitation fund. The Committee notes that a total of $116,000,000 has been provided to date (EPA and State Department appropriations) for the Montreal Protocol.
- +$31,645,700 for the working capital fund, transferred from the "Research and development" account. This new fund has not been approved.
- −$1,800,000 from lower priority environmental education activities. This is the same as fiscal year 1995.
- −$3,000,000 from lower priority activities in the Office of International Activities. This is the same level as fiscal year 1995.
- −$405,000 from the Building Air Quality Alliance.
- −$350,000 from activities related to electromagnetic fields. Section 2118 of the Energy Policy Act of 1992 established a Federal program to investigate and report on human health effects from electromagnetic fields [EMF]. Congress mandated that this program of research and public communication be managed jointly by the Department of Health and Human Services and the Department of Energy. No programmatic role was assigned to EPA, yet EPA has pursued a number of unintegrated activities on EMF that are of questionable value. Therefore, the Committee believes EPA should not engage in EMF activities.
- −$2,000,000 from the national service initiative.
- −$1,000,000 from the GLOBE Program.
- −$20,000,000 from enforcement activities.
- −$25,000,000 from regional and State oversight. The Committee concurs with the National Academy of Public Administration's recommendation that regional offices should focus on building

FCC Knowledge Database ("KDB") Publication 447498, RF Exposure Procedures and Equipment Authorization Policies for Mobile and Portable Devices

Federal Communications Commission
Office of Engineering and Technology
Laboratory Division

October 23, 2015

RF EXPOSURE PROCEDURES AND EQUIPMENT AUTHORIZATION POLICIES FOR MOBILE AND PORTABLE DEVICES

Table of Contents

1. INTRODUCTION

This document is one of a collection of guidance publications referred to as the *published RF exposure KDB procedures*.[1] The procedures in the collection are:

a) Product related KDB publications: Mobile and Portable Devices (KDB 447498), Handsets & Accessories (KDB 648474), Laptop/Notebook/Netbook & Tablet Devices (KDB 616217), USB Dongles (KDB 447498), UMPC Mini-Tablets (KDB 941225), Occupational PTT Two-Way Radios (KDB 643646).

b) Wireless technology related KDB publications: 3GPP/3GPP2 Technologies (KDB 941225), 802.11 (KDB 248227), WiMax (KDB 615223), Wireless Routers (KDB 941225), Wireless Power Transfer Applications (KDB 680106).

c) Test methodology related KDB publications: SAR Measurement and Reporting Requirements (KDB 865664).

d) Equipment approval policy related KDB publications: Pre-Approval Guidance (PAG) Procedures and PAG List (KDB 388624), Permissive Change Policies (KDB 178919), Modular Approval Policies (KDB 996369), SAR Numbers Listing (KDB 690783), etc.

This guidance document KDB Publication 447498 D01 serves as an entry point for the RF exposure guidance described in the collection of *published RF exposure KDB procedures*. It describes the general RF exposure evaluation requirements and certain test guidance that may also be applicable for all the other *published RF exposure KDB procedures*. In general, the *published RF exposure KDB procedures* are applied in conjunction with other FCC rules, policies, and procedures to prepare devices for equipment authorization according to the mobile device and portable device RF exposure requirements. Guidance in the most recent revision of the *published RF exposure KDB procedures* and TCB workshop updates,[2] whichever is the latest at the time when device testing begins, must be applied. The guidance in this document and the *published RF exposure KDB procedures* must be applied for equipment approval, unless further guidance provided by the FCC is applied. For the devices and conditions that are on the PAG List (KDB Publication 388624 D02), or when alternative procedures are applied, a PAG is required before equipment approval.

When anything is unclear, clarifications can be obtained from the FCC Laboratory by submitting inquiries to the KDB system. The FCC should also be contacted to determine if existing test guidance is sufficient for evaluating new and evolving products and technologies. In some cases, when new test procedures are under development, interim test guidance is often provided through TCB conference updates (presentations) before KDB procedures are published.

2. GENERAL EQUIPMENT APPROVAL REQUIREMENTS

Applications for equipment authorization must meet all the requirements described in the applicable *published RF exposure KDB procedures*, and all applicable equipment approval policy and procedure documents. Unless specific guidance has been otherwise provided by the FCC, any applications for devices that are categorically excluded from routine evaluation for RF exposure must also apply the *published RF exposure KDB procedures*, according to the test exclusion provisions and measurement requirements. When the *published RF exposure KDB procedures* are not fully applied, prior approval

[1] Guidance for RF exposure evaluation is available from the FCC website through Knowledge Database Publications (KDB) at www.fcc.gov/labhelp. These are collectively referred to in this document as the *published RF exposure KDB procedures* that provide RF exposure test and evaluation support for specific products, wireless technologies, test methodologies, and equipment approval policies.

[2] See Telecommunication Certification Body (TCB) Presentations, https://www.fcc.gov/oet/ea/presentations.

from the FCC is generally required before evaluating RF exposure compliance for equipment certifications. All deviations from these requirements must be confirmed through KDB inquiries. For applicants who want to apply alternative procedures, requesting substantial deviation(s) from the *published RF exposure KDB procedures*, or for devices that require significant FCC staff involvement to complete the review and approval process, the equipment approval is subject to PAG procedures. These types of conditions are determined during the pre-TCB KDB inquiry process, when test requirements are considered, and are applicable especially to new technologies and emerging products, or devices that require substantial test and approval considerations by FCC staff.

3. GENERAL RF EXPOSURE POLICIES FOR EQUIPMENT AUTHORIZATION

a) The RF exposure guidelines adopted by the FCC are based on SAR and MPE limits. The basic restrictions for human exposure is defined by SAR limits. MPE limits are derived from the SAR limits, in terms of free-space field strength and power density. SAR compliance is determined using tissue-equivalent media, at the applicable test frequencies. For devices that operate at larger distances from persons, where there are minimal RF coupling interactions between a device and the user or nearby persons, the more complex SAR evaluation can be avoided by evaluating RF exposure compliance using MPE limits. The RF exposure evaluation requirements of §2.1091 for mobile device exposure conditions subject to MPE limits and §2.1093 for portable device exposure conditions subject to SAR limits are different. When both exposure conditions apply to a device, compliance is determined according to the rules and policies established for each exposure condition; for example, due to differences in maximum output power or antenna configurations as described below in 3) c) 2) and 3) c) 3). Equipment authorization for devices that are categorically excluded from routine evaluation for RF exposure, according to §§ 1.1307(b)(2), 2.1091(c) and 2.1093(c), should apply the test exclusion procedures in this document and other KDB publications to demonstrate compliance. When § 2.1091(d)(4) applies, i.e., there may be the potential for a device to operate in portable device exposure conditions, the SAR test exclusion provisions should be applied. For devices that do not qualify for RF exposure test exclusions, the RF exposure test reduction provisions in this document and the other *published RF exposure KDB procedures* should be applied to verify compliance, typically according to worst case test configurations.[3] In some cases, the FCC may require RF exposure testing or analysis to be performed, based on the provisions of §§ 1.1307 (c) and (d).

b) Standalone and simultaneous transmission use conditions for mobile device and portable device exposure conditions must be determined according to the host platform and product operating configuration requirements. Transmitters approved only for use in standalone operations cannot be used in simultaneous transmission operations without further evaluation; this is typically accomplished through the test exclusion provisions or specific testing required for equipment approval. Except for transmitters that cannot operate in standalone configurations, when SAR measurement is required for simultaneous transmission conditions, approval for standalone use is required for each individual transmitter. For devices that do not support standalone transmission, there is no measured standalone SAR result to determine simultaneous transmission SAR test exclusion. The standalone SAR may be estimated according to procedures in 4.3.2 b) to determine simultaneous transmission SAR test exclusion; otherwise, the enhanced zoom scan measurement and volume scan post-processing procedures in KDB Publication 865664 D01 are required to determine SAR compliance. When transmitters are approved for use in dedicated host or product configurations,

[3] The test exclusion and test reduction procedures have been established to expedite equipment approvals. When a device is categorically excluded from routine evaluation for RF exposure, and it does not qualify for RF exposure test exclusion under the *published RF exposure KDB procedures*, the applicant or its test lab may submit a KDB inquiry request with the necessary justifications to avoid the additional testing.

according to the specific standalone and simultaneous transmission conditions tested for compliance, additional approvals are normally required for the transmitters to be used in other host and product configurations.

c) Transmitter modules must be approved according to one of the following host platform exposure conditions, with respect to the product configurations tested or evaluated for equipment approval for incorporation in qualified host products. The approved host platform exposure condition(s) must be identified in the test reports and equipment certification records. When transmitter modules are incorporated in host devices that qualify for RF exposure test exclusion and no other testing or equipment approval is required, the standalone and simultaneous transmission configurations and test exclusion conditions must be fully documented by both the grantee and host integrator according to Class I permissive change requirements.

   1) *Mobile exposure host* platform evaluation procedures can be applied only if all transmitters in the host devices support mobile device exposure conditions. Transmitters and modules approved only for use in the *mobile exposure host* platform cannot operate in hosts and product configurations that require standalone or simultaneous transmission operations in portable device exposure conditions. The *portable exposure host* platform or the *mixed mobile and portable exposure* platform is required to support portable device exposure conditions in qualified host configurations.

   2) *Portable exposure host* platform evaluation procedures can be applied only if all transmitters in the host devices support portable exposure conditions. Transmitters and modules approved for use in the *portable exposure host* platform may be used for standalone operations in *mobile exposure host* platforms, without further equipment approval, only when the same identical transmitter and antenna required for portable device exposure conditions are used.[4]

   3) The *mixed mobile and portable exposure host* platform enables host devices to incorporate transmitters in qualified mobile device and portable device exposure conditions, for standalone and simultaneous transmission operations, by applying the *published RF exposure KDB procedures* required for the host product to address RF exposure compliance. Transmitters and modules approved for use in *mixed mobile and portable exposure host* platform may be used for standalone and simultaneous transmission operations in mobile device and/or portable device exposure conditions according to the approved operating configurations and exposure conditions in qualified host configurations supported by the test results and exclusion conditions. When the simultaneous transmission test exclusion for mobile device exposure in 7.2 applies, a transmitter or module approved for use in the *portable exposure host* platform may be used for simultaneous transmission operations in the *mixed mobile and portable exposure host* platform according to Class I permissive change requirements without further equipment approval. When tests are required to support additional antenna or host configurations, the results must be sufficiently conservative to demonstrate compliance for all standalone and simultaneous transmission operations required by the hosts and product configurations through subsequent Class II permissive changes.

d) Transmitters operating in consumer products must comply with the general population exposure limits required for mobile device and/or portable device RF exposure conditions as appropriate. The test configurations used to qualify for test exclusion or used for compliance testing must be sufficiently conservative for all required operations to demonstrate compliance. The devices and accessories should be tested for normal use without requiring specific user intervention to maintain compliance. All device operating instructions and installation requirements must be supported by the

[4] Any transmitter or antenna changes required to support *mobile exposure host* platform use configurations must also satisfy *portable exposure host* platform requirements, and be addressed accordingly through Class II permissive changes. Alternatively, the *mixed mobile and portable exposure host* platform should be applied.

test configurations and results. It is unacceptable to apply instructions as a substitute for providing test data. Caution statements or warning labels are only acceptable for alerting users to avoid exposures in certain unintended use conditions that are not required for normal operations.

e) Occupational exposure limits only apply to "*work-related*" use conditions. Users must be "*fully aware of*" and be able to "*exercise control over*" their exposure to qualify for the higher occupational exposure limits. Occupational exposure limits do not apply to consumer devices and radio services intended for supporting public networks or Part 15 unlicensed operations.[5] When devices are authorized in accordance with the general population exposure limits, additional equipment approval is not required to satisfy occupational exposure requirements. Mandatory RF exposure training is required for workers to qualify devices for occupational exposure limits. When it can be demonstrated that users are required to adhere to the training instructions and are able to mitigate compliance concerns by applying the instructions, detailed training instructions incorporated in manuals in conjunction with conspicuous permanent labeling on the device may be considered as acceptable training to qualify workers to operate a device according to occupational exposure limits. The training information must be included in the equipment authorization application.

f) As required by §§ 2.1033(b)(3) and 2.1033(c)(3), users and installers shall be furnished with the required operating and installation instructions and, as appropriate, all persons who require such information to ensure or maintain compliance. These are reviewed for acceptance during equipment approval. The applicable instructions must be provided to installers, integrators, and end users to ensure proper installation and operation of the devices for meeting compliance.

   1) The instructions required for standalone products and modular transmitters are generally different due to varying host configurations; therefore, these must be considered differently, to ensure RF exposure compliance for both standalone and simultaneous transmission operations. User instructions must be sufficient for the typical consumers, who are generally unskilled, to install and operate the equipment to ensure RF exposure compliance. The acceptable host platform configurations and exposure conditions approved for a modular transmitter, including any restrictions, must be fully described in the equipment approval and required OEM integration instructions.

   2) When professional installation, OEM integration, or assembly by a third-party is expected, the installation instructions and assembly requirements approved for equipment authorization must be provided to the installers and integrators, to clearly identify the specific requirements necessary to maintain RF exposure compliance. The grantee of a transmitter, typically the manufacturer, is responsible for ensuring the installers and integrators have a clear understanding of the compliance requirements by including the required instructions and documentation with the product and, if necessary, to provide further support to fulfill grantee responsibilities for ensuring compliance. The installers and integrators must be fully informed of their obligations, and verify the resolution of any issues and concerns with each transmitter manufacturer or grantee. For transmitter modules, the different disclosures required for the entire supply chain to ensure compliance, including grantees of individual transmitters, host manufacturers, and OEM/ODM integrators, installers, as well as the end users, must be fully documented during equipment authorization.[6]

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[5] When general population and occupational limits are required for the different transmitters within a host device, due to radio service rules or are otherwise unclear, for example, LTE high power UE (user equipment) or U-NII transmitters, a KDB inquiry is required for case-by-case consideration; especially on how to evaluate and determine compliance for simultaneous transmission.

[6] User manuals, product integration or installation instructions and general disclosure conditions normally do not qualify for confidentiality. The rules of confidentiality typically apply to product design details that are considered

4. GENERAL RF EXPOSURE TEST GUIDANCE

4.1. General test requirements

a) The general SAR measurement concepts and test methodologies described in IEEE Std 1528-2013 should be applied in conjunction with the *published RF exposure KDB procedures* to perform SAR measurements.[7]

b) As required by §§ 2.1091(d)(2) and 2.1093(d)(5), RF exposure compliance must be determined at the maximum average power level according to source-based time-averaging requirements to determine compliance for general population exposure conditions. Unless it is specified differently in the *published RF exposure KDB procedures*, these requirements also apply to test reduction and test exclusion considerations. Time-averaged maximum conducted output power applies to SAR and, as required by § 2.1091(c), time-averaged effective radiated power applies to MPE. When an antenna port is not available on the device to support conducted power measurement, such as for FRS (Part 95) devices and certain Part 15 transmitters with built-in integral antennas, the maximum output power and tolerance allowed for production units should be used to determine RF exposure test exclusion and compliance.

c) SAR compliance for simultaneous transmission must be considered when the maximum duration of overlapping transmissions, including network hand-offs, is greater than 30 seconds. The simultaneous transmission SAR test exclusion procedures in 4.3.2 should be considered to streamline test requirements. When simultaneous transmission SAR evaluation is required to determine compliance the enlarged zoom scan measurement and volume scan post-processing procedures described in KDB Publication 865664 D01 must be applied.

d) Device test samples must have the same physical, mechanical, and thermal characteristics and operational tolerances expected for production units to ensure compliance. These factors often interact with each other and cannot be dealt with separately; therefore, they are considered collectively through testing representative device samples. Each device must be evaluated for SAR or MPE compliance in the required operating modes and test configurations, at the maximum rated output power and within the tune-up tolerance range specified for the product, but not more than 2 dB lower than the maximum tune-up tolerance limit.[8] When tune-up tolerance is not required to be reported for equipment approval, RF exposure compliance must be determined using similar testing criteria, according to the highest maximum output power and tolerance allowed for production units. The maximum output power of production units should be within the tune-up tolerance range specified for the equipment certification. When the maximum output power of production units is lowered by widening the tune-up tolerance, additional testing may be necessary for the original test results to support compliance.

e) When SAR or MPE is not measured at the maximum power level allowed for production units, the results must be scaled to the maximum tune-up tolerance limit according to the power applied to the

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as trade secrets. When applicable, such information may be included separately in the equipment approval and must be properly referenced in the non-confidential documents.

[7] While the fundamental SAR measurement concepts described in IEEE Std 1528 are applicable, the test requirements in the *published RF exposure KDB procedures* take precedence and must be applied, to address recent generation products and wireless technologies test requirements.

[8] The range of expected maximum output power variations from the rated nominal maximum output power specified for the product or wireless mode is referred to as the tune-up tolerance in this document. All devices must be tested within the tune-up tolerance specification range.

individual channels tested to determine compliance. For SAR measurements, some SAR systems may have provisions to scale the measured results by means of "power scaling" to compute the 1-g SAR at a higher output power level. When simultaneous transmission applies, unless the SAR system has provisions to scale each enlarged zoom scan separately to account for maximum tune-up tolerance before the volume scan post-processing, the measured aggregate SAR must be scaled according to the sum of the differences between the maximum tune-up tolerance and actual power used to test each transmitter.[9] When SAR or MPE is measured at or scaled to the maximum tune-up tolerance limit, the results are referred to as *reported*. At least, the highest *reported* results in each frequency band and all *reported* SAR or MPE results > 1.5 W/kg or within 5% of the applicable MPE limits, respectively, must be clearly documented in the test reports.[10] The highest *reported* SAR results are identified on the grant of equipment authorization according to procedures in KDB Publication 690783 D01.[11] When an antenna port is not available on the device to support conducted power measurement and test software is used to establish transmitter power levels, the power level must be demonstrated and verified separately, according to design and component specifications and product development information; otherwise, a KDB inquiry is necessary.

f) The *test separation distances* required for a device to demonstrate SAR or MPE compliance must be sufficiently conservative to support the *operational separation distances* required by the device and its antennas and radiating structures. For devices such as tablets and transmitters embedded in keyboard sections of laptop computers that are typically used in close proximity to users, the *test separation distance* is determined by the smallest distance between the outer surface of the device and the user.[12] For larger devices, as the antenna *operational separation distance* increases to where the SAR characteristics of the device and its antennas are not directly influenced by the user, such as antennas along the top and upper side edges of laptop computer displays or opposite and adjacent edges of tablets, the *test separation distance* is normally determined by the closest separation between the antenna and the user. When specific guidance is unavailable in the *published RF exposure KDB procedures*, these general criteria should be applied to determine the *test separation distances* required for SAR test reduction, exclusion, and measurements. For peripheral transmitters and modules where the final host configuration is not known and specific guidance is unavailable in the *published RF exposure KDB procedures*, the antenna to user separation distance should be applied to determine the SAR measurement and test exclusion requirements. When the *test separation distance* is specified as a "not to exceed" distance in the *published RF exposure KDB procedures*; for example, ≤ 5 mm, the *operational separation distance* of the host device cannot be less than the tested distance.[13] For incorporation into different host products, the *operational separation distance* with respect to the outer housing or antenna, according to the above, must be greater than or equal to the *test separation distance*.

g) When the frequency channels required for SAR testing are not specified in the *published RF exposure*

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[9] Scaling is applied to the measured data points in each enlarged zoom scan, before interpolation and extrapolation are applied, to determine the adjusted SAR distribution before further volume scan post-processing.

[10] When different tune-up tolerances are specified for different wireless modes and operating configurations, compliance must be determined separately according to the highest scaled results for each condition in each frequency band.

[11] See KDB Publication 865664 D01. The Commission also applies appropriate measurement uncertainty procedures when testing samples for compliance and comparing measured results to applicable limits.

[12] See 4.2.2 c) below for body-worn accessory SAR test configurations used by cellphones.

[13] In general, test separation distances specified in the *published RF exposure KDB publications* as less than or equal to (≤) a threshold distance should be treated as a "not to exceed distance," where smaller test distances may be necessary to satisfy more conservative exposure conditions.

KDB procedures, the following should be applied to determine the number of required test channels. The test channels should be evenly spread across the transmission frequency band of each wireless mode.[14]

$$N_c = Round\left\{\left[100\left(f_{high} - f_{low}\right)/f_c\right]^{0.5} \times \left(f_c/100\right)^{0.2}\right\},$$

where

- N_c is the number of test channels, rounded to the nearest integer,
- f_{high} and f_{low} are the highest and lowest channel frequencies within the transmission band,
- f_c is the mid-band channel frequency,
- all frequencies are in MHz.

h) Depending on the operating frequency and required antenna *test separation distance*, antenna gain usually does not apply to portable exposure conditions. Near-field exposure conditions can be highly dependent on the RF current distribution characteristics of individual transmitters, antennas, and host device configurations, which are not directly related to the far-field antenna gain. Except when it is specified in the *published RF exposure KDB procedures* for certain very low SAR conditions, it would be inappropriate to assume that lower gain antennas always produce lower SAR, or that testing is not required. Unless it can be demonstrated that the physical, mechanical, RF performance, SAR, and radiating characteristics are the same, within acceptable tolerances, and the highest *reported* SAR for the original antenna is < 0.8 W/kg, similar antennas must be considered separately to determine SAR compliance.[15]

i) A KDB inquiry is required to determine simultaneous transmission SAR test exclusion and SAR measurement requirements for the following conditions:

1) When coherent signals are involved in the simultaneous transmission, such as certain phased array, beam-forming, or similar configurations.[16]
2) When SAR is measured with MIMO chains transmitting simultaneously in a single measurement and the difference in maximum output power across MIMO chains is > 1 dB or when the *published RF exposure KDB procedures* are not suitable for testing the specific MIMO transmission or antenna configurations.
3) When there is more than 1 dB variation in maximum output power across all channels in a wireless mode or frequency band.[17]

j) The measurement setup used for SAR or MPE evaluation must not perturb the antennas and radiating structures of the test device, or influence it in manners that are inconsistent with the required test protocols; for example, field perturbations due to apparatuses used to secure test devices that are physically very small, such as USB dongles, thin edges of devices, or field scattering from nearby

[14] Any further reduction in test channels must be confirmed through KDB inquiries to qualify for equipment approval.

[15] A KDB inquiry with the necessary (preliminary) results and SAR distributions is required to determine if additional SAR test reduction may be considered for similar antennas.

[16] SAR and EMC measurement issues for coherent and correlated signals are different, and must be considered separately.

[17] All channels include those that are not required for testing. Maximum output power variations may be determined by combinations of measurements, design specifications, and other analyses, etc.

objects.[18] When necessary, a device should be secured with lossless foam material to provide ≥ 2.5 cm separation from the holding apparatuses to minimize potential perturbations. Scattering objects that may influence test results should also be relocated or repositioned.[19]

4.2. SAR test requirements for typical exposure conditions

4.2.1. Head exposure conditions

Devices that are designed to transmit next to the ear and operate according to the handset procedures in IEEE Std 1528-2013, or conditions described in the *published RF exposure KDB procedures*, must be tested using the SAM phantom defined in IEEE Std 1528-2013.[20] When antennas are near the bottom of a handset and the peak SAR location is located in regions of the SAM phantom where SAR probe access can be limited, the procedures in KDB Publication 648474 D04 must be applied. Other head exposure conditions, for example, in-front-of the face, should be tested using a flat phantom according to the required *published RF exposure KDB procedures*.[21]

4.2.2. Body-worn accessory exposure conditions

a) Devices that support transmission while used with body-worn accessories must be tested for body-worn accessory SAR compliance. SAR evaluation is required for body-worn accessories supplied with the host device. The test configurations must be conservative for supporting the body-worn accessory use conditions expected by users. Body-worn accessories that do not contain metallic or conductive components may be tested according to worst-case exposure configurations, typically according to the smallest *test separation distance* required for the group of body-worn accessories with similar operating and exposure characteristics. All body-worn accessories containing metallic components, either supplied with the product or available as an option from the device manufacturer, must be tested in conjunction with the host device to demonstrate compliance.

b) Body-worn accessory SAR compliance must be based on a single minimum *test separation distance* for all wireless and operating modes applicable to each body-worn accessory used by the host, and according to the relevant voice and/or data mode transmissions and operations. If a body-worn accessory supports voice only operations in its normal and expected use conditions (for example, belt-clips and holsters for cellphones), testing of data mode for body-worn compliance is not required.[22] The voice and data transmission requirements must be determined according to the wireless technologies and operating characteristics of the individual device and must be clearly explained in test reports to support the SAR results.

c) A conservative minimum *test separation distance* for supporting off-the-shelf body-worn accessories that may be acquired by users of consumer handsets should be used to test for body-worn accessory

[18] Influences of the hand holding a handset on the measured head SAR was investigated during the (on-going) revision of IEC 62209-1 in 2014. It was concluded that a different test device holding apparatus or further modification to existing test requirements for handsets are presently unnecessary, but will be reviewed in the future.

[19] The multi-meter mode available in some SAR systems may be used to quickly determine if influences due to test device positioning, field perturbations, or external objects are introducing noticeable SAR variations.

[20] The Commission has initiated a rulemaking to address several RF exposure testing issues relating to cellphones in ET Docket No. 13-84. Further updates to test and compliance requirements will be determined once the final rules are adopted.

[21] Unless specifically authorized through a KDB inquiry, the SAM (head) phantom is generally unacceptable for testing the SAR of other head and body exposure conditions; for example, testing headsets at the SAM phantom ear location is generally unacceptable.

[22] For example, when DTM is not applicable, GPRS and EDGE do not require body-worn accessory SAR testing.

SAR compliance. This distance is determined by the handset manufacturer according to the typical body-worn accessories users may acquire at the time of equipment certification, but not more than 2.5 cm, to enable users to purchase aftermarket body-worn accessories with the required minimum separation.[23] The selected *test separation distance* must be clearly explained in the SAR report to support the body-worn accessory test configurations.[24] Devices that are designed to operate on the body of users using lanyards and straps or without requiring additional body-worn accessories must be tested for SAR compliance using a conservative minimum *test separation distance* $\leq$ 5 mm to support compliance.[25]

d) Specific information must be included in the operating manuals to enable users to select body-worn accessories that meet the minimum *test separation distance* requirements. Users must be fully informed of the operating requirements and restrictions, to the extent that the typical user can easily understand the information, to acquire the required body-worn accessories to maintain compliance. Instructions on how to place and orient a device in body-worn accessories, in accordance with the test results, should also be included in the user instructions. All supported body-worn accessory operating configurations must be clearly disclosed to users, through conspicuous instructions in the user guide and user manual, to ensure unsupported operations are avoided. All body-worn accessories containing metallic components must be tested for compliance and clearly identified in the operating manual. The instructions must inform users to avoid using other body-worn accessories containing metallic components, to ensure RF exposure compliance.

4.2.3. Extremity exposure conditions

Devices that are designed or intended for use on extremities, or mainly operated in extremity only exposure conditions, i.e., hands, wrists, feet and ankles, may require extremity SAR evaluation.[26] When the device also operates in close proximity to the user's body, SAR compliance for the body is also required. The 1-g body and 10-g extremity *SAR Test Exclusion Thresholds* in 4.3 should be applied to determine SAR test requirements. When extremity SAR testing is required, a flat phantom must be used if the exposure condition is more conservative than the actual use conditions; otherwise, a KDB inquiry is required to determine the phantom and test requirements. Body SAR compliance is also tested with a flat phantom. For devices with irregular shapes or form factors that do not conform to a flat phantom, and/or unusual operating configurations and exposure conditions, a KDB inquiry is also required to determine the appropriate SAR measurement procedures. Unless it is specified differently in the *published RF exposure KDB procedures, w*hen simultaneous transmission applies to extremity exposure, the simultaneous transmission SAR test exclusion provisions in 4.3.2 should be applied. When simultaneous

[23] The Commission has initiated a rulemaking in ET Docket No. 13-84 and adopted a *Report & Order* in ET Docket No. 03-137. The *R&O* has discontinued Supplement C to OET Bulletin 65; a maximum (not to exceed) body-worn accessory SAR test separation distance of 2.5 cm may continue to be applied according to procedures in this document. The test and compliance procedures may be updated according to other applicable policy decisions or when ET Docket No. 13-84 is finalized.

[24] The IEC 62209 project team is updating the body-worn accessory SAR measurement procedures for cellphones. Regulatory requirements will take precedence over manufacturer recommendations, followed by the default configuration of either zero or the closest possible test distance.

[25] The test distance must not exceed 5 mm, and must also support compliance for the exposure and use conditions required by the device.

[26] Cellphones (handsets) are not normally designed to be used or operated in extremity only exposure conditions. The maximum output power levels of cellphones, in conjunction with the required head and body SAR test results, generally do not require extremity SAR testing to show compliance.

transmission SAR measurement is required, the enlarged zoom scan and volume scan post-processing procedures in KDB Publication 865664 D01 should be applied.

4.2.4. Transmitters implanted in the body of a user

When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is ≤ 1.0 mW, SAR test exclusion may be applied.[27] The maximum available output power requirement and worst case operating conditions must be supported by power measurement results, based on device design and implementation requirements, and fully justified in a SAR analysis report according to KDB Publication 865664 D02, in lieu of SAR measurement or numerical simulation.

4.3. General SAR test exclusion guidance

4.3.1. Standalone SAR test exclusion considerations

Unless specifically required by the *published RF exposure KDB procedures*, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding *SAR Test Exclusion Threshold* condition(s), listed below, is (are) satisfied. These test exclusion conditions are based on source-based time-averaged maximum conducted output power of the RF channel requiring evaluation, adjusted for tune-up tolerance, and the minimum *test separation distance* required for the exposure conditions.[28] The minimum *test separation distance* defined in 4.1 f) is determined by the smallest distance from the antenna and radiating structures or outer surface of the device, according to the host form factor, exposure conditions and platform requirements, to any part of the body or extremity of a user or bystander. To qualify for SAR test exclusion, the *test separation distances* applied must be fully explained and justified, typically in the SAR measurement or SAR analysis report, by the operating configurations and exposure conditions of the transmitter and applicable host platform requirements, according to the required *published RF exposure KDB procedures*. When no other RF exposure testing or reporting are required, a statement of justification and compliance must be included in the equipment approval, in lieu of the SAR report, to qualify for SAR test exclusion. When required, the device specific conditions described in the other *published RF exposure KDB procedures* must be satisfied before applying these SAR test exclusion provisions; for example, handheld PTT two-way radios, handsets, laptops and tablets, etc.[29]

a) For 100 MHz to 6 GHz and *test separation distances* ≤ 50 mm, the 1-g and 10-g *SAR test exclusion thresholds* are determined by the following:

   [(*max. power of channel, including tune-up tolerance, mW*) / (*min. test separation distance, mm*)] · [$\sqrt{f_{(GHz)}}$] ≤ 3.0 for 1-g SAR, and ≤ 7.5 for 10-g extremity SAR,[30] where

   - $f_{(GHz)}$ is the RF channel transmit frequency in GHz

[27] Maximum conducted and radiated power should both be taken into consideration to establish the worst case aggregate maximum output power.

[28] Test exclusion is applied to the required test channels on a channel by channel basis.

[29] When SAR evaluation is required by the hotspot mode or UMPC mini-tablet procedures, that is, where an antenna is ≤ 2.5 cm from a surface or edge, the *test separation distance* from the phantom to the antenna or device enclosure, as appropriate, should be applied to determine further SAR test exclusion according to the criteria in this document. Do not use the antenna to device surface or edge distance.

[30] This is equivalent to the formula written as: [(*max. power of channel, including tune-up tolerance, mW*)/(60/$\sqrt{f_{(GHz)}}$ mW)]·[20 mm/(*min. test separation distance, mm*)] ≤ 1.0 for 1-g SAR; also see Appendix A for approximate exclusion threshold numerical values at selected frequencies and distances.

- Power and distance are rounded to the nearest mW and mm before calculation[31]
- The result is rounded to one decimal place for comparison
- The values 3.0 and 7.5 are referred to as *numeric thresholds* in step b) below

The test exclusions are applicable only when the minimum *test separation distance* is ≤ 50 mm, and for transmission frequencies between 100 MHz and 6 GHz. When the minimum *test separation distance* is < 5 mm, a distance of 5 mm according to 4.1 f) is applied to determine SAR test exclusion.

b) For 100 MHz to 6 GHz and *test separation distances* > 50 mm, the 1-g and 10-g *SAR test exclusion thresholds* are determined by the following (also illustrated in Appendix B):[32]

1) {[Power allowed at *numeric threshold* for 50 mm in step a)] + [(test separation distance – 50 mm)·($f_{(MHz)}$/150)]} mW, for 100 MHz to 1500 MHz

2) {[Power allowed at *numeric threshold* for 50 mm in step a)] + [(test separation distance – 50 mm)·10]} mW, for > 1500 MHz and ≤ 6 GHz

c) For frequencies below 100 MHz, the following may be considered for SAR test exclusion (also illustrated in Appendix C):[33]

1) For *test separation distances* > 50 mm and < 200 mm, the power threshold at the corresponding test separation distance at 100 MHz in step b) is multiplied by [1 + log(100/$f_{(MHz)}$)]

2) For *test separation distances* ≤ 50 mm, the power threshold determined by the equation in c) 1) for 50 mm and 100 MHz is multiplied by ½

3) SAR measurement procedures are not established below 100 MHz.

When SAR test exclusion cannot be applied, a KDB inquiry is required to determine SAR evaluation requirements for any SAR test results below 100 MHz to be acceptable.[34]

4.3.2. Simultaneous transmission SAR test exclusion considerations

Simultaneous transmission SAR test exclusion is determined for each operating configuration and exposure condition according to the *reported* standalone SAR of each applicable simultaneously transmitting antenna. When the sum of 1-g or 10-g SAR of all simultaneously transmitting antennas in an operating mode and exposure condition combination is within the SAR limit, SAR test exclusion applies to that simultaneous transmission configuration. When the sum is greater than the SAR limit, the SAR to peak location separation ratio procedures described below may be applied to determine if simultaneous transmission SAR test exclusion applies. For the test exclusion to apply, the maximum output power, duty factor, and other applicable parameters used in the standalone SAR tests, must be the same or more conservative than those required for simultaneous transmission. When the maximum output power used for standalone operations is reduced in an operating mode or exposure condition during simultaneous transmission, often due to SAR or other implementation requirements, the standalone SAR tested at the

[31] Unless stated otherwise, the same rounding requirements should be applied to all similar equations in this document.

[32] These are interim SAR test exclusion provisions. More extensive considerations are necessary to address threshold discontinuity issues related to transitioning from SAR to MPE limits at intermediate distances and different frequencies. See *FNPRM* in ET Docket No. 13-84.

[33] See footnote 32.

[34] Certain SAR systems are beginning to support measurements at selected frequency ranges between 5 MHz and 100 MHz; however, tissue dielectric parameters and other measurement technical details remain unavailable. A KDB inquiry is required to determine the SAR measurement requirements on a case-by-case basis for individual circumstances.

higher output power may be applied to determine simultaneous transmission SAR test exclusion. Alternatively, additional standalone SAR at the reduced maximum output power applied for simultaneous transmission may be performed to determine simultaneous transmission SAR test exclusion, according to the sum of 1-g SAR or SAR to peak location separation ratio procedures. The power level of the standalone SAR used to qualify for SAR test exclusion must be clearly explained in the SAR report. When simultaneous transmission SAR test exclusion does not apply, enlarged zoom scan measurements must be performed at the maximum output power required in the power reduction modes for simultaneous transmission, within the tune-up tolerance requirements of all transmitters, for applying the volume scan post-processing procedures.[35]

a) The transmitters and antennas in a device are typically not designed to transmit simultaneously and concurrently across multiple exposure conditions, such as head, body-worn accessories and other next to the body use conditions. The wireless modes and frequency bands supporting simultaneous transmission may also vary for the different exposure conditions. In addition, some exposure conditions may require multiple test positions, such as touch and tilt on the left and right side of the head, or different edges of tablets and phones. As a result, these conditions require simultaneous transmission to be evaluated according to the combinations of wireless modes and frequency bands configured to transmit simultaneously in each applicable exposure condition. In some cases, the different test positions in an exposure condition may be considered collectively to determine SAR test exclusion according to the sum of 1-g or 10-g SAR; for example, if the sum of the highest *reported* SAR of each antenna for the touch and tilt positions on both sides of the head does not exceed the limit. When the sum of SAR considered in this manner does not qualify for test exclusion, the individual test positions of each exposure condition should be considered separately for the sum of 1-g or 10-g SAR test exclusion. For each simultaneous transmission configuration that does not satisfy the sum of SAR test exclusion, SAR to peak location separation ratio should be evaluated to qualify for SAR test exclusion. In all cases, the *reported* standalone SAR should be applied to determine simultaneous transmission SAR test exclusion.

b) When an antenna qualifies for the standalone SAR test exclusion of 4.3.1 and also transmits simultaneously with other antennas, the standalone SAR value must be estimated according to the following to determine the simultaneous transmission SAR test exclusion criteria:[36]

   1) [(*max. power of channel, including tune-up tolerance, mW*) / (*min. test separation distance, mm*)]·[$\sqrt{f_{(GHz)}}/x$] W/kg, for *test separation distances* ≤ 50 mm;

      where x = 7.5 for 1-g SAR and x = 18.75 for 10-g SAR.

   2) 0.4 W/kg for 1-g SAR and 1.0 W/kg for 10-g SAR, when the *test separation distance* is > 50 mm.[37]

   This SAR estimation formula has been considered in conjunction with the *SAR Test Exclusion Thresholds* to result in substantially conservative SAR values of ≤ 0.4 W/kg. When SAR is estimated, the peak SAR location is assumed to be at the feed-point or geometric center of the antenna, whichever provides a smaller antenna separation distance, and this location must be clearly identified in test reports. The estimated SAR is used only to determine simultaneous transmission SAR test exclusion; it should not be reported as the standalone SAR. When SAR is estimated, it must be applied to determine the sum of 1-g SAR test exclusion. When SAR to peak location separation ratio test exclusion is applied, the highest reported SAR for simultaneous transmission can be an estimated

[35] Within the tune-up tolerance, but not more than 2 dB lower than the maximum tune-up tolerance limit.

[36] See footnote 29; when SAR test exclusion is allowed by other *published RF exposure KDB procedures*, such as the 2.5 cm hotspot mode SAR test exclusion for an edge or surface, then estimated SAR is not required to determine simultaneous SAR test exclusion.

[37] Until appropriate estimation criteria can be determined, a conservative estimate of 0.4 W/kg is applied.

standalone SAR if the estimated SAR is the highest among the simultaneously transmitting antennas (see also KDB Publication 690783 D01). For situations where the estimated SAR is overly conservative for certain conditions, the test lab may choose to perform standalone SAR measurements, then use the measured SAR to determine simultaneous transmission SAR test exclusion. Estimated SAR values at selected frequencies, distances, and power levels are illustrated in Appendix D.

c) When the sum of SAR is larger than the limit, SAR test exclusion is determined by the SAR to peak location separation ratio. The simultaneously transmitting antennas in each operating mode and exposure condition combination must be considered one pair at a time to determine the SAR to peak location separation ratio to qualify for test exclusion. The ratio is determined by $(SAR_1 + SAR_2)^{1.5}/R_i$, rounded to two decimal digits, and must be ≤ 0.04 for all antenna pairs in the configuration to qualify for 1-g SAR test exclusion. When 10-g SAR applies, the ratio must be ≤ 0.10. SAR_1 and SAR_2 are the highest *reported* or estimated SAR values for each antenna in the pair, and R_i is the separation distance in mm between the peak SAR locations for the antenna pair. The antennas in all antenna pairs that do not qualify for simultaneous transmission SAR test exclusion must be tested for SAR compliance, according to the enlarged zoom scan and volume scan post-processing procedures in KDB Publication 865664 D01.

d) When standalone SAR is measured, the peak location is determined by the x, y, z coordinates of the extrapolated and interpolated results reported by the zoom scan measurement, or area scan measurement when area scan based 1-g SAR estimation is applicable. For the SAM phantom, the origin of the coordinates for data points reported by SAR systems is typically located at the ear reference point (ERP), on the inside surface of the phantom. This is also referred to as the measurement grid reference point by some systems. When standalone SAR is measured for both antennas in the pair, the peak location separation distance is computed by the square root of $[(x_1-x_2)^2 + (y_1-y_2)^2 + (z_1-z_2)^2]$, where (x_1, y_1, z_1) and (x_2, y_2, z_2) are the coordinates in the area scans or extrapolated peak SAR locations in the zoom scans, as appropriate. Some SAR systems may have provisions to compute this automatically; however, it must be verified that the peak location separation distance is determined according to the correct 1-g peak SAR locations to avoid unintended errors in noisy SAR distributions with scattered peaks.

When standalone test exclusion applies, thus SAR is estimated, the peak location is assumed to be at the feed-point or geometric center of the antenna. Due to curvatures on the SAM phantom, when SAR is estimated for one of the antennas in an antenna pair the measured peak SAR location should be translated onto the test device, to determine the peak location separation for the antenna pair. The ERP location on the phantom is aligned with the ERP location on the handset, with 6 mm separation in the z coordinate due to the ear spacer. A measured peak location can be translated onto the handset, with respect to the ERP location, by ignoring the 6 mm offset in the z coordinate. The assumed peak location of the antenna for estimated SAR can also be determined with respect to the ERP location on the handset. The peak location separation distance is estimated by the x, y coordinates of the peaks, referenced to the ERP location. While flat phantoms are not expected to have these issues, the same peak translation approach should be applied to determine peak location separation. When SAR is estimated for both antennas, the peak location separation should be determined by the closest physical separation of the antennas, according to the feed-point or geometric center of the antennas, whichever is more conservative. The coordinates of the peaks, whether measured or translated, should be clearly identified in the SAR report. When necessary, plots or illustrations should be included to support the distance applied to qualify for SAR test exclusion.

4.4. General SAR test reduction guidance

4.4.1. General SAR test reduction considerations

SAR test reduction procedures may be applied to similar transmission modes of individual wireless technologies based on time-averaged power levels; for example, due to different time slots in TDMA

systems. SAR test reduction procedures cannot be applied based solely on operating power across different wireless transmission modes, exposure conditions, or product implementations. Variations in implementation, design, and operating requirements across transmission modes and configurations can result in different SAR distributions and RF exposure characteristics. For some devices, the applicable SAR test reduction provisions are described separately in the product and technology specific *published RF exposure KDB procedures*. Otherwise, the following may be applied to each test position of an exposure condition in each wireless mode and frequency band.

Testing of other required channels within the operating mode of a frequency band is not required when the *reported* 1-g or 10-g SAR for the mid-band or highest output power channel is:[38]

a) ≤ 0.8 W/kg or 2.0 W/kg, for 1-g or 10-g respectively, when the transmission band is ≤ 100 MHz

b) ≤ 0.6 W/kg or 1.5 W/kg, for 1-g or 10-g respectively, when the transmission band is between 100 MHz and 200 MHz

c) ≤ 0.4 W/kg or 1.0 W/kg, for 1-g or 10-g respectively, when the transmission band is ≥ 200 MHz

4.4.2. Area scan based 1-g SAR estimation

Some SAR systems have the provision to estimate 1-g SAR based on the interpolated and extrapolated results of a normally required complete area scan. When the implementation is based on the specific polynomial fit algorithm as presented at the 29th Bioelectromagnetics Society meeting (2007)[39] and the *estimated 1-g SAR* is ≤ 1.2 W/kg, for measurements ≤ 3 GHz a zoom scan measurement is not required when the following criteria are satisfied. For measurements above 3 GHz, or for SAR systems using similar or equivalent but not the exact algorithm implementations, users should contact the SAR system manufacturer to have them submit a KDB inquiry to determine if such implementations may be applied.

a) The area scan is measured at a distance ≤ 4 mm from the phantom surface and the measurement requirements of KDB Publication 865664 D01 are met.

b) The *estimated 1-g SAR* determined by the area scan for SAR system verification must be within 3% of the 1-g SAR determined by the corresponding zoom scan.[40]

c) When all of the SAR results for each exposure condition in a frequency band and wireless mode are based on *estimated 1-g SAR*, the 1-g SAR for the highest SAR configuration must be determined by a regular zoom scan. When the *estimated 1-g SAR* (fast SAR) of all the test positions required for head SAR measurements (left, right, touch and tilt, etc.) are all less than 0.8 W/kg, all the test positions can be considered as a single exposure condition; a regular zoom scan is then required only for the highest fast SAR configuration among all the test positions. When the estimated 1-g SAR (fast SAR) of any test position is greater than or equal to 0.8 W/kg, that test position should be considered as a separate exposure condition; a regular zoom scan is then required for the highest fast SAR measured for that test position. If the SAR for the remaining test positions are all less than 0.8 W/kg, these other test positions can be grouped together and considered as a single exposure condition. A zoom scan is

[38] IEEE Std 1528-2013 requires the middle channel to be tested first. This generally applies to wireless devices that are designed to operate in technologies with tight tolerances for maximum output power variations across channels in the band. When the maximum output power variation across the required test channels is > ½ dB, instead of the middle channel, the highest output power channel must be used.

[39] Douglas, M.G., Chou, C-K., "Accurate and Fast Estimation of Volumetric SAR from Planar Scans from 30 MHz to 6 GHz," *Bioelectromagnetics Society 29th Annual Meeting*, June 2007. This is referred to as the "*estimated 1-g SAR*" in this document. It is often called the Motorola fast SAR implementation for the early-on linear and subsequent polynomial fit methods. The polynomial fit is the only method that applies to this KDB.

[40] The *area scan based 1-g SAR estimation* does not apply to SAR system verification; zoom scan is required.

required for the highest fast SAR measured among these test positions.

d) When *estimated 1-g SAR* is applied to an exposure condition in a specific frequency band and wireless mode, for the configurations that require zoom scans, the *estimated 1-g SAR* determined by the area scan, and the 1-g SAR determined by the zoom scan must be within 0.10 W/kg of each other.[41] When the zoom scan is measured, the zoom scan 1-g SAR is used to determine compliance. The *estimated 1-g SAR* is compared with the zoom scan 1-g SAR to confirm the validity of the algorithm. When the *estimated 1-g SAR* and zoom scan 1-g SAR differ by more than 0.1 W/kg, a KDB inquiry should be submitted with all SAR distributions and results in the frequency band and wireless mode for that exposure condition to determine if additional zoom scans are required. When the difference is greater than 0.2 W/kg, the *estimated 1-g SAR* can become highly inaccurate. The *estimated 1-g SAR* should not be applied to the exposure condition in that frequency band and wireless mode; therefore regular zoom scans are required.

e) The peak SAR location(s) required by the *published RF exposure KDB procedures*; for example, determining SAR to peak location separation ratios, is distinctly identified by the area scan result and all SAR levels at 1 cm surrounding the peak are ≥ 40% of the peak value.[42]

f) A zoom scan is not required for any other purpose; for example, if the peak SAR location required for simultaneous transmission SAR test exclusion can be determined accurately by the SAR system, or manually, to discriminate between distinctive peaks and scattered noisy SAR distributions from the area scan.

g) There must not be any warning or alert messages due to various measurement concerns identified by the SAR system; for example, noise in measurements, peaks too close to scan boundary, peaks are too sharp, spatial resolution and uncertainty issues, etc.

For occupational exposure, when it is allowed by the applicable *published RF exposure KDB procedures,* the *estimated 1-g SAR* should be ≤ 6.0 W/kg to avoid zoom scan measurements. When supported by the SAR system, the 1-g SAR estimation procedures may be adapted for 10-g SAR measurements.

4.5. SAR evaluation using numerical simulation

SAR simulations based on the FDTD method may be used to demonstrate compliance. When other numerical computation methods are used, in accordance with specific FCC provisions, the equivalent considerations as required for the FDTD method must be applied.[43] Methods from the most recent draft of IEC 62704-1 must be used to perform the SAR simulation and FDTD numerical code validation.[44] The equivalent of IEC 62704-1 must be applied when other numerical methods are used. Any difference in the numerical codes and algorithms, including the gram-averaging requirements, used in the SAR simulations and those required by the IEC draft, must be fully explained in the SAR report. The differences must be

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[41] Published results indicate that the difference in 1-g SAR between those estimated from an area scan and measured by a zoom scan should generally be less than 3% to 5% (< 0.08 W/kg at 1.6 W/kg) for SAR distributions that are applicable for applying this estimation method. The estimation may not be suitable for certain SAR distributions where the peaks are not distinctive, with erratic energy absorption characteristics or at low frequencies; for example, less than 300 MHz to 400 MHz.

[42] The 1 cm margin and 40% can be approximate, provided it can be ensured that the field gradient surrounding the peak is not an issue for the algorithm to accurately estimate the 1-g SAR. When it is unclear if the algorithm is suitable for certain sharp peaks, zoom scan should be performed.

[43] For example, see ET Docket No. 10-166, DA 11-192.

[44] The IEC 62704-1 draft standard supports 30 MHz to 6 GHz; lower and higher frequency simulations require case-by-case consideration through KDB inquiries to apply equivalent concepts and procedures.

demonstrated to be insignificant to ensure that the simulated results are acceptable for demonstrating compliance. While there is no restriction for the types of devices and exposure conditions to apply numerical simulations to demonstrate SAR compliance, there could be difficulties in applying numerical simulation to complex devices and exposure configurations. It may be necessary to discuss with the FCC to determine the appropriate parameters and modeling approaches required to simulate specific devices and anatomical models. The tissue dielectric parameters from the FCC/OET website should be applied to heterogeneous anatomical human models.[45] The head and body tissue dielectric parameters required for SAR measurements should be applied to homogeneous models. Due to certain simplified assumptions required to model complex transmitters, devices, and anatomically-equivalent human models, and also due to the limitations associated with various modeling constraints required for SAR simulation, it is necessary to confirm the validity of transmitter and human models against field strength and/or SAR measurement results in selected SAR test configurations. The details of a transmitter model used in the simulation and its validity must be fully justified and explained in the SAR report. When applicable, comparisons of simulated and measured return loss and field strength results in free-space conditions may also be required. A detailed test report is required, similar to that required for SAR measurements, and in accordance with the FDTD reporting guidelines in KDB Publication 865664 D02. The SAR simulation procedures can be adapted to compute power density distributions for portable devices that operate above 6 GHz and at close proximity to users; however, a KDB inquiry is required to address the simulation and device modeling concerns at higher frequencies.

5. RF EXPOSURE GUIDANCE FOR MODULES AND PERIPHERAL TRANSMITTERS

5.1. RF exposure equipment approval considerations

Modules and peripheral transmitters are approved for either standalone operations only, or for standalone and simultaneous transmission with other transmitters in a host.[46] The transmitters and antennas operating in a host device must remain compliant for the standalone and simultaneous transmission operations required by all host configurations. Whether additional equipment approval is required for separately approved transmitters installed in a host device, or installed in a previously approved host containing integral transmitter(s), generally depends on influences introduced by the newly added transmitter(s) to the existing transmitters, with respect to the host device form factor, transmitter/antenna configurations, and exposure conditions, etc. Preliminary assessment is normally required to determine if Class I or Class II permissive change requirements apply. For example, adding a modular transmitter with its antenna in the display of a laptop computer may have little or no impact to the existing transmitters when antennas are installed sufficiently far apart from each other in the host device. However, if the same transmitter module is incorporated in a mini-tablet or handset, a re-evaluation of the transmitters in the host is typically necessary to determine SAR compliance. The same considerations also apply when adding or substituting equivalent antennas of the same type and gain for a modular transmitter.

Transmitters installed in certain host devices, such as cellphones, cannot be approved as modules as a result of potential RF energy coupling concerns due to the close proximity of transmitters and antennas within the device and to the users. The correct and practical approach is to test such host devices with all transmitters incorporated; therefore, certain complex influences among transmitters can be taken into consideration in the normally required SAR measurements, and are inherently accounted for by the

[45] http://transition.fcc.gov/oet/rfsafety/dielectric.html; a KDB inquiry is required to determine tissue-equivalent dielectric parameters below 10 MHz.

[46] A peripheral transmitter requires a host to support its operations; it cannot operate independently by itself. Peripheral transmitters can be attached to hosts through user accessible external standard interface connections or incorporated internally within the host device.

normal test process. Similarly, when high SAR may be expected for a device due to close proximity between antennas and users, transmitters may not be approved as modules because of difficulties to ensure compliance for all host configurations that may not be easily assessed in advance.

When subsequent equipment approval is required for modules to support additional host and antenna configurations, compliance of the individual transmitters may be addressed through Class II permissive changes submitted by the grantee of a corresponding transmitter to enable it to be incorporated in qualified host devices.[47] Compliance of all transmitters in a host device can also be addressed through a new equipment approval filing submitted by the host device manufacturer, where all transmitters are approved under a new host FCC ID. Alternatively, the manufacturer of the host device, or the transmitter with the highest maximum output power, or the most recently added transmitter that triggers the additional approval requirements, may choose to apply for a change of FCC ID for the transmitter modules that require additional approval, and address all subsequent approval issues under its direct responsibility through Class II permissive changes, to enable the transmitter module to be incorporated in qualified host devices.[48] The host manufacturer may also consider a *modular* and *dedicated host mixed approach*; for example, as described in KDB Publication 616217 D04, to address compliance for transmitters with higher output power and SAR in dedicated host configurations and apply the modular approach to certain low power transmitters that have low SAR or do not require any SAR testing. This also enables the presence of low power transmitters, and associated influences introduced by the hardware, to be taken into consideration during normal SAR testing of the higher output transmitters in the dedicated host without requiring separate testing for the low power transmitters in the host device. The grantee of a dedicated host, and/or the grantees of the individual modular transmitter(s) incorporated in the host are all responsible for coordinating and ensuring the final implementations are compliant.

Modular transmitters are approved according to the operating configurations and exposure conditions tested for compliance to support qualified host device configurations. Unless a transmitter or module is designed to operate in host devices that do not support portable device exposure conditions or simultaneous transmission operations, seeking equipment approval for mobile device exposure conditions or only standalone operations in the initial equipment approval may require subsequent new filings to qualify for other intended or reasonably expected operating and exposure conditions. To avoid subsequent equipment approval requirements and complications, it is highly recommended that the initial applications for equipment authorization for such transmitters take into account all the applicable operating modes. The qualified installation and use conditions must be clearly identified in the equipment approval and OEM integration requirements, including all restrictions. Appropriate grant conditions must be specified, according to the following combinations of operating conditions that are applicable to the individual approval:

a) When a modular transmitter is approved for use in the *mobile exposure host* platform or *portable exposure host* platform, it must be clearly explained in the test reports and equipment certification records that the transmitter is either limited to standalone operations only or allowed for operation in both standalone and simultaneous transmission configurations, for either mobile device only or portable device only exposure conditions. Any restrictions in host platform configurations and operating requirements must also be identified.[49] All grant conditions must be supported by the test results and test exclusion conditions.

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[47] See also KDB Publication 178919 D01, Permissive Change Policies.

[48] Change of ID requires coordination between an original grantee and the third-party applicant.

[49] Standalone use in certain platform configurations may need restriction; for example, the test configurations and results for a modular transmitter may not fully support multiple standalone transmitters that do not transmit simultaneously in a host. Transmitters and antennas in device with small form factors can influence the SAR

b) When a modular transmitter is approved for use in a *mixed mobile and portable exposure host* platform, the standalone and simultaneous transmission operations allowed for the mobile device and/or portable device exposure conditions in qualified hosts and product configurations must be clearly explained in the test reports and equipment certification records. Any restrictions in host platform configurations and operating requirements must also be identified. All grant conditions must be supported by the test results and test exclusion conditions. The *mixed mobile and portable exposure host* platform is required for a mobile or portable modular transmitter to operate in simultaneous transmission conditions with other portable or mobile transmitters in a host.

5.2. SAR evaluation of modules and peripheral transmitters used in portable device exposure conditions for standalone operations

5.2.1. General requirements

Generic modules and peripheral transmitters are approved according to the exposure conditions tested for compliance. Generic modules may be incorporated in specific host platforms, or unknown host configurations that often have unclear exposure conditions. Peripheral transmitters can include USB dongles and internal or external plug-in cards that operate according to standard interface connections. Typical host platforms can include certain consumer electronics products (printers, cameras, etc.), laptop/notebook/netbook and tablet computers, etc. The *SAR Test Exclusion Threshold* condition in 4.3.1 should be applied to streamline test requirements for standalone operations. The *portable device host platform* requirements and operating restrictions described in 5.2.2 are determined according to the highest *reported* SAR to ensure compliance due to variations in host configurations.

5.2.2. SAR test and approval considerations

When the following procedures are applied, in conjunction with the *published RF exposure KDB procedures*, additional SAR evaluation is generally not required to incorporate modules and peripheral transmitters in qualified host platform configurations.

a) When the standalone SAR test exclusion of 4.3.1 applies and no SAR test is required, or the highest *reported* 1-g SAR is ≤ 0.4 W/kg, modules and peripheral transmitters may be approved to operate in qualified host and portable device exposure conditions with no restriction for most host platform configurations.[50] This applies to both OEM installed and user accessible external peripheral transmitters. A *test separation distance* of 5 mm must be applied to determine test exclusion, according to the *SAR Test Exclusion Threshold* requirements. Except for modules with built-in integral antennas embedded within self-contained outer housings where the *test separation distance* may be considered from the outer housing, the antenna to user separation distance should be applied for all other configurations. The separation distance for incorporation into host devices is described in 4.1 f). When SAR measurement is required, a test separation distance ≤ 5 mm must be applied and the energy coupling enhancement test in 5.2.4 is also required.[51] This unrestricted host platform approval approach does not apply when the *reported* 1-g SAR required by the energy coupling enhancement

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characteristics of adjacent transmitters and antennas due to close proximity even when they are not transmitting simultaneously; therefore, the *published RF exposure KDB procedures* for specific host types may have further testing requirements for these types of standalone transmitters and antennas to qualify for collocation in the host. When specific guidance is unavailable, these types of standalone configurations may need to be limited to low SAR conditions or require demonstration of no SAR influence concerns; for example, where the antennas are spaced > 5 cm apart.

[50] See footnote 49 for concerns about incorporating multiple standalone transmitters in small form factor devices.

[51] The 5 mm is a "not to exceed" *test separation distance*; the test distance must be able to support the host device exposure conditions.

test is > 0.45 W/kg or when a *test separation distance* greater than 5 mm is necessary to maintain compliance; for example, through specific installation requirements or restricted use conditions, which must be considered separately in other host platforms. The approval conditions for incorporation into host devices must be clearly identified in the equipment certification and in all required OEM integration and installation instructions.

b) Single and multiple host platform considerations:
   1) When the highest *reported* 1-g SAR is > 0.4 W/kg and ≤ 0.8 W/kg, modules and peripheral transmitters may be approved to operate in multiple host platforms.[52]
   2) When the highest *reported* 1-g SAR is > 0.8 W/kg and ≤ 1.2 W/kg, the equipment approval must be limited to a single host platform.
   3) Each host platform must be tested independently to determine SAR compliance, according to the *published RF exposure KDB procedures* required for the host platform, based on the operating configurations and exposure conditions of the host family attributes and operating requirements. When specific test requirements are unavailable in the *published RF exposure KDB procedures*, the most conservative exposure conditions must be tested for each host platform, according to the operating and exposure characteristics of the host family attributes.[53]
   4) To qualify for multiple host platforms, the modular transmitter may be approved for multiple platforms either in the initial filing or through Class II permissive changes. All subsequent Class II permissive changes must be within the scope of the defined host platform configurations and exposure conditions in the original equipment approval.

c) When the highest *reported* 1-g SAR is > 1.2 W/kg, modules and peripheral transmitters should be limited to operate internally within the dedicated host configurations tested for compliance. It is typically not possible to restrict certain types of peripheral transmitters to a dedicated host, such as USB dongles and external interface plug-in cards with integral antennas that operate through user accessible external interface connections; therefore, transmitter design changes are often necessary for these types of peripheral transmitters to satisfy SAR compliance. Depending on the test configurations and SAR results, when only a few of the *reported* SAR values are > 1.2 W/kg and ≤ 1.4 W/kg, additional user instructions, caution statements or warning labels may be sufficient for incorporating such transmitters internally to the host. However, this may not be the case for user accessible external peripheral transmitters when a large number of the reported SAR results are above 1.2 W/kg; for example, more than 10% to 20%. When the reported SAR is > 1.2 W/kg, a KDB inquiry is required to determine if additional instructions and labeling, or dedicated host testing, are necessary for these situations. For transmitters that are internal to the host, dedicated host testing is required when the SAR is > 1.4 W/kg. Dedicated host testing cannot be applied to user accessible external peripheral transmitters; when the *reported* SAR is > 1.4 W/kg, equipment approval requires a PAG for case-by-case consideration.

5.2.3. Other SAR test considerations

When specific test guidance and provisions are not fully specified in the *published RF exposure KDB procedures* for testing modules and peripheral transmitters, the following general guidance should be used, as applicable.

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[52] When a host platform requires testing, the *published RF exposure KDB procedures* for the platform should be applied to determine if testing in a representative host is required. The host families within the platform should be tested independently when different host family attributes can introduce changes to SAR characteristics, due to varying operating configurations and exposure conditions for which the most conservative exposure conditions are different.

[53] See footnote 52.

a) SAR compliance must be determined according to the minimum *test separation distance* required for all applicable operating configurations of the host platform. The test distance must be fully justified in the SAR report. All required operating restrictions must be clearly explained in test reports to support the test setup and results.

b) When certain components, operating parameters or control functions that manage the operation of the transmitter are not fully contained within the approved module or peripheral transmitter, the SAR characteristics of the transmitter and antenna can be affected by how these external functions are implemented in individual host devices. When operation and control functions are shared or provided by the host device or through other mechanisms, SAR compliance and equipment approval should be limited to the dedicated host device. These types of operations may include certain power reduction and proximity sensor functions implemented or provided by host devices.[54]

c) Peripheral transmitters that operate through user accessible external interface connections must be tested conservatively as required by the *published RF exposure KDB procedures* or according to a minimum *test separation distance* applicable to all operating configurations and exposure conditions required by the host platform. Certain less conservative conditions that do not require testing to show compliance must be fully justified in the SAR report. A *test separation distance* ≤ 5 mm is required for these types of peripheral transmitters to operate in host devices that transmit next to users. A test distance of up to 10 mm may be applied if it is confirmed through prior approval from the FCC that smaller distances are not possible for the normal operation of the host devices in a platform. When a peripheral transmitter, such as a USB dongle, must be connected to the host through an external cable or adapter, a *test separation distance* ≤ 15 mm should be applied to test the required device orientations; provided it can be demonstrated that smaller separation distances are not applicable for normal operations. The same consideration also applies when a cable, adapter, or accessory antenna is available for a peripheral transmitter to offer alternative connection and use conditions.

5.2.4. RF energy coupling enhancement considerations

For transmitters and modules with no host platform restrictions, as described in 5.2.2 a), it is necessary to determine if additional SAR evaluation is required due to RF energy coupling enhancements at increased *test separation distances*. For the highest *reported* SAR of each test configuration, the tip of the SAR probe is positioned at the peak SAR location of the zoom scan, at a distance of half the probe tip diameter, rounded to the nearest mm from the phantom surface. The test device is initially positioned in direct contact with the phantom and subsequently moved away from the phantom in 5 mm increments. At least three repeated single-point SAR (not 1-g SAR) results should be measured for each device position until the measured SAR is < 50% of that measured with the device in contact with the phantom.[55] When there is more than 15% variation in the single-point measurements at each position, additional measurements are required to ensure a representative high range value is recorded. The highest of the single-point SAR values, adjusted for tune-up tolerance should be reported for each position. When the highest measured single-point SAR among all positions is 25% greater than that measured with the device positioned at 5 mm from the phantom, a complete 1-g SAR evaluation is required for that test configuration at the device position producing the highest single-point SAR.

5.2.5. OEM instructions

The operating and exposure characteristics of the host configurations in a platform must be substantially equivalent to the conditions tested and clearly documented in both the equipment authorization filings and

[54] Approval policies for these types of operations in different host platforms may vary due to operating requirements and other RF coupling and exposure concerns; for example, handsets and tablets etc. See also KDB Publication 594280 D01 and D02 for software security requirements.

[55] These single point measurements can generally be configured using the multi-meter or time-sweep modes available in most SAR systems to record the measured results.

all OEM and installation instructions. Detailed OEM integration and installation requirements must be included in the equipment approval filing. These instructions should include guidance for host manufacturers and OEM integrators to provide the specific information required for end users to ensure RF exposure compliance. Grantee responsibilities and third party obligations, to incorporate and use the transmitter in approved host platforms and configurations, must be clearly identified in the instructions. The approved and required antenna configurations in qualified host platform(s), such as separation distances to users and other antennas, and antenna polarization and orientation requirements in different host configurations, must be fully specified in the installation requirements.

5.3. SAR evaluation of modules and peripheral transmitters used in portable exposure conditions for simultaneous transmission operations

The procedures in 4.1 f) are applied to evaluate simultaneous transmission SAR compliance for modules and peripheral transmitters.

6. SAR TEST GUIDANCE FOR UNIQUE HOSTS AND EXPOSURE CONDITIONS

6.1. Handheld push-to-talk (PTT) two-way radios

The operating configurations of handheld PTT two-way radios generally require SAR testing for in-front-of the face and body-worn accessory exposure conditions. A duty factor of 50% should be applied to determine compliance for radios with maximum operating duty factors ≤ 50%.[56] Radios with higher duty factors must apply the maximum duty factor supported by the device to determine compliance. For example, up to 100% duty factor may be required for certain radios that support operator-assisted PSTN calls. A duty factor of 75% may be applied for PTT radios with Bluetooth or voice activated transmission capabilities to avoid the justification required for using a lower duty factor than what is supported by certain features built-in within the radio. When TDMA applies, the time slot inherent duty factor should also be taken into consideration. For PTT radios operating in the 100 MHz to 1 GHz range, according to general population exposure requirements, SAR test exclusion may be applied for in-front-of the face and body-worn accessory exposure conditions, according to the *SAR Test Exclusion Threshold* conditions and duty factor compensated maximum conducted output power.[57] When a body-worn accessory is not supplied with the PTT radio, a *test separation distance* ≤ 10 mm, applicable to the device form factor, must be applied to determine body-worn accessory SAR test exclusion. A *test separation distance* of 25 mm must be applied for in-front-of the face SAR test exclusion and SAR measurements. When body-worn accessory SAR testing is required, the body-worn accessory requirements in 4.2.2 should be applied. PTT two-way radios that support held-to-ear operating mode must also be tested according to the exposure configurations required for handsets in KDB Publication 648474 D04. This generally does not apply to cellphones with PTT options that have already been tested in more conservative configurations in applicable wireless modes for SAR compliance at 100% duty factor. When occupational exposure limits apply, the procedures in KDB Publication 643646 D01 are required.

6.2. Wrist watch and wrist-worn transmitters

Transmitters that are built-in within a wrist watch or similar wrist-worn devices typically operate in speaker mode for voice communication, with the device worn on the wrist and positioned next to the mouth. Next to the mouth exposure requires 1-g SAR and the wrist-worn condition requires 10-g extremity SAR.[58] The 10-g extremity and 1-g SAR test exclusions may be applied to the wrist and face

[56] The 50% duty factor only applies to exposure conditions where the radio operates with a mechanical PTT button.

[57] A KDB inquiry is recommended to confirm SAR test requirements above 1 GHz for PTT two-way radios.

[58] It must be ensured that wrist operations are limited to the wrist only. Operations with a device worn on the arm above the wrist require 1-g SAR compliance. Other use conditions may require additional SAR testing.

exposure conditions. When SAR evaluation is required, next to the mouth use is evaluated with the front of the device positioned at 10 mm from a flat phantom filled with head tissue-equivalent medium. The wrist bands should be strapped together to represent normal use conditions. SAR for wrist exposure is evaluated with the back of the device positioned in direct contact against a flat phantom filled with body tissue-equivalent medium. The wrist bands should be unstrapped and touching the phantom. The space introduced by the watch or wrist bands and the phantom must be representative of actual use conditions; otherwise, if applicable, the neck or a curved head region of the SAM phantom may be used, provided the device positioning and SAR probe access issues have been addressed through a KDB inquiry. When other device positioning and SAR measurement considerations are necessary, a KDB inquiry is also required for the test results to be acceptable; for example, devices with rigid wrist bands or electronic circuitry and/or antenna(s) incorporated in the wrist bands. These test configurations are applicable only to devices that are worn on the wrist and cannot support other use conditions; therefore, the operating restrictions must be fully demonstrated in both the test reports and user manuals.

6.3. Low transmission duty factor devices

For devices that transmit only intermittently in data mode, without any voice support, the time-averaged exposure can be low. When transmissions are sporadic and duty factor is not inherently built-in to the device, source-based time-averaging may not be easily applied. These types of operations may include location trackers, emergency alert responders, point of sales (POS) devices, certain black and white display e-readers, and devices supporting location-based services. SAR measurement is not required when an acceptable worst case or most conservative transmission duty factor is determined and the *SAR Test Exclusion Threshold* conditions are satisfied for the duty factor adjusted maximum output power and minimum *test separation distance* required for all applicable operating configurations. To qualify for SAR test exclusion, the supporting details for determining this type of transmission duty factor, with respect to the design and implementation of the device, operating configurations, and exposure conditions, must be fully documented in a SAR analysis report according to KDB Publication 865664 D02. When SAR evaluation is required to determine compliance, the duty factor established in the SAR analysis may be applied to scale the measured SAR.[59] Voice-mode communication generally does not qualify for low duty factor considerations; however, exceptions may be considered for certain short (e.g., < 30 seconds) and infrequent transmissions.

6.4. After-market accessories

Transmitters and devices are approved for use according to the operating configurations and RF exposure conditions evaluated at the time of equipment approval. For body-worn accessories, the SAR characteristics of the host device can be affected by the device to user *test separation distance*. After market accessories may change the operating characteristics of an approved device. Accessories that contain transmitters may support standalone and/or simultaneous transmission while operating independently or with a host device. Typical host devices may include handsets, music players, and other small consumer electronic devices. Accessories may include various attachments in the form of snap-on sleeves, plug-in components, host device attachments that contain built-in transmitters, and other strap-on, clip-on, or device cover options that may contain certain passive radiating structures or antenna elements.[60]

a) When an accessory is available from the original transmitter manufacturer and does not contain any transmitter, compliance of the host and accessory can be addressed according to Class I or Class II permissive change procedures. The SAR distribution and exposure conditions of the original host approval tested without the newly introduced accessory attached are generally not comparable or equivalent to the configurations tested with the accessory for determining whether there is SAR

[59] Scaling for maximum tune-up tolerance must be considered separately.

[60] See also KDB Publication 648474 D04 for after-market accessories, such as sleeves, used with cellphones.

degradation; therefore additional testing may be required. Accessories provided by the grantee that have potential to influence the SAR characteristics of a host and have never been identified in previous equipment approval filings typically require a Class II permissive change for inclusion in the host equipment authorization.

b) For third-party accessories that do not contain transmitters, the accessory suppliers should consult with the host equipment manufacturer to determine accessory approval options; for example, through a Class I or Class II permissive change submitted by the host grantee. If applicable, a change of FCC ID followed by a Class II permissive change by the third-party accessory supplier may be considered.[61] The assessment required to determine whether Class I or Class II permissive change is applicable may include analysis of the relevant parameters, such as *test separation distance*, metallic content, changes to exposure conditions, etc. and preliminary measurements; for example, measuring SAR for the highest SAR configurations with equivalent SAR distributions and exposure conditions reported in the preceding equipment approval.

c) Separate equipment approval is required for accessories containing transmitter(s) that are available from the host manufacturer or third-party accessory suppliers. If the transmitter in the accessory supports standalone operations, with or without the host equipment, both conditions must be evaluated for RF exposure compliance. Some accessories with built-in transmitters are designed to support host devices that do not contain transmitters; therefore, separate host approval is not required. When simultaneous transmission applies, all transmitter combinations must be addressed for the accessory alone and also with the accessory operating in conjunction with the host equipment. Due to significant variations for the types of accessories and host use conditions, when the test configurations required to show compliance are unclear a KDB inquiry should be submitted to confirm the test requirements.

6.5. Other consumer electronic devices

The exposure conditions of transmitters and modules incorporated in certain consumer electronic devices, such as printers, cameras, and camcorders may vary according to the installation and operating configurations required by the host products. Details of the transmitter and antenna configurations, antenna to user *test separation distance*, device operating configurations, etc., are required to determine SAR test exclusion or SAR measurement requirements for each host product. When SAR tests are required, a KDB inquiry is recommended to confirm the test setup. Unless the transmitter is used in a specific/dedicated host device, the standalone and simultaneous transmission SAR procedures for transmitters and modules should be applied. These must be fully explained in the permissive change documentation or equipment approval filing, whichever is applicable.

7. RF EXPOSURE EVALUATION GUIDANCE FOR MOBILE CONDITIONS

7.1. Transmitters used in mobile device exposure conditions for standalone operations

Devices operating in standalone mobile device exposure conditions may contain a single transmitter or multiple transmitters that do not transmit simultaneously. A minimum *test separation distance* $\geq$ 20 cm is required between the antenna and radiating structures of the device and nearby persons to apply mobile device exposure limits.[62] The distance must be at least 20 cm and fully supported by the operating and installation configurations of the transmitter and its antenna(s), according to the source-based time-averaged maximum power requirements of § 2.1091(d)(2). In cases where cable losses or other

[61] Change of ID requires coordination between an original grantee and the third-party applicant.

[62] When the *test separation distance* is < 20 cm, only SAR limits apply; therefore, it is not acceptable to demonstrate compliance for mobile device exposure conditions with respect to MPE limits for distances less than 20 cm. See also §2.1091(d)(4) to determine if SAR may be required for certain mobile device exposure conditions.

attenuations are applied to determine compliance, the most conservative operating configurations and exposure conditions must be evaluated. The minimum *test separation distance* required for a device to comply with mobile device exposure conditions must be clearly identified in the installation and operating instructions, for all installation and exposure conditions, to enable users and installers to comply with RF exposure requirements. For mobile devices that have the potential to operate in portable device exposure conditions, similar to the configurations described in § 2.1091(d)(4), a KDB inquiry is required to determine the SAR test requirements for demonstrating compliance.

When a device qualifies for the categorical exclusion provision of § 2.1091(c), the minimum *test separation distance* may be estimated, when applicable, by simple calculations according to plane-wave equivalent conditions, to ensure the transmitter and its antenna(s) can operate in manners that meet or exceed the estimated distance.[63] The source-based time-averaged maximum radiated power, according to the maximum antenna gain, must be applied to calculate the field strength and power density required to establish the minimum *test separation distance*. When the estimated *test separation distance* becomes overly conservative and does not support compliance, MPE measurement or computational modeling may be used to determine the required minimum separation distance.[64]

When a device does not qualify for the categorical exclusion provision of § 2.1091(c), routine evaluation using MPE measurement or computational modeling is required to determine compliance. For mobile devices operating in mostly stationary configurations; for example, on walls or ceiling, where a sufficiently large separation distance is inherent in the installation conditions, MPE estimates instead of measurements or numerical simulation may be acceptable with prior FCC confirmation through a KDB inquiry.[65] However, when numerical simulation is used for MPE evaluation, a PAG is required. The following procedures should be considered for mobile devices when guidance is not available in the *published RF exposure KDB procedures*.

a) Except when certain sectors of an antenna are permanently blocked or restricted from access by the nature of the installation conditions, MPE compliance must be assessed in all directions surrounding the antenna and radiating structures of the device. When symmetrical exposure conditions are expected; for example, from an omni-directional antenna, such conditions must be clearly demonstrated in test reports to avoid testing in all directions. RF exposure evaluation equipment with isotropic sensors designed to measure the orthogonal field components is required to determine the total exposure field.[66] Either peak or spatially averaged results may be applied to determine compliance; and with respect to plane-wave equivalent power density limits when ≥ 300 MHz, and electric and magnetic field strength limits when < 300 MHz.

b) Depending on the radiating characteristics of an antenna, for non-directional antennas, the evaluation points in horizontal planes should be along radials extending from the antenna (axis) that are approximately 45° apart. The direction of maximum exposure should be aligned with one of the radials. When the minimum *test separation distance* from the antenna is > 60 cm, the evaluation points should be along radials that are ≤ 30° apart. For exposures in the vertical orientation, spatial averaging is not required in horizontal planes and should not be applied, except when the exposed

[63] The type of calculations used to estimate minimum test separation distance for MPE compliance must be appropriate for the type of antenna(s) and exposure conditions evaluated.

[64] Computational modeling requires PAG.

[65] While simple calculations may be acceptable for estimating the far-field exposure conditions of fixed transmitters (§ 1.1307), the distances estimated with similar calculations for mobile exposure conditions (§ 2.1091) are often not suitable or impractical for the installation conditions required for mobile devices. When routine evaluation is required for mobile exposure conditions, MPE estimates are unacceptable without prior FCC confirmation.

[66] Additional information on test equipment is available in OET Bulletin 65 Edition 97-01.

person is aligned horizontally. Spatial averaging is applied along the longest dimension of a person's body. The evaluation points in the vertical direction or longest dimension, when applicable, should extend at least 10 cm beyond the exposed portions of a person's body or until the evaluated results are < 10% of the MPE limit, for each specific exposure condition with a spatial resolution ≤ 10 cm.[67] For exposures next to the ground or a ground plane, the evaluation points should generally be ≥ 10 cm from the ground. The evaluated points along a person's body should be spatially averaged to determine compliance.

When the antenna of a device transmits in multiple frequency bands, users and bystanders generally would not know which frequency band is transmitting at any specific time. The most restrictive *test separation distance* among all frequency bands is required for the antenna installation to ensure compliance. When specific antennas are not identified in the installation requirements, where users and installers may choose different antennas or antennas with different gain requirements, the maximum antenna gain allowed for each frequency band must be determined according to the most restrictive *test separation distance* required for all of the frequency bands. The required antenna type, radiating characteristics, antenna gain, and the requirement of a unique minimum *test separation distance* must all be fully explained in the operating and installation instructions. Installers should be cautioned that failure to comply with the specific antenna requirements can result in operations that exceed FCC RF exposure limits.

7.2. Transmitters used in mobile device exposure conditions for simultaneous transmission operations

For *mobile exposure host* platform devices to qualify for simultaneous transmission MPE test exclusion, all transmitters and antennas in the host must either be evaluated for MPE compliance, by measurement or computational modeling, or qualify for the standalone MPE test exclusion in 7.1. When modular transmitters are used, the minimum *test separation distance* required for each simultaneously transmitting antenna installed in the host device must satisfy MPE compliance for both standalone and simultaneous transmission operations. When simultaneous transmission MPE test exclusion applies, transmitter modules may be incorporated in host devices according to Class I permissive change requirements to document the test exclusion conditions.[68]

Simultaneous transmission MPE test exclusion applies when the sum of the MPE ratios for all simultaneously transmitting antennas incorporated in a host device is ≤ 1.0, according to calculated/estimated, numerically modeled, or measured field strengths or power density. The MPE ratio of each antenna is determined at the minimum *test separation distance* required by the operating configurations and exposure conditions of the host device, according to the ratio of field strengths or power density to the MPE limit at the test frequency.[69] Either the maximum peak or spatially averaged results from measurements or numerical simulations may be used to determine the MPE ratios. Spatial averaging should not be applied when MPE is estimated using simple calculations based on far-field plane-wave equivalent conditions. The antenna installation and operating requirements for the host device must meet the minimum *test separation distances* required for all antennas, in both standalone and simultaneous transmission operations, to satisfy compliance.

When one of the following test exclusion conditions is satisfied for all combinations of simultaneous

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[67] 1.8 m should be assumed as the longest dimension for a typical standing adult. The average height of persons in other exposure positions should be considered for evaluation.

[68] For simple antenna configurations, the Excel spreadsheet at http://transition.fcc.gov/oet/ea/presentations/files/oct05/MPE-mobile.xls may be used to estimate the MPE compliance boundary.

[69] MPE ratios for all antennas within a single product must be considered, regardless of whether any antennas are separated by 20 cm or more within the product.

transmission configurations, further equipment approval is not required to incorporate transmitter modules in host devices that operate in the *mixed mobile and portable host* platform exposure conditions. The grantee is responsible for documenting this according to Class I permissive change requirements. Antennas that qualify for standalone SAR test exclusion must apply the estimated standalone SAR to determine simultaneous transmission test exclusion.

a) The [∑ of (the highest measured or estimated SAR for each standalone antenna configuration, adjusted for maximum tune-up tolerance) / 1.6 W/kg] + [∑ of MPE ratios] is ≤ 1.0.

b) The SAR to peak location separation ratios of all simultaneously transmitting antenna pairs operating in portable device exposure conditions are all ≤ 0.04, and the [∑ of MPE ratios] is ≤ 1.0.

When RF exposure test exclusion does not apply, simultaneous transmission evaluation is required for mixed mobile device and portable device exposure conditions. For each simultaneous transmission configuration, the sum of the MPE ratios for the simultaneously transmitting antennas operating in mobile device exposure conditions must be determined according to the calculated/estimated, numerically modeled or measured field strengths or power density. For each simultaneous transmission configuration, the enlarged zoom scan measurement and volume scan post-processing procedures in KDB Publication 865664 D01 must be applied to test the simultaneously transmitting antennas operating in portable device exposure conditions. The [(highest measured simultaneous transmission SAR, adjusted for maximum tune-up tolerance) / 1.6 W/kg] + [∑ of MPE ratios] must be ≤ 1.0 for each simultaneous transmission configuration; otherwise, a PAG is required for the FCC to determine compliance on a case-by-case basis, with respect to antenna-to-antenna and antenna-to-user separation, device form factor, operating requirements and exposure conditions, etc.

Change Notice

05/28/2013: 447498 D01 General RF Exposure Guidance v05r01 replaces 447498 D01 General RF Exposure Guidance v05: Relevant comments for 04/05/2013 have been taken into consideration.

02/07/2014: 447498 D01 General RF Exposure Guidance v05r02 replaces 447498 D01 General RF Exposure Guidance v05r01: Added footnote to clarify handling of pre-grant and post-grant measurement uncertainty, updated footnotes 24 and 30, and limiting area scan estimated 1-g SAR procedures to 3 GHz.

10/23/2015: 447498 D01 General RF Exposure Guidance v06 replaces 447498 D01 General RF Exposure Guidance v05r01. Changes include update to reference latest IEEE Std 1528-2013, replacing PBA with PAG, updated certain text and added several footnotes for clarification, changing section numbering format and removing submitting approvals directly to the FCC (per FCC 14-208).

Appendix A

SAR Test Exclusion Thresholds for 100 MHz – 6 GHz and ≤ 50 mm

Approximate SAR Test Exclusion Power Thresholds at Selected Frequencies and Test Separation Distances are illustrated in the following Table. The equation and threshold in 4.3.1 must be applied to determine SAR test exclusion.

MHz	5	10	15	20	25	mm
150	39	77	116	155	194	*SAR Test Exclusion Threshold* (mW)
300	27	55	82	110	137	
450	22	45	67	89	112	
835	16	33	49	66	82	
900	16	32	47	63	79	
1500	12	24	37	49	61	
1900	11	22	33	44	54	
2450	10	19	29	38	48	
3600	8	16	24	32	40	
5200	7	13	20	26	33	
5400	6	13	19	26	32	
5800	6	12	19	25	31	

MHz	30	35	40	45	50	mm
150	232	271	310	349	387	*SAR Test Exclusion Threshold* (mW)
300	164	192	219	246	274	
450	134	157	179	201	224	
835	98	115	131	148	164	
900	95	111	126	142	158	
1500	73	86	98	110	122	
1900	65	76	87	98	109	
2450	57	67	77	86	96	
3600	47	55	63	71	79	
5200	39	46	53	59	66	
5400	39	45	52	58	65	
5800	37	44	50	56	62	

Note: 10-g Extremity SAR Test Exclusion Power Thresholds are 2.5 times higher than the 1-g *SAR Test Exclusion Thresholds* indicated above. These thresholds do not apply, by extrapolation or other means, to occupational exposure limits.

Appendix B

SAR Test Exclusion Thresholds for 100 MHz – 6 GHz and > 50 mm

Approximate SAR test exclusion power thresholds at selected frequencies and test separation distances are illustrated in the following table. The equation and threshold in 4.3.1 must be applied to determine SAR test exclusion.

MHz	50	60	70	80	90	100	110	120	130	140	150	160	170	180	190	mm
100	474	481	487	494	501	507	514	521	527	534	541	547	554	561	567	
150	387	397	407	417	427	437	447	457	467	477	487	497	507	517	527	
300	274	294	314	334	354	374	394	414	434	454	474	494	514	534	554	
450	224	254	284	314	344	374	404	434	464	494	524	554	584	614	644	
835	164	220	275	331	387	442	498	554	609	665	721	776	832	888	943	
900	158	218	278	338	398	458	518	578	638	698	758	818	878	938	998	
1500	122	222	322	422	522	622	722	822	922	1022	1122	1222	1322	1422	1522	mW
1900	109	209	309	409	509	609	709	809	909	1009	1109	1209	1309	1409	1509	
2450	96	196	296	396	496	596	696	796	896	996	1096	1196	1296	1396	1496	
3600	79	179	279	379	479	579	679	779	879	979	1079	1179	1279	1379	1479	
5200	66	166	266	366	466	566	666	766	866	966	1066	1166	1266	1366	1466	
5400	65	165	265	365	465	565	665	765	865	965	1065	1165	1265	1365	1465	
5800	62	162	262	362	462	562	662	762	862	962	1062	1162	1262	1362	1462	

Appendix C

SAR Test Exclusion Thresholds for < 100 MHz and < 200 mm

Approximate SAR test exclusion power thresholds at selected frequencies and test separation distances are illustrated in the following table. The equation and threshold in 4.3.1 must be applied to determine SAR test exclusion.

MHz	< 50	50	60	70	80	90	100	110	120	130	140	150	160	170	180	190	mm
100	237	474	481	487	494	501	507	514	521	527	534	541	547	554	561	567	
50	308	617	625	634	643	651	660	669	677	686	695	703	712	721	729	738	
10	474	948	961	975	988	1001	1015	1028	1041	1055	1068	1081	1095	1108	1121	1135	
1	711	1422	1442	1462	1482	1502	1522	1542	1562	1582	1602	1622	1642	1662	1682	1702	mW
0.1	948	1896	1923	1949	1976	2003	2029	2056	2083	2109	2136	2163	2189	2216	2243	2269	
0.05	1019	2039	2067	2096	2125	2153	2182	2211	2239	2268	2297	2325	2354	2383	2411	2440	
0.01	1185	2370	2403	2437	2470	2503	2537	2570	2603	2637	2670	2703	2737	2770	2803	2837	

Appendix D

Applying Estimated SAR for Simultaneous Transmission SAR Test Exclusion

The following Table illustrates the approximate SAR values estimated at selected frequencies, test separation distances and power levels for determining simultaneous transmission SAR test exclusion when standalone SAR is not required. The equation and threshold in 4.3.2 b) must be applied to determine the estimated SAR.

Estimated SAR higher than 0.4 W/kg do not apply; therefore, they are not indicated								
Red numbers **in "mW" column are the approximate maximum output power at the *SAR Test Exclusion Threshold* for standalone SAR test exclusion. Top row indicates different levels of test device maximum output power in mW**								
MHz	10	25	50	100	150	200	mW	Min. Distance
150	0.1	0.3					39	
300	0.1	0.4					27	
450	0.2						22	
835	0.2						16	
900	0.3						16	
1500	0.3						12	5
1900	0.4						11	(mm)
2450							10	
3600							8	
5100							7	
5400							6	
5800							6	
MHz	10	25	50	100	150	200	mW	
150	0.1	0.1	0.3				77	
300	0.1	0.2	0.4				55	
450	0.1	0.2					45	
835	0.1	0.3					33	
900	0.1	0.3					32	
1500	0.2						24	10
1900	0.2						22	(mm)
2450	0.2						19	
3600	0.3						16	
5100	0.3						13	
5400	0.3						13	
5800	0.3						12	
MHz	10	25	50	100	150	200	mW	
150	0.0	0.1	0.2	0.3			116	
300	0.0	0.1	0.2				82	
450	0.1	0.1	0.3				67	
835	0.1	0.2					49	
900	0.1	0.2					47	
1500	0.1	0.3					37	15
1900	0.1	0.3					33	(mm)
2450	0.1	0.3					29	
3600	0.2						24	
5100	0.2						20	
5400	0.2						19	
5800	0.2						19	

MHz	10	25	50	100	150	200	mW	
150	0.0	0.1	0.1	0.3	0.4		155	
300	0.0	0.1	0.2	0.4			110	
450	0.0	0.1	0.2				89	
835	0.1	0.2	0.3				66	
900	0.1	0.2	0.3				63	
1500	0.1	0.2					49	20
1900	0.1	0.2					44	(mm)
2450	0.1	0.3					38	
3600	0.1	0.3					32	
5100	0.2	0.4					27	
5400	0.2	0.4					26	
5800	0.2						25	
MHz	10	25	50	100	150	200	mW	
150	0.0	0.1	0.1	0.2	0.3		194	
300	0.0	0.1	0.1	0.3			137	
450	0.0	0.1	0.2	0.4			112	
835	0.0	0.1	0.2				82	
900	0.1	0.1	0.3				79	
1500	0.1	0.2	0.3				61	25
1900	0.1	0.2	0.4				54	(mm)
2450	0.1	0.2					48	
3600	0.1	0.3					40	
5100	0.1	0.3					33	
5400	0.1	0.3					32	
5800	0.1	0.3					31	
MHz	10	25	50	100	150	200	mW	
150	0.0	0.0	0.1	0.2	0.3	0.3	232	
300	0.0	0.1	0.1	0.2	0.4		164	
450	0.0	0.1	0.1	0.3			134	
835	0.0	0.1	0.2				98	
900	0.0	0.1	0.2				95	
1500	0.1	0.1	0.3				73	30
1900	0.1	0.2	0.3				65	(mm)
2450	0.1	0.2	0.3				57	
3600	0.1	0.2					47	
5100	0.1	0.3					40	
5400	0.1	0.3					39	
5800	0.1	0.3					37	
MHz	10	25	50	100	150	200	mW	
150	0.0	0.0	0.1	0.1	0.2	0.3	271	
300	0.0	0.1	0.1	0.2	0.3		192	
450	0.0	0.1	0.1	0.3	0.4		157	
835	0.0	0.1	0.2	0.3			115	
900	0.0	0.1	0.2	0.4			111	
1500	0.0	0.1	0.2				86	35
1900	0.1	0.1	0.3				76	(mm)
2450	0.1	0.1	0.3				67	
3600	0.1	0.2	0.4				55	
5100	0.1	0.2					46	
5400	0.1	0.2					45	
5800	0.1	0.2					44	

MHz	10	25	50	100	150	200	mW	
150	0.0	0.0	0.1	0.1	0.2	0.3	310	
300	0.0	0.0	0.1	0.2	0.3	0.4	219	
450	0.0	0.1	0.1	0.2	0.3		179	
835	0.0	0.1	0.2	0.3			131	
900	0.0	0.1	0.2	0.3			126	
1500	0.0	0.1	0.2				98	40
1900	0.0	0.1	0.2				87	(mm)
2450	0.1	0.1	0.3				77	
3600	0.1	0.2	0.3				63	
5100	0.1	0.2	0.4				53	
5400	0.1	0.2	0.4				52	
5800	0.1	0.2					50	
MHz	10	25	50	100	150	200	mW	
150	0.0	0.0	0.1	0.1	0.2	0.2	349	
300	0.0	0.0	0.1	0.2	0.2	0.3	246	
450	0.0	0.0	0.1	0.2	0.3	0.4	201	
835	0.0	0.1	0.1	0.3			148	
900	0.0	0.1	0.1	0.3			142	
1500	0.0	0.1	0.2	0.4			110	45
1900	0.0	0.1	0.2				98	(mm)
2450	0.0	0.1	0.2				86	
3600	0.1	0.1	0.3				71	
5100	0.1	0.2	0.3				60	
5400	0.1	0.2	0.3				58	
5800	0.1	0.2	0.4				56	
MHz	10	25	50	100	150	200	mW	
150	0.0	0.0	0.1	0.1	0.2	0.2	387	
300	0.0	0.0	0.1	0.1	0.2	0.3	274	
450	0.0	0.0	0.1	0.2	0.3	0.4	224	
835	0.0	0.1	0.1	0.2	0.4		164	
900	0.0	0.1	0.1	0.3	0.4		158	
1500	0.0	0.1	0.2	0.3			122	50
1900	0.0	0.1	0.2	0.4			109	(mm)
2450	0.0	0.1	0.2				96	
3600	0.1	0.1	0.3				79	
5100	0.1	0.2	0.3				66	
5400	0.1	0.2	0.3				65	
5800	0.1	0.2	0.3				62	

Italy Supreme Court sentence no. 17438/2012 (Oct. 3, 2102)

[Translated]

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Azar Rashidfarokhi
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2) **Sentence issued by the Supreme Court of Cassation with General Register No. 11864/2010 between INAIL (National Institute for Insurance Against Labor Accidents) and the Cross petitioner stated at the hearing on October 3, 2012 by Judge Maura La Terza.**

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STATE OF ILLINOIS, COUNTY OF COOK

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(Signature of Notary Public)

Deborah F. Martin
(Print Name)

My commission expires on: 5-31-2023.
Notary Seal:

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EXEMPT OF REGISTRATION, TAX STAMPS AND FEES

[coat of arms]

Subject

ITALIAN REPUBLIC

IN THE NAME OF THE ITALIAN PEOPLE

THE SUPREME COURT OF CASSATION

LABOR SECTION

General Register No. 11864/2010
Chron. 17438
Folder

Consisting of the following judges:

Dr. MAURA LA TERZA	- Presiding Judge - Hearing of October 3, 2012
Dr. GIANFRANCO BANDINI	- Reporting Judge - Public hearing
Dr. DANIELA BLASUTTO	- Panel Judge
Dr. CATERINA MAROTTA	- Panel Judge
Dr. IRENE TRICOMI	- Panel Judge

delivered the following

SENTENCE

in Appeal No. 11864-2010 filed by:

INAIL - *Istituto nazionale per l'Assicurazione contro gli Infortuni sul Lavoro* [National Institute for Insurance against Labor Accidents... , represented by interim counsel, whose choice of domicile is in Rome at Via ... , at the law offices of

... , to represent and defend it as assigned in the records;

Petitioner

versus

, whose

domicile of choice is in Rome at Via ... , at the law

offices of

... , to represent and defend him as assigned in the records;

Cross petitioner

against Sentence No. 614/2009 of the COURT OF APPEAL of BRESCIA, filed on December 22, 2009, General Register No. 361/2008;

having heard the case report given by Judge GIANFRANCO BANDINI at the public hearing on October 3, 2012;

having heard Counsel ... ;

having heard Counsel ... ;

having heard on behalf of the Public Prosecutor, the Deputy Public Prosecutor GIANFRANCO SERVELLO,

whose concluding decision was to grant the petition.

TRIAL PROCEEDINGS

In its ruling of December 10-22, 2009, the Court of Appeal of Brescia reversed the lower-court decision and sentenced INAIL to pay to Innocente …, the benefits for recognized occupational disease for an 80% disability.

Mr. ... had filed a court case claiming that, as a consequence of his prolonged work use of cordless and cellular phones at his left ear for five to six hours per day over a period of twelve years, he had developed a severe cancer pathology. The evidence gathered and medical-legal investigations made it possible to confirm, over the course of the proceedings, that grounds did indeed exist both with regard to telephone use for the periods indicated while performing work activities and the actual onset of a "Gasserian ganglion neurinoma" (tumor of the cranial nerves, in particular, the acoustic nerve, and, more rarely, as in the case in question, the trigeminal cranial nerve), with absolutely serious effects despite the therapy administered, including surgery. As seen in the appeal sentence, the existence of these factual elements was not contested during the appeal, since the issue examined by the appeal Judge was the causal link between telephone use and the onset of the disease.

After requesting a new medical-legal opinion, the territorial court considered it necessary to follow the conclusions reached by the court-appointed expert witness at the appeal proceedings, specifically noting the following:

- Mobile phones (cordless) and cell phones operate using electromagnetic waves, and according to the court-appointed expert witness: *"In the literature, studies on brain tumors that report on neurinomas focus on tumors in the area of the acoustic nerve, which is the most common. Since the histotype is the same, it is entirely logical to compare the data to trigeminal neurinoma*". Specifically, it was observed that the two neurinomas are found in the same area of the body, since both the nerves involved are in the cerebellopontine angle, which is a well-defined and limited area of the cranial cavity that is, indeed, within the magnetic field generated by the use of cell and cordless phones.

- The court-appointed expert witness report summarized in a table some of the studies conducted from 2005 to 2009, among which three studies conducted by the ... group showed a significant increase in the risk for neurinoma (risk here meaning risk relating to the degree of association between exposure to a particular risk factor and the onset of a certain disease, calculated as the ratio of the rates of incidence in exposed cases [numerator] to those in unexposed cases [denominator]).

- a 2009 study of the same group had also considered other factors such as age at time of exposure, side of use, and exposure time, and, in the case of acoustic neurinomas, indicated an odds ratio for the use of cordless phones of 1.5, and of 1.7 for cell phones. Taking into account greater use over a period of 10 years, the odds ratios were 1.3 and 1.9, respectively. Odds ratio is defined as the ratio of the frequency with which an event occurs within a group of patients to the frequency with which the same event occurs within a group of control patients. Therefore, if the odds ratio is greater than 1, the probability that the event in question (such as a disease) will occur in a group (such as exposed subjects) is greater in comparison to another group (such as unexposed subjects), while ratios of less than 1 have the opposite meaning.

-A recent review of the International Commission on Non-ionizing Radiation Protection drew attention to the limitations of the epidemiological studies conducted up to that point, concluding that, at the time, no convincing evidence existed on the role played by radiofrequencies in causing tumors, but added that nor had the studies ruled out the association.

- Another authoritative review (Kundi in 2009) had confirmed the suspicions raised by the epidemiological studies about exposure time, and concluded that individual risk was low, but present. Exposure could affect the development of a tumor in various ways: by interacting during the initial induction stage, by changing the rate of development of slow-growing tumors (such as neurinomas) and accelerating their growth, and by preventing potential natural involution.

- An analysis of the literature did not result in a conclusive judgment, but despite all the limitations inherent in these types of studies, an added risk for brain tumors, and for neurinoma in particular, was documented in cases of exposure to radiofrequencies from cordless and cell phones over periods of more than ten years.

- Exposure time was a very significant evaluative element, since the 2006 study had found that exposure over periods of more than ten years resulted in a relative risk of 2.9, which was definitely significant.

- This was, therefore, considered an "*individual*" case that the experts attributed to the "*probabilistic-inductive model*" and to "*weak causality*", but which was, nonetheless, valid in the area of social security.

- According to the court-appointed expert witness, it had to be recognized that radiofrequencies played at least a concausal role in the development of the insured's

tumor, thus representing a conditional probability.

- INAIL's criticism of the studies used by the court-appointed expert witness missed the mark, since the WHO 2000 study that had ruled out negative health effects was based on data that was even more dated. Therefore, it had not taken into account the recently more widespread and frequent use of these devices, and the fact that these types of tumors grow slowly, thus making the 2009 studies more reliable.

- In addition, as pointed out by the expert witness for... , the 2009 studies had not been conducted on a low number of cases, but rather on the total number of cases (679) that had occurred in one year in Italy. In addition, unlike the IARC study, which was co-funded by cell phone manufacturers, the studies cited by the court-appointed expert witness were independent;

- Furthermore, as noted by the expert witness for... , the comparison of the individual risk level calculated by the court-appointed expert witness of 2.9 to the universally recognized risk factor for exposure to ionizing radiation would mean, considering that for the Japanese survivors of atomic explosions in Hiroshima and Nagasaki, the relative risk for "all cancers" combined is estimated to be 1.39 (ranging from a minimum of 1.22 for "uterine and cervical" cancer to a maximum of 4.92 for "leukemia"), that the average cancer risk for ionizing radiation is lower than the risk from exposure to radiofrequencies with respect to intracranial neurinomas, which further supports the real significance of the statements made by the court-appointed expert witness.

- According to the jurisprudence of legality, in cases of uncharted occupational disease, as well as in cases of multifactorial disease, evidence of a work-related cause that affects workers must be evaluated in terms of reasonable certainty, so that, having ruled out the relevance of the mere possibility of occupational origin, the origin

may instead be recognized as having a significant degree of probability. In this respect, the judge must not only allow the insured to submit admissible and legally-established evidence, but must also evaluate the expert witness' probabilistic conclusions on causal links, taking into consideration that the occupational nature of the disease may be inferred with a high degree of probability based on the type of work performed, the nature of the machinery present in the workplace, the duration of the work activity, and the absence of other alternative or concurrent non-occupational factors that could constitute the cause of the disease;

- Therefore, it should have been concluded that the high probability of a causal link had been established as is required under the legislation.

The appeal filed by INAIL against the above sentence of the territorial court is based on two reasons and presented in the pleadings.

The respondent, Innocente …, issued the counter-petition presented in the pleadings.

REASONS FOR DECISION

1. In the first reason, the appellant, INAIL, alleges the violation of Article 3 of Presidential Decree No. 1124/65, noting that in accordance with legal principles based on the jurisprudence of legality, the correct application of the above law requires an assessment, based on epidemiological data and literature that are considered reliable by the scientific community, which establishes that the party appearing before the court developed a disease, with minimum probability, for the specific disease alleged and diagnosed. Therefore, the above causal relationship could not be supported "*by the personal evaluation of the court official, based on a preference for certain*

epidemiological data over others, but must be upheld by a judgment on the reliability of the actual data made by the scientific community." In the case in question, the court-appointed expert witness had focused solely on the findings of the ... group, instead of on those of the scientific community. In addition, the court-appointed expert witness had arbitrarily used the correlation between exposure to radiofrequencies and the acoustic nerve neurinoma, suggested by the Hardell group, to confirm a causal relationship, including with a judgment of conditional probability, between these radiofrequencies and trigeminal neurinoma. It should have been pointed out that when updating the list of diseases approved by Ministerial Decree on December 11, 2009, [Italy's] scientific board for the identification and monitoring of disease, which it is obligated to report in accordance with Article 139 of Presidential Decree No. 1124/65, did not consider it necessary to include cranial nerve tumors caused by exposure to radiofrequencies among the diseases of possible occupational origin.

1.2 Based on the jurisprudence of this Court, in cases of uncharted occupational diseases, as well as multifactorial diseases, the onus of proving an occupational cause, which lies with the worker, must be evaluated in terms of reasonable certainty, in the sense that, having ruled out the relevance of the mere possibility of occupational origin, the origin may instead be recognized as having a significant degree of probability. In this respect, the judge must not only allow the insured to submit admissible and legally established evidence, but must also evaluate the expert witness' probabilistic conclusions on causal links, by using any official measures to gather additional evidence in relation to degree and the workers exposure to risk factors, and also taking into consideration that the occupational nature of the disease may be inferred with a high degree of probability based on the type of work performed, the nature of the machinery present in the workplace, the duration of the work activity,

and the absence of other alternative or concurrent non-occupational factors that could constitute the cause of the disease (see, among others, Cassation Nos. 6434/1994, 5352/2002, 11128/2004, 15080/2009).

The sentence under appeal applied these principles and, based on the considerations made throughout the case records, recognized that the high probability of a causal link had been established.

Therefore, the Court does not recognize the claim of an error in violation of the law, which is based on the alleged erroneous evaluation (by the court-appointed expert witness and the territorial court) of the reliability of the data taken into consideration in order to support this requirement, and therefore, essentially on an error in motive (as argued in the second reason of the appeal).

The reason in question is therefore dismissed.

2. In the second reason, the appellant, INAIL, alleges an error in motive, based on the following assumptions:

- After having shown that the review of the International Commission on Non-ionizing Radiation Protection had concluded that, at the time, no convincing evidence existed on the role played by radiofrequencies in causing cancer, while not ruling out the association, the court-appointed expert witness at the appeal level, with no logical consequence and without providing a reason, had reached the conclusion of the conditional probability of a role for radiofrequencies at least as concausal in the development of the type of cancer that they cause.

- The alleged similarity in the etiopathogenesis of neurinoma of the acoustic nerve and trigeminal neurinoma was ompletely lacking in any scientific foundation, claiming a “widely held view" in medical science that tumors of the same histotype, but in different locations, even if within the same anatomical region, may have different

causes, and that any potential carcinogen that comes into contact with the human body modifies its action according to the tissues that it passes through or that it comes into contact with. In fact, the acoustic nerve and the trigeminal nerve, especially the Gasserian ganglion, are located in different areas in the skull, and different anatomical structures separate them from the outside and from each other.

- The territorial Court did not respond to the observations made by INAIL, including with reference to the fact that an international *"Interphone"* epidemiological study, which was "*in progress",* was being coordinated by IARC [International Agency for Research on Cancer], and that based on the precautionary principle, the WHO had suggested that *"a risk-management policy be applied in situations of 'scientific uncertainty;'"*

- The territorial Court's statement on the reliability of the Hardell group's study, because it was independent in comparison to the *"Interphone"* study, which was co-funded by cell phone manufacturers, should have been considered scientifically irrelevant, since it overlooked that the latter study was funded by the European Union, and managed and coordinated by the IARC (WHO's International Agency for Research on Cancer);

- The territorial Court also did not ask the court-appointed expert witness for clarifications in response to the cited critical comments.

2.1 The jurisprudence of legality has repeatedly stated that in cases that call for a medical-legal court-appointed expert witness, when the judges involved rely on the conclusions of the court official, in order for the alleged errors and omissions of the expert witness to constitute an error in motive of a sentence that may be brought before the Cassation Court, the related errors in formal logic must constitute a clear

deviation from the notions of medical science, or consist of illogical or scientifically incorrect statements. The onus lies with the interested party to provide the related sources, and not merely to make statements about the presentations made by the counterparty, which are inadmissible as criticism of the decision of the judge who had relied on the findings of the expert witness (see among others Cassation, Nos. 16392/2004, 17324/2005, 7049/2007, 18906/2007).

In the case in question, in contesting the alleged similarity in the etiopathogenesis of the acoustic nerve neurinoma and trigeminal neurinoma, the appellant, INAIL, made reference to a *"widely-held view",* not specifying the legally established scientific sources entered in the record, on the basis of which the statements made by the court-appointed expert witness, and contained in the contested sentence, should have been considered scientifically incorrect, and concluded by asking the Court for an evaluation of inadmissibility based on legality.

Also irrelevant is the claim of an alleged lack of logical consequence and reason with regard to the conclusion of the conditional probability of the role that radiofrequencies play even as concausal in the development of the type of cancers that they cause, since the ruling, as was shown throughout the case records, did not rest merely on the conclusions (with obvious differences) that had been reached by the cited review of the International Commission on Non-ionizing Radiation Protection, but rather on the findings of other epidemiological studies conducted on this subject.

Also relevant is the fact that, based on the observations of the court-appointed expert witness, the sentence under appeal had to attribute particular importance to the studies that had taken into consideration other elements, such as the length of the exposure, side of use, and exposure time, given that in the case in question, a causal link had to be established with a specific factual situation characterized by exposure to

radiofrequencies for an extended and continuous period of time (approximately 12 years) for an average of 5 to 6 hours per day, concentrated mainly on the insured's left ear (which, as is plainly evident, describes a situation that is not at all unlike the normal, non-occupational use of a cell phone).

The observation regarding the greater reliability of these studies, because, unlike other studies, they were independent, not having been co-funded by the cell phone manufacturers themselves, constitutes a further logical basis for the conclusions reached.

Nor was it inferred—and much less shown—that the epidemiological research, whose conclusions were taken into particular consideration, originated from working groups that lacked credibility and authority, and as such, were essentially outside the scientific community.

The petitioner maintained that the alleged preponderance should have been attributed to the conclusions of other research groups (whose investigations were understood at the time of the proceedings to still be "in progress"), and further requested a review of the case on the grounds of legality, which was not allowed.

In addition, since the territorial court had found in the considerations already made by the court-appointed expert witness and the expert witness for... sufficient evidence to rebut INAIL's complaints, there was no need to instruct the court-appointed expert witness to provide further clarifications.

Therefore, the second reason for an appeal is also dismissed.

3. In conclusion, the appeal is rejected.

In view of the different findings of the rulings in this case, and of the novelty of the case in question from the perspective of factual distinction, the Court recommends the payment of court costs.

FOR THESE REASONS

the Court dismisses the appeal; payment of court costs.

So decided in Rome on October 3, 2012.

Reporting Judge
(Dr. Gianfranco Bandini)
[signature]

Presiding Judge
(Dr. Maura La Terza)
[signature]

[stamp:] Registered with the Court Clerk
October 12, 2012
[signed:] Virgilio Poleggi
Court Clerk
[round stamp:] Supreme Court of Cassation

Italian Court of Appeals of Turin sentence no. 721/2017 (Dec. 3, 2019)

[Translated]

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Azar Rashidfarokhi
Company Representative

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1) **Sentence issued by the Court of Appeals of Turin in case no. 721/2017 between INAIL (National Institute for Insurance Against Labor Accidents) and Romeo Roberto stated at the hearing held on December 3, 2019 by Judge Rita Mancuso.**

2) **Sentence issued by the Supreme Court of Cassation with General Register No. 11864/2010 between INAIL (National Institute for Insurance Against Labor Accidents) and the Cross petitioner stated at the hearing on October 3, 2012 by Judge Maura La Terza.**

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Signed on October 13, 2020

Azar Rashidfarokhi
Company Representative for Day Translations, Inc.

STATE OF ILLINOIS, COUNTY OF COOK

Subscribed and affirmed, or sworn to, before me on this 13th day of October 2020 by Azar Rashidfarokhi who proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

(Signature of Notary Public)

Deborah F. Martin
(Print Name)

My commission expires on: 5-31-2023.
Notary Seal:

OFFICIAL SEAL
DEBORAH F MARTIN
NOTARY PUBLIC, STATE OF ILLINOIS
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As a translator for Day Translations, Inc., I, Emily Della Fera, declare that I am a bilingual translator who is thoroughly familiar with the English and Italian languages. I have translated the attached document to the best of my knowledge from Italian into English and the English text is an accurate and true translation of the original document presented to the best of my knowledge and belief.

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ITALIAN REPUBLIC

IN THE NAME OF THE ITALIAN POPULATION

THE COURT OF APPEALS OF TURIN

LABOR SECTION

Consisting of:

Dr. Rita MANCUSO	PRESIDING JUDGE
Dr. Caterina BAISI	PANEL JUDGE
Dr. Silvia CASARINO	REPORTING JUDGE

delivered the following

S E N T E N C E

in the labor case registered under no. **721/2017** R.G.L. instituted by: **ISTITUTO NAZIONALE PER L'ASSICURAZIONE CONTRO GLI INFORTUNI SUL LAVORO – I.N.A.I.L.** (National Institute for Insurance against Labor Accidents) -, located in Rome, at Via IV Novembre no. 144, in the person of the pro-tempore Regional Director of Piedmont, represented and defended by general power of attorney to appear in court, Roman Notary from Chivasso on 08/07/2013 rep no. 55082, Register No. 16699 by Attorneys Loretta Clerico and Elia Pagliarulo, and electively domiciled in Turin at Corso Galileo Ferraris no. 1 at the INAIL Regional Attorney's Office.

APPELLANT

AGAINST

ROMEO ROBERTO, residing in Leinì (TO), at Via Lamarmora

no. 11, represented and defended by proxy stated at the bottom of the introductory appeal of the first instance judgement, jointly and severally, by the Attorneys Renato Ambrosio, Stefano Bertone and Chiara Ghibaudo, and electively domiciled at their firm located in Torino, at Via Bertola n. 2

APPELLEE

subject: occupational disease

CONCLUSIONS

For the appellant:

as per the appeal filed on 8/31/2017

For the appellee:

as per the defense statement filed on 10/22/2018

FACTS OF THE CASE

Mr. Roberto Romeo called INAIL before the Court of Ivrea, arguing the professional nature of the right acoustic neurinoma that he is affected by, as a pathology contracted due to the abnormal use of cell phones during the period 1995-2010, when he worked at Telecom s.p.a., and therefore, asked for the defending Institute to be sentenced to pay him the benefit due by law, commensurate with the percentage of disability, indicated as at least 37%.

INAIL contested the plaintiff's request and asked for its rejection. The case was investigated through the examination of some witnesses and with two Court-appointed, expert, medical-legal witness reports (one on the causal link and the other on the amount of permanent disability). With sentence no.

96/2017 published on 04/21/2017, the Court, in acceptance of the appeal, sentenced INAIL to pay the appellant the benefit due with reference to a 23% disability, with the order to reimburse the appellant for the litigation costs and to pay the costs of the administrative Court.

INAIL appeals; the appellee opposes.

New Court-appointed, expert, medical-legal witnesses were arranged (jointly entrusted to Dr. Carolina Marino and Dr. Angelo D'Errico, the former a legal-medical specialist and the latter a specialist in occupational medicine, Medical Director of the Servizio Sovrazonale di Epidemiologia ASL TO3 [Suprazonal Epidemiology Service Local Health Authority TO3]) for the hearing on 12/03/2019. At the conclusion of the discussion, the Court decided the case as per the separate operative part of the judgment.

REASON FOR THE DECISION

The Court accepted the appeal, noting that:

-the claimant, as contact person/coordinator of other Telecom employees, used cell phones in an abnormal manner during the period 1995-2010, as demonstrated by preliminary testimony (Musso, Nani, Bilucaglia witnesses);

-based on this, it should be considered that the claimant, coordinating about fifteen colleagues, in the most conservative assumption, used his phone for at least two and a half hours per day (2 phone calls x 5 minutes x 15 colleagues), and that, at most, he spent more than seven hours on the phone (3 phone calls x 10 minutes x 15 colleagues), to which is added the time spent on the phone to report to superiors and to coordinate with the

institutions' labor manager and with external firms that they collaborated with for labor matters, as well as on the weekend, as confirmed by the witness, Romeo, the claimant's son;

-moreover, at the time, there were no tools to mitigate exposure to radiofrequencies, and this was aggravated by the type of technology used for the first mobile phones (ETACS technology) and by the fact that, often, its use occurred inside an automobile;

-scientific literature is divided on the harmful consequences of cell phone use: on the one hand, the International Agency for Research on Cancer (IARC), part of the World Health Organization (an impartial and authoritative global entity), on 5/31/2011 announced an assessment of exposure to high frequency electromagnetic fields defining them as "possible carcinogens for humans" (category 2B); on the other hand, the Interphone study identifies a 40% higher risk for glioma (a family of tumors to which the tumor that affected the claimant belongs) in individuals who have used cell phones for long periods of time over long periods of time; the only scholars who firmly exclude any causal link between the use of cell phones and brain tumors are Professors Ahlbom and Repacholi, but said authors are in a position of conflict of interest, the first being a consultant for cell phone operators and the second for electrical industries;

-the results achieved by the studies financed by cell phone companies cannot be considered

particularly reliable in consideration of the authors' position of conflict of interest, as ruled by the Supreme Court in sentence no. 17438/2012 in a case relating to another brain tumor (Gasserian ganglion neurinoma);

-the Court-appointed expert witness has ascertained the existence of the causal link;

-therefore, and considering the peculiarities of the specific case (association between a rare tumor and rare exposure in terms of duration and intensity; latency period consistent with the values relating to non-epithelial tumors; the fact that the pathology arose in the right side of the claimant's head, right-handed subject; lack of other plausible explanation of the disease), a causal link, or at least concausal, between technopathy and exposure must be considered proven, based on the "more likely than not" rule;

-permanent disability should be recognized at measurement of 23%, as per the conclusions of the Court-appointed expert witness, not contested by any of the parties.

With the first ground of appeal, INAIL complains that the Court failed to rule on the objection of inadmissibility of the appeal, pursuant to article 152 avail. att. c.p.c. (code of civil procedures) due to the lack of certificate of qualification of requested services. The reason is unfounded, as the Constitutional Court declared the unconstitutionality of this rule with sentence no. 241 dated 11/20/2017.

With the second ground, the Institute maintains that the Court erroneously held that the abnormal cell phone use for 15 years had been proven for work needs, as the testimonies on this point were contradictory. Specifically, according to the testimony of witness Bilucaglia, the duration of the phone calls (and therefore, the exposure to radiofrequencies) was one hour and forty minutes a day, while according to what the witness Musso said, it lasted up to 10 hours, an unlikely duration as it exceeded the length of the workday itself. Furthermore, according to what emerged from the witness investigation, the telephone calls between the appellee and colleagues also took place via a landline phone, and, on the other hand, the son of the appellee was unable to quantify the amount of telephone calls his father received outside of work hours when he was available. Nor on the basis of the witnesses' testimony is it possible to determine the quantity and duration of phone calls inside the car.

Although it cannot be assumed, contrary to what the appellee claims, that the historical circumstances related to the exposure are proven not to have been contested by INAIL pursuant to Articles 115 and 416 paragraph 3 c.p.c., since these facts are not known to the Institute, and therefore it is unable to contest or not, the reason is unfounded.

The preliminary testimony has, in fact, confirmed the remarkable exposure of Mr. Romeo to radiofrequencies for cell phone use during the period 1995-2010.

6

The witness, Musso, colleague of the appellee from 1990 to 2010, reported that the appellee coordinated his activity and that of the other external technicians (of which, the appellee was the hierarchical superior), totaling 15-20 people. The witness stated that he spoke with the appellee every day several times a day, about 2-3 times a day or even more, with the calls lasting 5-10 minutes each.

The witness, Nani, colleague of the respondent from 2000 to 2011, said he had spoken with him often, even a couple of times an hour, and that the phone calls lasted 5 minutes, or even less.

The witness, Bilucaglia, who worked with the appellee from the early 1990s to 1996, stated that the latter coordinated about 10-12 colleagues, and they were in contact 2-3 times per day with phone calls that lasted 5-10 minutes each.

As noted by the Court, the appellee's phone calls also were exchanged with the labor manager, with external companies, and with superiors (see witnesses Musso and Bilucaglia).

Therefore, excluding the maximum values (which are obtained considering the highest number of telephone calls made by the technicians to the appellee and their maximum duration, as indicated by witnesses) and taking into consideration the minimum number and the average number of telephone calls of each technician (2 and 2.5 respectively) for the number of them (15-20 according to Musso, 10-12 according to Bilucaglia), according to the testimonies of Musso and Nani, an exposure is obtained from a minimum of 3.30

7

hours per day (200 minutes) to an average of 5 hours per day (300 minutes), and, according to Bilucaglia's testimony, from a minimum of 1 hour and 40 minutes (100 minutes) to an average of 3 hours and 50 minutes (230 minutes).

Therefore, even with the degree of precision compatible with the fact that this is referring to circumstances which, even after a considerable measure of time, are repeated over a long period, and even with an inevitable degree of variability, in the opinion of the Court, the preliminary framework allows a very high exposure to radiofrequencies to be deemed proven, which should be prudently quantified as approximately 4 hours per day for the entire period referred to in the appeal.

At the time, there were no tools that would allow for the avoidance of direct contact between the cell phone and the face, such as headphones or earphones (see witness Musso, and see witness Nani, according to which the headphones, which were personally purchased by Telecom technicians, started to be used from the beginning of 2000, and , in the same sense, see witness Bilucaglia).

It is true, as noted by INAIL, that the appellee had an office equipped with a landline telephone (see witness Musso) but the witnesses reported that they contacted him on his cell phone, as it was easier to find him, considering that he often traveled around outside of the office, and it was not as easy to reach him on the landline phone, as in this case, it was necessary to go through the switchboard (see witnesses Musso, Nani, Bilucaglia).

Then, ETACS technology emerged (that, as will be said later with reference to the Court-appointed expert witness report carried out to this degree,

8

emitted much more powerful radiofrequencies than those currently used by cell phones) and lasted about 7 years (witness Musso, see also witness Nani, who stated that as of 2000, GSM technology dominated; in the same sense, see witness Bilucaglia).

These circumstances made the exposure, which was already prolonged, particularly intense.

The appellee's son, heard as a witness, then confirmed that his father is right-handed.

With the third ground of appeal, INAIL argues that the Court's conclusion was erroneous with regard to the existence of the etiological link between the disease and occupational exposure to radiofrequencies.

Specifically:

-observes in the first place, that acoustic nerve neurinoma is not a charted disease, so the burden of proving the professional nature that caused the pathology lies with the claimant;

-criticizes the Court-appointed expert witness report, highlighting material errors therein and arguing that they arrive at incorrect conclusions, since said conclusions are not supported by generally accepted scientific law or, at least predominately agreed upon by scientific law;

- deduces that the Court-appointed expert witness, whose conclusions were acknowledged by the Court, was based on the 2013 IARC classification, without adequately accounting for subsequent studies, and did not correctly assess the meaning of the classification

of radiofrequencies in relation to carcinogenic evidence, i.e. as category 2B ("possibly carcinogenic to humans"), and therefore, is the weakest among those used by the Agency to classify agents with positive evidence of carcinogenicity (compared to category 2A, "probably carcinogenic to humans" and category 1, "carcinogenic to humans");

-argues that the Interphone study must be considered reliable, as an independent case-control study, admittedly with only partial funding from cell phone industries and cell phone operators, as must Hardell's studies be considered reliable. These studies and the further ones, albeit with limitations highlighted by the report by Dr. Grandi (researcher of the INAIL Department of Medicine, Epidemiology, Occupational and Environmental Hygiene), produced to this degree, do not support the association between the use of cell phones and the onset of cancer;

-argues that, unlike what is claimed by the Court-appointed expert witness (and shared by the Court), the mechanisms of action of radiofrequencies are not known;

-claims that it is not proven that the appellee (right-handed) always used the cell phone at his right ear;

-argues further that it is incorrect, as the Court did, to infer a cause-effect link from the coexistence of two rare phenomena

(in this case, a rare tumor and rare exposure to radiofrequencies);

-finally, argues that a tumor latency period (according to scientific doctrine, at least 10 years) has been erroneously considered compatible with exposure to radiofrequencies since 1995, considering that the tumor (very slow-growing) was already appearing in December 2009, and, therefore, the individual risk of 1.44 reported instead, by the Court-appointed expert witness, is not applicable.

In light of the Court-appointed expert witness in this instance, this ground for appeal is unfounded.

The Expert Consultants correctly complied with the question formulated by the Court order dated 01/16/2019 in which they were required to carry out expert assessments based on an exposure equal to 4 hours a day (as demonstrated by the preliminary testimony previously mentioned), albeit by mere error. In the assignment report on 03/19/2019, reference was made to the question formulated in the first instance, which did not specify the duration of the exposure. Therefore, in accordance with the exposure times indicated in the question given, a working time of cell phone use was estimated to be 840 hours/year (4 hours x 210 work days) with an estimated overall time of use in the interval of 15 years between 1995 and 2010 equal to 12,600 hours (840 hours/year x 15 years) (see page 51 of Court-appointed expert witness report).

The experts also considered that, as emerged from the investigation, the cell phones the appellee used until the end of 1999 were analog (they used ETACS technology), and then, as of 2000, they were digital (they used GSM technology), highlighting that "*Analog and digital phones based on GSM 2G technology were characterized by much higher radiofrequency (RF) emissions than the current 3G and 4G digital emissions, with RF emission intensity levels nearly two orders of magnitude higher (IARC, 2013) or almost 100 times higher*" (see pages 51-52 of the Court-appointed expert witness report, statement taken from the IARC Monograph (2013) on radiofrequencies, as specified by the Expert Consultants on page 121 of the report).

Given that acoustic neurinoma (or vestibular schwannoma, indicated for brevity by the Court-appointed expert witness as "AN"), a rare and slow-growing, benign brain tumor, is characterized by a latent period from the beginning of exposure to a risk factor until the time of the diagnosis of the illness equal to no less than 10-15 years (see page 54 et seq.), the Expert Consultants cited numerous studies on the subject, acknowledging that most of them are case-control studies which were conducted by the Interphone working group and by the research group from University of Orebro, Sweden led by Professor Hardell, highlighting their characteristics and methodologies, as well as the limitations and criticisms made about them in scientific literature (see page 58 et seq.).

After the Interphone study published in 2010 on the relationship between CP (cell phone) exposure and gliomas and meningiomas (which did not include AN), "*In 2011, the INTERPHONE study group published, in another article, the results of the international case-control study on the use of cell phones and the risks of developing acoustic neurinoma which included more than 1,000 cases and over 2,000 controls enrolled between 2000 and 2004* ***(INTERPHONE, 2011)***.

This study found no difference in previous exposure to CP in cases and controls for "regular use" defined on the basis of at least one call per week.

On the contrary, it observed a ***statistically significant excess of risk of developing AN*** *(almost 3 times in exposed subjects compared to unexposed subjects),* ***in subjects*** *classified in the highest exposure class corresponding to an* ***overall CP use of greater than 1,640 hours*** *(translatable into average exposure duration of 1 hour per day for 4 years, or 2 hours per day for 2 years or half an hour per day for 8 years),"* also stating that the results of the study showed in the class with higher cumulative exposure (overall cell phone use greater than or equal to 1640 hours) a statistically significant association of AN with ipsilateral cell phone use only (OR, or Odds Ratio, = 3.74), so that "*As it is acknowledged that, and also observed by Cardis (****Cardis, 2008)*** *the radiofrequencies (RF)/electromagnetic emissions emitted by portable phones*

13

are primarily absorbed by the side of the head to which the portable telephones are held during use (so-called ***ipsilateral use****) and that with increasing distance of the telephone from the head, the dose of electromagnetic radiation absorbed by tissues decreases abruptly, the finding of a statistically significant association of AN only with the ipsilateral use of CP supports the hypothesis that RF emitted by CPs play a causal role in inducing/developing an AN."*

In reference to one of the appellant's previously reported observations, the Court notes that, not contested and confirmed by the testimony of the appellee's son that the former is right-handed, the fact that one tends to use the telephone, exclusively or almost exclusively, by supporting it to the ear of the "dominant" side of the body, falls within well-known fact, as it is usually found in common experience.

The Expert Consultants then cited the 2011 IARC (International Agency for Research on Cancer) classification, according to which the radiofrequencies are "possibly carcinogenic to humans," an assessment confirmed in the 2013 monograph on non-ionizing radiation, highlighting that in April 2019, an IARC Advisory Group, composed of 29 researchers from 19 countries, included radiofrequencies among the agents for which a carcinogenicity reassessment by the IARC in the period 2020-2024 is considered a priority (IARC Monographs Priorities

14

Group, 2019). Then, they mentioned later studies (see pages 68-69).

In the table drawn up by the Expert Consultants on pages 70 and 71 of the report, the characteristics and results of the epidemiological studies published on the association between the use of CP and AN are reported, relating to the risk of AN estimated for subjects with the highest cumulative exposure in each study in terms of duration of exposure, cumulative duration of exposure time, or the duration of the telephone subscription service, also divided by the ipsilateral and contralateral use with respect to the onset of the tumor.

As noted by the Expert Consultants, the examination of the table shows the majority of the studies show excess risk associated with a long duration of use or cumulative exposure to CP, which in various studies are statistically significant, with higher risks associated with ipsilateral use of CP.

The report highlights *"The fact that in studies in which the risk of AN is estimated based on the number of cumulative hours of use, the category with the highest estimated cumulative exposure (which finds the highest number of hours of 1640 hours in the 2011 INTERPHONE study) has a limit that is at least about 8 times lower than the number of hours (approximately 12,600 hours) of CP use estimated in the case of Mr. Romeo"* (see page 69 Court-appointed expert witness report).

The Expert Consultants then examined the evidence from experimental studies on animals, published after the 2013 IARC monograph, one of which was conducted by the Ramazzini

Institute and the other by the United States National Toxicology Program (NTP). The first observed a statistically significant increase in Schwannoma of cardiac Schwann cells in male rats, although it is estimated in a limited number of cases (3 cases in the highest exposure group vs. 0 cases in the unexposed group), and a non-statistically significant increase in cardiac Schwann cell hyperplasia, which constitutes a pre-tumor lesion, in both sexes (Falcioni et al., 2018); and the second also showed, in male rats, an increased number of cases of cardiac Schwannoma, compared to unexposed male rats, which was statistically significant for both CDMA radiofrequency exposure (3 cases in the intermediate exposure group, 6 cases in the group with the highest exposure, and 0 cases among the non-exposed) and GSM exposure (5 cases in the most exposed group and 0 cases among the non-exposed) (NTP, 2018).

The Expert Consultants specified that "*cardiac Schwannomas are of the same histological type as acoustic nerve neurinomas (which, in fact, are also called vestibular Schwannomas), which supports a causal relationship between radiofrequency exposure and incidence of AN"* (see Court-appointed expert witness report page 76).

Based on these elements, the Expert Consultants concluded that *"In the specific case in question, the risk deriving from the professional use of cell phones is definitely aggravated primarily in relation to the long*

period of exposure (15 years) and the high intensity of exposure, the latter due both to the type of cellular telephone devices used (ETACS and then, GSM 2G, with emissions levels close to 100 times higher with respect to modern cell phones) and to the high number of hours of cell phone use (with an average exposure of 840 hours/year, resulting in overall exposure in 15 years estimated to be on the order of 12,600 hours).

Therefore, also in light of the results of the most recent animal studies conducted by the NTP and the Ramazzini Institute (that show an excess of tumors of the same histological type as the AN, even if elsewhere) and the recent indications of the IARC Advisory Group on the need for a priority reassessment by the IARC of the carcinogenicity of radiofrequencies, considering that the results of the epidemiological studies available, which, although not entirely concordant, still frequently show an excess of cases of AN in the presence of prolonged exposure or intense exposure, ***it is believed that, in this specific case in question, with a criterion of high logical probability, an etiological link can be assumed between the prolonged and conspicuous occupational exposure to radiofrequencies emitted by cell phones and the disease reported by the expert to INAIL (neurinoma of the right eighth cranial nerve)"*** (see preliminary conclusions page 77-78, reiterated on pages 123-124 in the conclusions and answers to questions).

17

The conclusions are based on an accurate and up-to-date examination of scientific literature sources, applied to the peculiarities of this specific case (for quantity and duration of exposure), in the absence of alternative risk factors, according to probabilistic certainty standards ("more likely than not").

With respect to the conclusions of the Expert Consultants, the INAIL Consultants made detailed observations (reported on pages 79-80 of the report), while the defendants of the appellee underlined the position of conflict of interest of some authors of studies who denied the carcinogenicity of radiofrequencies (see pages 84-97 expert witness report), in particular, in the context of the literature cited by INAIL (see pages 94-95).

The Court considers that the Expert Consultants have provided exhaustive answers regarding the observations of the Consultants of the appealing party.

Particularly:

1) the data relating to the exposure on which the Expert Consultants relied is not, as claimed by the INAIL Consultants, taken *"substantially from the patient history information reported by the insured"* but rather, as already observed, is the subject of the question formulated by the Court with reference to the circumstances proven by the primary testimony already described above;

2) with reference to criticisms on reliability of the studies according to which there is an etiological link between exposure to

radiofrequencies and the acoustic neurinoma, the Expert Consultants made the following detailed replies:

a) with respect to the possible distortions (*"bias"*), the Expert Consultants illustrated the differences between case-control studies and cohort studies, specifying that, in the case in question, the literature is almost entirely made up of case-control studies. In this type of study (unlike cohort studies, which yield the ratio between the incidence of the disease in the population exposed to the risk factor and the incidence of the same disease in non-exposed populations), the relative risk (RR) is approximated by another risk indicator, namely the Odds Ratio (OR), which is calculated on the basis of the ratio between the frequency of exposure to the risk factor among (sick) cases compared to the frequency of exposure to the risk factor between controls (not sick).

This makes non-differential misclassifications (affecting both cases and controls to the same extent) possible, which, as highlighted by the Expert Consultants, always results in an underestimation of the risk compared to the real risk of disease due to exposure, and the most serious threat to the validity of the results is constituted by a form of differential misclassification of the exposure called "*recall bias*," due to the possibility

that subjects suffering from tumor disease search in their memory for data relating to their previous exposure to possible health risk factors that may have caused this disease.

However, the results of the available studies (the study by Vrijheid et al., 2009, the study by Aydin et al., 2011, and the study of Petterson et al., 2015) indicate that studies on CP exposure and the risk of AN have been affected by a differential misclassification of exposure to RF by CP, such as to overestimate the exposure between cases compared to controls and, therefore, a consequent overestimation of the risk of AN associated with exposure to RF from CP. On the contrary, both the results of these studies and those of other studies that evaluated the validity of exposure to "self-reported" CP in healthy subjects (i.e. reported by the same subjects included in the study and detected by means of a questionnaire or interview administered to them) indicate the presence of a strong non-differential misclassification of exposure (Samkange-Zeeb et al., 2004; Toledano et al., 2014; Vanden Abeele et al., 2013), with consequent underestimation of the strength of association between CP exposure and the risk of AN compared to the real risk, so that the risk estimates (OR) obtained in the different studies would be highly underestimated and the real risk of developing AN would be much higher than observed in the studies themselves (see pages 99-103 Court-appointed expert witness report);

b) also, with regard to the ipsilateral nature of cell phone use with respect to the side of tumor appearance, the available studies (Shimizu and Yamaguchi, 2012) highlight the possibility of a strong, non-differential misclassification, with consequent underestimation (see page 103 of the Court-appointed expert witness report);

c) unlike what was claimed by the INAIL consultants, a dose-response effect, i.e. a significant increase in the risk of developing tumor disease (AN) as the cumulative dose of exposure to RF from CP increases, is present in the results of the pooled analysis by Hardell et al. (2013), as shown in the table on p. 104 of the report, which shows a progressively increasing risk of AN associated with the use of cell phones as the cumulative dose of exposure to CP increases (calculated based on the hours of CP use): see pages 103-105 of the Court-appointed expert witness report;

d) a possible reason for the lack of a dose-response effect in the Interphone study (2011) and in other studies is that the cumulative exposure categories used were too low. For example, in the Interphone study, the lower limit for the highest cumulative exposure category was set at only 1,640 hours of CP use, corresponding to less than half an hour a day for 10 years. As noted in the expert report, an exposure dose below this limit may not be sufficient to determine the development of AN (see page 105 of the Court-appointed expert witness report);

Furthermore, it is an exposure dose, as emerges from the report, that is absolutely not comparable with the massive and prolonged exposure to radiofrequencies suffered by the respondent for 15 years;

e) the statement by INAIL Consultants, that hearing impaired subjects, who have hearing aids that they use daily for the entire day with an attached Bluetooth function have never found cases of acoustic neurinomas is not supported by any bibliographic reference (see page 107 of the Court-appointed expert witness report);

f) contrary to what was claimed by the INAIL Consultants, the pathology trend for which it is causing (schwannoma of the VIII cranial nerve) shows an increase of this disease over the last few decades, coinciding with the spread of cell phones. The Expert Consultants indicated the various studies on the issue on pages 55-57 of the report, noting that, according to some of them, the increase in incidence of the disease would be attributable to the improvement of instrumental techniques – based on the diffusion of new technologies such as CT and MRI – used to diagnose this tumor; but noting, however, that studies based on the most recent data show a further increase in the incidence of AN, also referring to periods in which the diffusion of the best diagnostic tools for these tumors had already occurred (Kleijwegt et al., 2016: increase in the incidence of AN in the Leyden region by more than 3 times in a

time span of 11 years between 2001 and 2012; Marinelli et al., 2018: an increase in the incidence of AN in Minnesota, USA, more than 2 times in a time span of 11 years between 1995 and 2016; also in the USA, the Central Brain Tumor Registry, CBTRUS, published an annual report from 2007 to 2016 with data recorded from 2004 to 2013 that show a doubling of the annual incidence of AN: from 0.88 to 1.73 x 100,000). Page 108 of the report recalled Danish Tumor Registry data that show an increase in incidence of brain tumors between 2001 and 2010, with an increase of 40% among men and 29% among women (Sundhedsstyrelsen, 2010).

Therefore, the conclusion of the Expert Consultants that it is unlikely the increase in the incidence of AN is solely attributable to the possibility to get more diagnoses of AN - deriving from the refinement of diagnostic methods of said tumor or even from greater accessibility of the population to health facilities - is acceptable.

3) With reference to the NTP and the Ramazzini Institute studies, on the critical observations of their scientific validity by INAIL Consultants, also through reference to the very recent article published by the International Commission on Non-ionizing Radiation Protection (ICNIRP) in Health Physics, Expert Consultants (see pages 108-113 of the report) have exhaustively repeated that:

- these are the largest experimental animal studies conducted so far and are characterized by high standardization of research protocols and high quality of the methods used;
- the main purpose of conducting experimental studies on tumors in animals is to evaluate whether or not exposure to a suspected carcinogen causes excess tumors in the groups of exposed animals. Therefore, the fact that different exposure times and modalities can be envisaged for the animals under study compared to those of humans (for rodents, unlike for humans, "total body" and for the whole life), does not make the study results less valid.

Furthermore, with reference to the observation of the INAIL defense during the oral debate about the unreliability of these studies as they were not carried out on humans, the Court considers the reply of the Expert Consultants to be exhaustive and acceptable (also through reference to sources of scientific literature on the NTP study) according to which the rational criterion for conducting carcinogenicity studies in animal models *"is based on experimental data showing that every agent that is known to cause cancer in humans has been shown to be carcinogenic in animals when adequately tested (IARC, 2006) and that almost one-third of human carcinogens were identified after carcinogenic effects were found in well-conducted animal studies (Huff, 1993). ... There is no reason to believe that a physical agent such as RFR would affect animal tissue but not human tissue"* (Melnick, 2019, cited

on pages 76-77 and 109 of the report). Experiments on the carcinogenicity of agents or substances are usually carried out on animals, such as rodents, that present elements of similarities with humans, so that the scientific value of the results of the study is not prejudicially negated;

- the fact that excess tumors were only found in rats (and almost exclusively in males) does not affect the validity of the study, considering that cardiac schwannoma occurs in different varieties of rat strains (and more frequently in males), but has never been seen in mice;

- notwithstanding, in the Ramazzini Institute study, the rats' exposure occurred at the maximum dose tested, the specific absorption rate resulting for the exposure was just above the maximum limit for irradiation to the whole body for humans. Meanwhile, as for the NTP study, although the exposure dose is much higher than the maximum allowable exposure limit for irradiation to the whole body for humans, the dose absorbed locally is only a small part of the dose administered to the whole body, and, particularly for the brain, the absorbed dose was estimated at about 10% of the total dose administered to the whole body;

- the number of cases of tumors found in the animals is statistically significant in the NTP study: 6 cases in the group with the highest exposure to CDMA RF and 5 cases in the group with the highest exposure to GSM RF, while no cases were verified in the unexposed group. In the Ramazzini Institute

study, 3 cases were observed in the highest exposure group and none in the unexposed group;

-with regard to the different locations of the schwannomas found in rats exposed in the NTP and Ramazzini Institute studies (located in the heart instead of in the brain), it seems probable that the irradiation modality of the animals influenced this result, in how much the administration of RF was addressed to the whole body and not concentrated to only the head of the experimental animals, as is the case for exposure to RF in CP users;

- cardiac schwannomas are of the same histological type as acoustic nerve neurinomas (which, in fact, are also called vestibular schwannomas), which supports a causal relationship between radiofrequency exposure and the incidence of AN. Therefore, the fact that the ANs are benign tumors, as opposed to the malignant cardiac schwannomas observed in the rats from the NTP and Ramazzini Institute studies, appears irrelevant, considering that these studies show that RF exposure can lead to a neoplastic transformation of the Schwann cells, a process both benign and malignant tumors have in common;

- the NTP study concluded by stating that the results demonstrate clear evidence of carcinogenic activity of RF (NTP, 2018);

- carrying out multiple comparisons in the analyses conducted in both the NTP and Ramazzini Institute studies certainly increased the risk of spurious associations occurring in these two studies, but the probability that three independent analyses found a significant increase in developing tumors of the same histological type and in the same anatomical site only by chance is very low, which unequivocally support the carcinogenic effect of RF, even considering the many comparisons made in analyses;
- the presence of a carcinogenic effect is also supported by the observation of a significant increase in DNA damage, evaluated with the Comet assay method by means of the presence of DNA breaks in various organs, especially in the brain, in both rats and mice (Wyde, 2016);
- unlike what was claimed by the INAIL Consultants, the analyses were conducted "blindly" (see Melnick's 2009 article in response to the ICNIRP's criticism regarding the NTP study);

4) Regarding the reason why the IARC Advisory Group has included radiofrequencies among the agents for which a carcinogenicity reassessment by IARC in the period 2020-2024 is considered a priority (according to the INAIL Consultants, not for any particularly alarming reasons, but as a re-evaluation falling within the normal procedures for periodic updating of the assessments of carcinogenic evidence promoted by the Agency), the table shown in the article is transcribed in the expert report,

which shows that non-ionizing radiations (radiofrequencies) are among the agents for which an urgent ("high priority") reassessment of carcinogenicity for humans is recommended, an indication, specified in the table itself, motivated by the fact that the new evidence deriving from biological and mechanistic tests *"requires a re-evaluation of the classification."* In the Advisory Group article, it is also specified that the priority for the reassessment was assigned on the basis of evidence on human exposure and on the basis of the degree of evidence available to assess carcinogenicity (see pages 113-115 of the Court-appointed expert witness report);

5) As for the INAIL Consultants' observations about the incompatibility of the evolution of the appellee's pathology (since the tumor was already 2.6 cm in size in 2010 compared to a growth rate of 1.5 mm per year) and the latency periods of the same (over 15-20 years, not less than 10-15 years), the Expert Consultants observed that, according to the author quoted by the INAIL Consultants (Dr. P. Ferroli, Besta Institute of Milan) the tumor's growth rate of about 1.5 mm per year refers to about 75% of acoustic neurinomas, while a quarter of them tend to grow more rapidly and in a more aggressive way (see page 116 of the Court-appointed expert witness report). Additionally, the Expert Consultants, on pages 116-117 of the report, cited extensive scientific literature in which the growth rates of acoustic neurinoma are quite variable. Specifically, in the case of AN characterized by cystic and hemorrhagic

phenomena (such as that of the appellee), growth rates of over 4 mm/year were observed (Paldor et al., 2016), and, in the Paldor review, some case reports are also cited in which cases of AN with growth rates up to 25 mm/year have been described (Fayad et al, 2014).

The conclusion on the point of the Expert Consultants, therefore, appears to be shared, according to which *"AN growth rates observed in the scientific literature, the presence in the case in question of cystic-necrotic phenomena (also cited by INAIL Court-appointed expert witnesses) and the long period between the first exposure and the AN diagnosis (15 years) are certainly not suitable elements to justify an exclusion of the causal link between exposure to RF from CP and the onset of AN, as claimed by the INAIL Court-appointed expert witnesses.*

On the contrary, this data represents elements absolutely compatible with the existence of the finding of an AN with a size of 2.6 cm at the time of diagnosis in a subject exposed to RF from CP for 15 years in the case in question" (see page 117).

6) Therefore, considering the exposure period of the appellee to radiofrequencies (from 1995 to 2010, the year in which he was diagnosed with AN), the time elapsed between the start of exposure and the appearance of the tumor (equal to 15 years, and not at 4 years as claimed by the INAIL Consultants) is absolutely compatible with the induction and development of AN on the basis of literature data, also considering 5 years for tumor initiation and 10 years for its development.

In addition, unlike what was claimed by the appellant's defense during the oral debate, there is no contradiction between the Expert Consultants' arguments on pages 115-118 regarding the latency of the disease, its development and the size of the tumor at the time of diagnosis in 2010 (2.6 cm), and what is written on pages 57-58 of the report on the latency period recognized in the scientific literature (at least 10-15 years), with the Expert Consultants being motivated on the compatibility between the latency period of the disease and the size of the tumor, mentioning (unlike the INAIL Consultants) copious scientific literature on the extreme variability of the average tumor growth, which also recorded cases of maximum values of 17 mm/year and even up to 25 mm/year (see pages 116-117 of the Court-appointed expert witness report).

7) There is no contradiction between the statement of the Expert Consultants (see note 25 on page 70 of the report) that "*It, therefore, appears unlikely that the possible effects of CP use on the incidence of ANs can be seen, at least on the data up to 2010, given the relatively recent spread of CP and the long induction period of these tumors*" and the statement of the existence of the etiological link in the present case, since the above sentence clearly refers to the fact that it seems unlikely that any effects of the use of cell phones could be seen in the epidemiological studies, since in the populations examined by these studies, the beginning of the exposure, for most of the subjects, was too recent, while in the case

in question, the appellee's exposure started in 1995, or 15 years prior to the diagnosis of the tumor (AN) and in a historical period in which CP were still not widespread, for the most part, in European Countries (see pages 118-119 of the Court-appointed expert witness report).

The Expert Consultants have therefore recognized the causal link by correctly taking into consideration the actual exposure of the appellee to radiofrequencies, which, due to its peculiarities (duration and intensity resulting from the abnormal use of the cell phone), has characteristics completely different from those averages found in general by the population in the period for which it is the cause;

8) regarding the INAIL Consultants' conclusions, which, in order to exclude the causal link, refer to the ISS document, ISTISAN 19/11 report, the Expert Consultants have exhaustively replied that,

"*the ISTISAN report on RF and tumors has been criticized by the Doctors for the Environment (ISDE, acronym for International Society of Doctors for the Environment) for various reasons (Di Ciaula, 2019), including: the selection of studies included in the meta-analyses presented; the interpretation of the associations observed between RF and intracranial tumors; the inappropriate use of data on the trend in incidence of brain tumors to refute the association between RF and brain tumors; not having taken into account in their evaluation the results of recent experimental studies on animals,*

…, that showed carcinogenic effects on rats (NTP, 2018; Falcioni et al., 2018) and, above all, for not having

31

obtained the declared uncertainty about the effects associated with intense and prolonged use of CP with more stringent recommendations on RF exposure limits, in particular for children and adolescents, who may be more susceptible to these effects (Di Ciaula, 2019) (see page 119 of the Court-appointed expert witness report).

The Expert Consultants then mentioned the report by ANSES (French National Agency for Food, Environmental, and Occupational Health and Safety) on the effects of waves emitted by cell phones on health, which concludes by pointing out that the scientific studies published to date do not allow to exclude the appearance of biological effects for humans beyond certain thresholds of RF exposure from CP, also highlighting that 76% of cell phones examined emit radiofrequencies higher than the maximum limit recommended by the ICNIRP for head and trunk exposure (see pages 119-121 of the Court-appointed expert witness report).

In the opinion of the Court, the Expert Consultants replied point by point to the observations of the INAIL Consultants, mentioning copious scientific literature in support of their arguments, and providing, in conclusion, solid elements to affirm a causal role between the appellee's exposure to cell phone radiofrequencies and the pathology which it is causing.

The epidemiological data, the results of animal experiments (not contradicted, at present, by other experiments of the same type), the duration and intensity of exposure (absolutely peculiar for their abnormality), which assume

particular importance considering the ascertained - at a scientific level - dose-response relationship between exposure to radiofrequencies from cell phones and the risk of acoustic neurinoma, together with the lack of another factor that may have caused the disease, assessed as a whole, allow us to believe that, in this specific case, there is a scientific law of coverage that supports the affirmation of the causal link according to probabilistic criteria ("more likely than not").

In fact, much of the scientific literature that excludes the carcinogenicity of exposure to radiofrequencies, or that at least maintains that the researches reached opposite conclusions, cannot be considered conclusive, as also highlighted by the Expert Consultants commenting on the observations of the defense of the appellee (reported on pages 84-97 of the report), is in a position of conflict of interest, however, not always declared: see in particular, on page 94 of the report, the observation of the defendant's defense (in no way contested by the counterparty) that the authors of the studies indicated by INAIL, listed by name, are members of ICNIRP and/or SCENIHR, which have received industry funding directly or indirectly.

In this regard, the Expert Consultants observed: *"Furthermore, in light of the extensive documentation on conflicts of interest of various researchers involved in the INTERPHONE study, also produced by the appellant's consultants, it is believed that less weight should be given to the studies published by*

authors who have not declared the existence of conflicts of interest and that greater weight should be given to the results of studies conducted by researchers free from such conflicts, such as studies carried out by Hardell and collaborators.

In the case in question, conflict of interest situations can arise with respect to the evaluation of the health effects of RF, for example, those cases in which the author of the study has carried out consultancy for the telephone industry or has received funding from the telephone industry to conduct studies or (as also established by the Karolinska Institutet of Stockholm, in relation to the complaint filed against Professor Ahlbom, then dismissed from the presidency of the IARC working group on RF precisely because of his membership of the ICNIRP) if the author himself is a member of the ICNIRP (International Commission on Non-Ionizing Radiation Protection). In fact, ***ICNIRP*** *is a private organization, whose RF guidelines have great economic and strategic importance for the telecommunications industry, with which several ICNIRP members have links through consultancy relationships ... Apart from possible links with industry, it is clear that ICNIRP members should refrain from evaluating the health effect of RF levels that ICNIRP itself has already declared safe and, therefore, not harmful to health (****Hardell, 2017****)"* (see page 107 of the report).

34

The Expert Consultants' approach is entirely acceptable, it being evident that the investigation and the conclusions by independent authors give greater guarantees of reliability than those commissioned, managed, or financed, at least in part, by subjects interested in the outcome of studies.

The extensive scientific literature cited and applied by the Expert Consultants, who are completely independent, must therefore be considered reliable, as well as the conclusions, at an epidemiological level, which they have reached.

Moreover, precisely in a dispute against INAIL relating to occupational disease (intracranial tumor) due to exposure to radiofrequencies from cell phones, the Supreme Court considered that *"The further emphasis on the greater reliability of these studies, given their position of independence, i.e. for not having been co-financed by the cell phone manufacturers, unlike others, constitutes a further and not illogical basis of the accepted conclusions*" (see Court of Cassation 10/12/2012 no. 17438).

Since this is an uncharted occupational disease with multifactorial etiology, the proof of the occupational cause, undoubtedly burdening the worker, by constant jurisprudence of legitimacy must be assessed in terms of reasonable certainty, and therefore, excluding the relevance of the mere possibility of professional origin, it can be identified in the presence of a significant degree of probability (see, among many, Cass. 4/10/2018

no. 8773), which, for the reasons illustrated, emerged from the Court-appointed witness arranged in this instance.

The percentage of disability to the extent of 23%, already recognized in the Court-appointed expert witness ordered by the Court and confirmed by the consultancy carried out in this instance, was expressly accepted by the appellee (see page 3, point a, appealed brief).

In conclusion, the appeal must be rejected.

The expenses of this proceeding follow the loss and are settled in accordance with the parameters in force, taking into account the value of the case and the defensive activity carried out, payable to the defenders.

The expenses of the Court-appointed expert witness, given the conclusions reached, must be definitively borne by INAIL.

The rejection of the appeal is followed by law (Article 1, paragraphs 17-18, Law 228/2012) the declaration that the conditions exist for the further payment, to be paid by the appellant, of an amount equal to that of the unified contribution due for the appeal.

FOR THESE REASONS

Regarding article 437 c.p.c.,

the appeal is rejected;

INAIL is sentenced to reimburse the appellee for the expenses of the proceedings, in the amount of 10,000.00 euros, plus lump-sum reimbursement of the VAT and CPA (Lawyers Provident Fund) payable to the defenders;

the appellant is responsible for the Court-appointed expert witness fees, paid as per separate decree;

the existence of conditions for further payment by the appellant is declared, for the amount equal to that of the unified contribution due for the appeal.

As such, the Court has decided at the hearing on 12/3/2019

THE REPORTING JUDGE	**THE PRESIDING JUDGE**
Dr. Silvia CASARINO	Dr. Rita MANCUSO

CERTIFICATE OF SERVICE

I hereby certify that, on November 12, 2020, I filed the foregoing in the United States Court of Appeals for the District of Columbia Circuit via the CM/ECF system. I further certify that all parties are registered CM/ECF users, and that service will be accomplished via electronic filing.

/s/ *W. Scott McCollough*
W. Scott McCollough