Planning for Medical Implant Communications Systems (MICS) & Related Devices

Proposals Paper

Spectrum Planning Team
Radiofrequency Planning Group
Australian Communications Authority

Document: SPP 6/03
Date: October 2003

Planning for
Medical Implant Communications Systems
(MICS) and Related Devices
- Proposal Paper

Contents

Introduction

The Australian Communications Authority (ACA) has received enquiries from the manufacturers of medical implant devices and from the Therapeutic Goods Administration (TGA) regarding introduction of radiocommunications regulatory arrangements that would support the use of low power two-way Medical Implant Communications Systems (MICS) and similar one-way telemetry medical implant systems in Australia.

A MICS is a low power short-range radiocommunications system involving a programmer/ controller station that communicates with an ultra-low power radiocommunications device incorporated within a medical implant. A MICS enables an implanted medical device to be controlled and monitored from outside the patient; that is, it supports bi-directional communications. One-way telemetry medical implant systems provide radiocommunications data transfer in one direction, from the implanted device to an external monitoring receiver.

Typical medical implants incorporating MICS or similar systems include heart pacemakers and defibrillators; in the future this might include medical aids such as automated drug delivery and pain control systems.

Regulatory arrangements supporting the use of MICS (and similar) devices are in place in various parts of the world, including Europe and the United States of America (USA). The International Telecommunication Union Radiocommunications sector (ITU-R) has also developed a Recommendation on MICS that includes technical sharing arrangements with the meteorological aids service.

As a general approach to new technology, the Australian Communications Authority (ACA) attempts, where possible, to align its regulations with international arrangements in order to promote the adoption of new technology, minimise costs, and to facilitate free trade. Recognising the level of international support for the use of MICS and the practicalities associated with the international travel of patients fitted with MICS devices, this paper explores how the operation of MICS and similar devices are supported overseas and proposes radiocommunications regulatory arrangements that might be adopted to support their use in Australia.

Medical Implant Communications Technologies

Until recently, implanted medical devices were monitored and controlled using magnetic (inductive) coupling techniques. These magnetically coupled systems required the external monitor or controller to be in very close proximity to the patient, often requiring physical (surface-of-the-skin) contact, for the data communication to occur.

MICS Devices

MICS devices provide two-way radiocommunications between the medical implant and a programmer/controller. They are designed to operate in the band 402 – 405 MHz, which is a part of the spectrum that has characteristics favourable to the transmission of radio signals into the human body. MICS devices incorporate frequency agility and apply an interference avoidance strategy to select an appropriate frequency for a communications session.

The limited power available to the implanted device means that the implanted MICS devices must use short duration messages within a communications session. The growing complexity of implant devices has led to the need to transfer greater amounts of data during a communications session; the use of MICS devices with bandwidths up to 300 kHz can support these and future developments.

The use of a MICS removes the need for the physical contact required by inductively coupled systems, allowing greater patient mobility during communications sessions. A typical communications distance for a MICS device is intended to be around 2 metres or less – that is, very short range.

One-way Telemetry Implant Devices

The other group of medical implant communication devices considered in this report provide one-way radiocommunications. Telemetry from an implanted device is communicated via an integrated radio transmitter to an external monitoring receiver. These devices are also designed to operate within the band 402 – 405 MHz, though they typically do not have the frequency agility of MICS devices to assist with interference mitigation.

ITU Arrangements

The allocation of services in the ITU Radio Regulations (6) Table of Allocations in the spectrum 402 – 405 MHz is identical for all three ITU Regions. The service allocations are:

BAND (MHz)	SERVICE ALLOCATION	
	Primary Status	Secondary Status[1]
402 – 403	METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space)	Fixed Mobile except aeronautical mobile
403 – 405	METEOROLOGICAL AIDS	Fixed Mobile except aeronautical mobile

Table 1.

MICS devices, which are a form of mobile communications, are typically required to share the band 402 – 405 MHz with various other types of primary and secondary radiocommunications services.

ITU–R Recommendation SA.1346 (7) sets out recommended characteristics for MICS devices to facilitate sharing with stations operating in the Meteorological Aids service in the band 401 – 406 MHz. The recommendations include:

- limiting MICS devices to a maximum of -16 dBm equivalent isotropically radiated power (EIRP) in a reference bandwidth of 300 kHz to prevent interference to meteorological aids; and

[1] A secondary service may not cause harmful interference to or claim protection from a primary service even if the primary service was assigned after the secondary service.

- that MICS utilise a range of interference mitigation techniques to minimise the impact of meteorological aids on their operation.

The Recommendation identifies a number of possible interference mitigation techniques that MICS devices might use including:

- to avoid a false activation, the implanted device should use techniques such as requiring activation by a strong magnetic field;
- when the system is used for home monitoring, the system could poll at long intervals;
- the use of multiple error correction codes and automatic repeat requests to avoid impulsive interference and ensure sent and received data is accurate; and
- to avoid narrow band interference, use frequency agility and techniques where the MICS equipment chooses a channel based upon the lowest ambient noise level.

This last technique also reduces the possibility of MICS equipment causing interference to other services by avoiding channels known to be in use. The table in Appendix 1 lists the key technical parameters used in ITU-R SA.1346 for the sharing analysis between MICS and stations operating in the meteorological aids service.

ITU-R Recommendations regarding sharing arrangements for MICS with the other services allocated to the band have not been found.

Overseas Developments

Europe (ITU Region 1)

The European Radiocommunications Committee (ERC) in decision ERC/DEC/(01)17 of March 2001 decided to designate the frequency band 402-405 MHz for the use of equipment for medical implant communications systems. The committee also decided to exempt the short range devices for medical implants communications systems covered by the decision from individual licensing. Equipment covered by this decision was required to comply with the relevant European Telecommunication Standard which at the time was EN 300 220[2].

The European recommended Table of Allocations set out in ERC Report 25 (2) differs from that set out in the ITU Radio Regulations in that there are no fixed or mobile service allocations in the band 402 – 405 MHz.

The decision by the ERC to support MICS is currently reflected in the arrangements for MICS devices set out in ERC Recommendation 70-03 (1). This Recommendation sets out the general position on common spectrum allocations for short range devices for countries within the European Conference of Postal and Telecommunications Administrations (CEPT). ERC Recommendation 70-03 (1) lists EN 301 839 (3) adopted in June 2002 as the current applicable standard for MICS devices.

The main requirements for MICS devices under this standard include:

[2] EN 300 220 is the European generic standard for short range devices operating in the frequency range 25 MHz to 1000 MHz with output power levels up to 500 mW.

- a maximum effective radiated power (ERP) of 25μW[3];
- a channel spacing of 25 kHz with the use of a number of channels to provide for a bandwidth of up to 300 kHz; and
- detailed listen-before-transmit requirements for programmer/control transmitters.

MICS communications sessions are required to be initiated by a programmer/control transmitter, except for a communications session resulting from a 'Medical Implant Event'. A medical implant event is one that requires the medical implant device to transmit data immediately in order to protect the safety of the person in whom the medical implant device has been placed; it is made clear that this provision is not to be used for routine spectrum access by MICS devices.

ERC Recommendation 70-03 (1) indicates that all short range devices covered by the Recommendation are to be operated on the basis that they must not cause interference to other services and are offered no protection from interference.

European regulatory arrangements specifically supporting the use of one-way telemetry implant devices in the band 402-405 MHz have not been found. It appears that these devices could have been supported in Europe under the generic arrangements for short-range devices, ie EN 300 220, that existed prior to the adoption of EN 301 839 in June 2002. EN 301 839 specifies 13 March 2004 as the date for withdrawal of any conflicting National Standards, within the countries covered by the CEPT. Noting these developments, it is not clear how or whether new one-way telemetry implant devices will be supported in this band after that date.

United Kingdom (ITU Region 1)

The United Kingdom Radiocommunications Agency supports the use of MICS in the band 402 - 405 MHz in line with ERC Recommendation 70-03, as set out in UK Radio Interface Requirement 2030 (11) for short range devices.

The UK Table of Radio Frequency Allocations (12) varies from both that of the ITU and that recommended for Europe by the ERC. Specifically, the Fixed, Mobile and Space Operations services are allocated on an equal primary basis in the band 402 – 405 MHz. The Meteorological-satellite service is allocated on a secondary basis in this band and there is no allocation to the Earth exploration-satellite service.

No additional information regarding the sharing arrangements between MICS and the primary fixed, mobile and space operations services has been found. Information on licensing arrangements for mobile radio services on the Radiocommunications Agency website indicates that frequencies in the 402-405 MHz band are not currently used by either private business radio or public access mobile radio systems.

No specific arrangements that would support the use of one-way telemetry implant devices in this band have been found.

[3] This level is 2.2 dB higher than that recommended by ITU-R SA.1346. The reason for this difference is not clear but may be due to the use of mixed units in Annex1 to ITU-R SA.1346 where a calculated EIRP value has been mislabelled as ERP.

USA (ITU Region 2)

The Federal Communications Commission (FCC) has authorised the operation of MICS devices in the band 402 – 405 MHz on a shared secondary basis since January 2000 under Part 95 (General Mobile Radio Service and Personal Mobile Radio Services) of its Rules and Regulations (4).

The USA table of allocations (5) differs from the ITU Radio Regulations for the band 402 - 405 MHz in several ways. The only service with a primary allocation is the meteorological aids service. The Earth exploration-satellite service and meteorological-satellite service have secondary allocations in the band 402 – 403 MHz.

There is no fixed service allocation in the band. The mobile (except aeronautical) service is allocated by way of USA footnote 345. Under this footnote the allocation to this service is on a secondary basis and is limited, with the exception of military tactical mobile stations, to use by the medical implant communications service.

The rules of the medical implant communications service are set out is Subpart I of Part 95 of the FCC Rules and Regulations, with technical requirements listed in Subpart E. These rules and requirements include that:

- MICS devices are limited to a maximum EIRP of -16 dBm/300 kHz;
- A MICS programmer/controller must go through a series of internal tests to ensure the channel to be used is subject to minimal interference before it initiates a communication session with the MICS implant transceiver;
- A MICS implant transmitter must not transmit independently of a programmer/control transmitter or external actuation device, except in response to a medical implant event;
- MICS transmitters may be operated without the need of an individual licence by duly authorised health care professionals and the person who has the device implanted;
- MICS devices must not cause interference to stations in the Meteorological Aids, Meteorological satellite, or Earth Exploration-satellite services;
- MICS must accept interference from the Meteorological Aids, Meteorological satellite, or Earth Exploration-satellite services operating in this and adjacent bands; and
- MICS users are required to cooperate with each other to resolve any mutual interference that might arise.

The operation of one-way telemetry implant devices was initially supported in the USA in this band under an application granted in April 2001. In February 2003 the FCC decided to withdraw authorisation for periodic transmissions from these devices, following critical representations from a manufacturer of MICS compliant products[4]. Subsequently in March 2003 the manufacturer of the one-way telemetry devices made a request to the FCC for waiver to permit certification of implanted devices that emit scheduled periodic transmissions. The FCC decision on whether to grant this waver was still pending on 1 October 2003 (6).

[4] Note that the Memorandum Opinion and Order FCC 03-32 denied the MICS manufacturer’s challenge that one-way telemetry devices should not be permitted to operate under the FCC rules applying to the MICS service.

New Zealand (ITU Region 3)

The New Zealand Table of Allocations for the band 402-405 MHz reflects the ITU Radio Regulations allocations except that the secondary mobile allocation does not exclude aeronautical mobile. The New Zealand Table of Allocations contains the note that land mobile usage in the band is restricted to medical telemetry.

The New Zealand Ministry of Economic Development radio spectrum policy document, Spectrum Band Plan 003[5] notes that this spectrum has been identified as being possibly available to support low power medical telemetry systems. Neither this Band Plan nor its associated reports refer specifically to MICS or one-way telemetry implant devices.

Spectrum Band Plan 003 states that the land mobile medical telemetry systems operating in the band 404-405 MHz are subject to coordination with other services. The two frequency fixed links operating in the band are currently being removed as part of an overall restructuring of the 400 MHz band.

Domestic Aspects

Service Allocations

The service allocations in the Australian Radiofrequency Spectrum Plan (13) Table of Allocations for the band 402 – 405 MHz are:

BAND (MHz)	**SERVICE ALLOCATION**	
	Primary Status	**Secondary Status**
402 – 403	METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space)	Fixed Mobile except aeronautical mobile Radiolocation AUS11 AUS29
403 – 405	FIXED MOBILE except aeronautical mobile	Meteorological Aids Radiolocation AUS11 AUS29

Table 2.

These allocations differ from that in the ITU radio regulations and the other overseas countries examined in this paper in a number of ways. Australia allocates the Radiolocation service on a secondary basis in the band 402 – 405 MHz. Australian footnotes AUS11 and AUS29 attached to this allocation advise that the service is intended to be used principally for the purpose of defence and that the service has primary status in offshore areas.

The fixed and mobile (except aeronautical mobile) services are allocated as primary services in the band 403-405 MHz, and the Meteorological Aids service is allocated as a secondary service in the band.

[5] Radio Spectrum Policy 400-450 MHz Band and Transition Plan.

Spectrum Usage

The spectrum between 402 – 403 MHz carries a relatively small number of frequency assignments (37) in accordance with the service allocations above. A number of these assignments are made on an Australia-wide or Australian-waters basis reflecting the nomadic nature of the stations in the Radiolocation service. This sub-band is not subject to detailed planning because of the small number of assignments.

Spectrum in the band 403 – 405 MHz is part of the popular 400 MHz land mobile radiocommunications bands[6]. Detailed allocation and channelling arrangements for these frequencies are set out in the 400 MHz Plan[7]. In particular, the sub-band 403 – 403.9875 MHz is the base receive (mobile transmit) portion of an allocation for use by two-frequency land mobile systems using 25 kHz channelling.

This sub-band contains 926 land mobile system assignments most of which are on licences held by State government bodies and are located typically within 100 km of the State capital cities. The number of mobile transmitters associated with these assignments is unknown but is likely to run to some tens of thousands.

The sub-band 403 – 403.9875 MHz also contains 52 assignments for wideband fixed links located in rural areas at least 200 km from the State capital cities. These links have emission band widths between 150 and 750 kHz.

The sub-band 403.9875 – 405.0125 MHz is the lower portion of an allocation used for narrowband (25 kHz channelling) single channel two-frequency fixed links. The sub-band contains 3633 assignments. The assignments are attached to licences typically held by State government bodies. Figure 1 below shows the distribution of narrowband fixed and land mobile assignments.

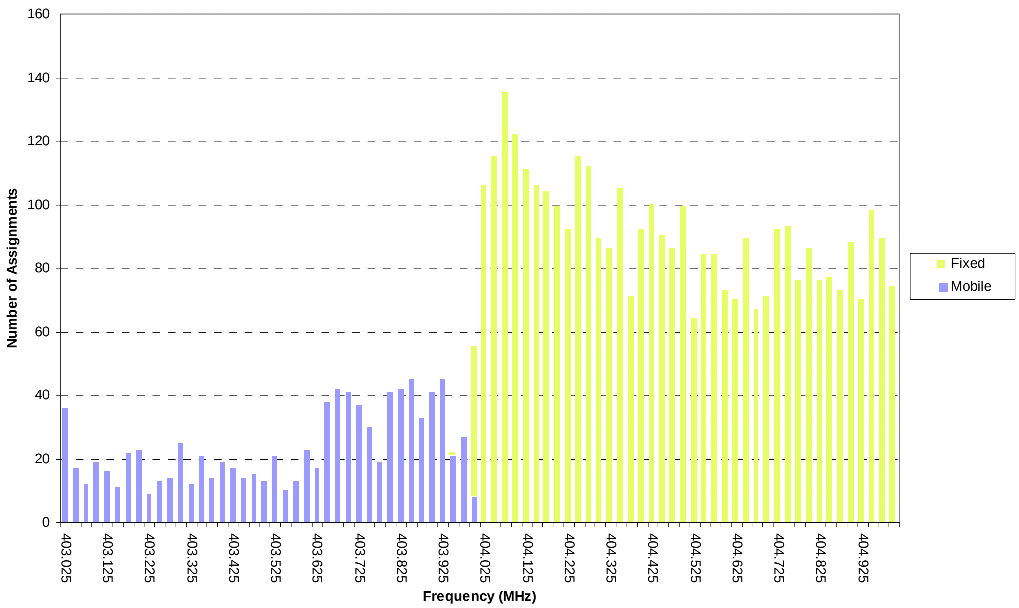


Figure 1. **Assignments in the 402 – 405 MHz Band**

---

[6] The 400 MHz mobile radiocommunications bands are 403 – 420 MHz and 450 – 520 MHz. These bands are used extensively for private land mobile radio and single channel fixed applications. As well, wideband fixed systems are assigned in parts of the bands in rural and remote areas of Australia.

[7] A pictorial representation of the 400 MHz Plan for narrowband services is at Appendix 2. A copy of the full plan is available at: http://www.aca.gov.au/radcomm/frequency_planning/band_plans/400mplan.htm

Discussion

General

The regulatory arrangements in the overseas countries examined in this report indicate a significant level of international cooperation and support for the operation of MICS devices in the band 402-405 MHz. These overseas regulatory arrangements allow for the operation of MICS devices without the need for individual licences or frequency coordination.

However, Australian uses of the 402-405 MHz band differ in some substantive ways to those found overseas. Careful examination of the interference risk between MICS and stations of other services allocated in Australia is needed.

The Sub-band 402 – 403 MHz

The allocation of services in this band in Australia most closely reflects the international allocation of services, the exception being the allocation to the Radiolocation service. The sub-band contains a relatively small number of assignment and licensees. These aspects reduce the risk of interference between systems and simplify the introduction of MICS.

The ITU-R Recommendation setting out arrangements for MICS devices to facilitate sharing with devices in the meteorological aids service operating in this band provides an internationally agreed basis for sharing between MICS and stations of this primary service in Australia.

The Earth Exploration-Satellite and Meteorological-satellite services are allocated on a primary basis for communications in the Earth-to-space direction. In other words, the receivers in these services that could be affected by MICS transmitters are on satellites, not earth stations. The large separation distance effectively eliminates any risk of interference from MICS devices to stations in these services, substantiated by the absence of specific arrangements to protect receivers in these services in the countries examined in this paper.

The risk of interference from transmitters in these services to MICS receivers is minimised by the frequency agility and other interference avoidance techniques recommended by the ITU to protect MICS from the Meteorological Aids service (ITU-R SA.1346). The Bureau of Meteorology operates a number of data collection platforms (DCPs) in this band on remote islands and reefs around Australia. DCPs are used to collect meteorological and other data from sensors in the vicinity of the DCP. The interference risk to MICS receivers from DCPs is considered in ITU-R SA.1346 to be of low probability because of their operation in remote locations and typically low duty cycle.

Receivers operating under the offshore primary radiolocation service allocation are considered to be at very low risk of interference from MICS transmitters. The likelihood of MICS implant devices transmitting while at sea is very low given that MICS devices do not transmit independently of programmer/controller equipment except in response to a medical event and then only in short bursts.

The likelihood of MICS programmer/controller equipment being carried on board ships is low as this equipment is typically located in hospitals or specialist medical clinics. Receivers operating under the offshore primary radiolocation service allocation have significant physical separation from any land based MICS programmer and monitoring facilities.

The radiolocation assignments are typically used for meteorological related purposes. They are low power (0.25W or less) and typically broadband (>120 kHz) indicating that these systems are of no greater interference risk to or from MICS devices than devices in the Meteorological Aids service, as analysed in ITU-R SA.1346.

There are a number of fixed (point-to-multipoint) assignments in this band that are associated with meteorological aids systems. Should other fixed systems be considered in the future, the technical characteristics of the equipment will necessarily be conservative to provide the required protection to the primary services in the band. This leads to the conclusion that the introduction of MICS devices is unlikely to present an increased risk of interference to or from these systems.

The Sub-band 403 - 403.9875 MHz

Australia uses this band to support high power land mobile systems (LMS) and wideband fixed links operating under primary service allocations. The high power, receiver sensitivity and number of assignments to these services indicate the need for more detailed analysis of the interference risks between stations operating in these services and MICS devices.

The land mobile system receivers operating in this band are located at base stations, which in two-frequency land mobile systems are typically located at high sites to provide maximum coverage[8].

Table 1 below summarises the results from the technical analysis on interference risk between MICS and LMS (details of the assumptions and methodology used in the analysis can be found in Appendix 3 of this report). Note that the worst case minimum separation distance (co-frequency) between a MICS device and a land mobile base station has been calculated based on the MICS device not causing interference to the reception of a wanted signal from a mobile at the reference sensitivity of the base station receiver. This worst case deterministic approach represents a very conservative assessment of the distance over which interference could occur – a more complex probabilistically based analysis can be expected to lead to a significantly smaller minimum separation distance.

Interference Source	Potential Victim Receiver	Path Loss Model	Worst Case Minimum Separation (km) (co-frequency)
MICS programmer/ controller	LMS base station	Free space	2.1
LMS mobile transmitter	MICS programmer/ controller	Hata	2.2

Table 1

[8] The technical modelling for this service can be found in RALI LM8.

In consideration of these findings, LMS base station receivers are considered to be at low risk of interference from implanted MICS transmitters because these devices do not transmit independently of a programmer/controller except in response to a medical event and then only in short bursts.

The risk of interference to a MICS implant receiver is minimised by the interference avoidance techniques built into MICS programmer/controller (to protect communications with the MICS implant from interference from stations in the meteorological aids service).

The risk of interference to an LMS base station from a MICS programmer/controller is related to the likelihood of the programmer/controller being within the worst case minimum separation distance of an LMS base station and being unaware of mobile transmissions on that channel. The likelihood of a specialist clinic or hospital being in close proximity to the base station is likely only where the base station is located in an urban area.

Should the base station be located in an urban area the path loss to the MICS programmer/controller will invariably be significantly greater than that calculated using the free space model used in Appendix 3 due to greater numbers of obstructions and lower base station antenna height. Mobile density in the vicinity of the base station can be expected to be high, increasing the likelihood that the programmer/controller will be aware of the use of the channel by the LMS. The likelihood seems high, therefore, that the programmer/controller will avoid the channel in these circumstances.

Wideband fixed links operating in this band may only be assigned in areas at least 200 km from mainland State capital cities. This typically places them in regional and rural areas well away from major urban areas. The stations are typically located at high sites and use directional antennas. The risk of a hospital or specialist clinic being in close proximity and within the beam width of the antenna in these regional and rural areas is considered to be low.

The Sub-band 403.9875 – 405 MHz

There are two types of narrowband fixed systems operating in this band, point-to-point and point-to-multipoint.

The few (14) point-to-multipoint systems are all located in remote areas and therefore are at little risk of interference from MICS implant devices as MICS devices do not transmit independently of a programmer/controller except in response to a medical event and then only in short bursts. The likelihood that MICS programmer/ controllers would be located in these areas is considered to be low.

These point-to-multipoint systems are relatively short range systems. They radiate less power, and are a lesser interference risk, than the mobile radio equipment considered in the previous section. This aspect, combined with the remote location of these systems and the interference avoidance technology incorporated into MICS devices, means there is little risk of these systems causing interference to MICS.

The point-to-point systems operating in this band use directional antennas typically located at high sites in rural or regional areas, although some may be located on buildings in urban areas. The risk of MICS programmer/controller being located within the main beam of the antenna within a short distance of the antenna is considered low. These systems typically operate with signal levels well above the reference sensitivity level used in the technical analysis in Appendix 3, and this would reduce the worst case minimum separation distance value to negligible levels.

The risk of interference to MICS devices from these narrowband fixed links is similar to that for mobile systems. The use of interference avoidance techniques built into the MICS devices to cope with meteorological aids transmissions will eliminate the risk of interference to MICS from these links.

Discussion Specific to One-way Telemetry Implant Devices

The overseas regulatory support for one-way telemetry devices is not as clear as that for MICS. These devices have been approved and operated in Europe and the USA for a number of years. However there is uncertainty regarding the ongoing support for these devices. These devices may be a historical stepping stone in the development of MICS technology.

Known examples of these one-way telemetry implant devices use a single fixed frequency channel, which reduces the complexity of the implanted devices. Typically, they are pre-programmed to transmit at periodic intervals. The limited availability of power for data transmission naturally leads to the use of very low power short duration transmissions with long periods between transmissions from these devices. This leads to a very low probability (less than 0.01% of the time) of interference occurring to receivers in other services.

The interference risk from transmitters in other services to receivers monitoring these one-way telemetry devices is, however, significantly greater than the risk to MICS. Without the ability to recognise and avoid channels subject to interference the one-way telemetry device is at risk of being ineffective in some locations where the particular channel is being used by a transmitter or transmitters in another service. This is particularly the case where there are large numbers of stations operating in the band, such as in the case of the radiocommunications bands above 403 MHz.

Licensing Considerations

The *Radiocommunications Act 1992* (the Act) prohibits unlicensed operation of radiocommunications transmitters, except in emergency situations. Generally speaking, there are no similar requirements for radio reception. Three licensing mechanisms are provided for in the Act: apparatus licensing, spectrum licensing and class licensing.

Apparatus licences authorise a user to operate a specified category of service, eg, fixed, broadcasting or mobile, subject to complying with specified technical characteristics including the location, power, frequency of operation and the radiofrequency emission type. These licences are usually site-based, usually require prior frequency coordination to have been done, are usually issued over-the-counter, attract fees and represent the majority of the ACA’s licensing activity.

Spectrum licences are area-based licences and are intended to be technology and service neutral to the extent possible (ie, the type of service is not specified) so as to give maximum flexibility to the licensee. Once allocated, these spectrum assets are fully tradeable, and can be sub-divided or amalgamated in either the geographic or the frequency band domain. This allows licensees to acquire, through participation in auctions or through trading in the secondary market, whatever spectrum space is necessary to deploy the type of service required.

Class licences are open, standing authorities that allow anyone to operate particular radiocommunications devices provided that the operation and the devices are in keeping with the conditions of the licence. A class licence sets out the conditions under which any person is permitted to operate a specified class of device – the licence is not issued to an individual user, and does not involve licence fees or separate licence conditions being applied to that individual.

Each is explained in further detail on the ACA website at:

http://www.aca.gov.au/aca_home/licensing/radcomm/about_radcomms_licensing/index.htm.

Class licensing is an appropriate option for users where a class of devices can be operated without frequency or geographic coordination between individual devices and it is expected that operating in this way is unlikely to result in mutual harmful interference, or harmful interference involving users of other types of radiocommunications equipment. Whilst such devices can be described generically as low interference potential devices, operation must necessarily be on a no-interference, no-protection basis to assist with resolving the occasional specific instances of interference that might arise from time to time. The use of many types of short-range devices is authorised by class licensing.

Proposals

MICS Equipment

The ACA proposes to introduce regulatory arrangements that would support the operation of MICS devices in the 402 - 405 MHz band on a no-protection no-interference basis, inline with ITU-R Recommendation SA.1346 and overseas regulatory arrangements.

The ACA notes that the existing heavy use of the sub-band 403 - 405 MHz by other services may effectively reduce the number of channels available to MICS in some areas. This is a natural consequence of the interference avoidance techniques used by MICS devices and is incorporated in their design. Allowing MICS to operate in the band 403-405 MHz where possible, provides harmonisation with international arrangements, and avoids legal technicalities that might arise from MICS devices coming into Australia from overseas and otherwise transmitting, even if only temporarily, on unauthorised frequencies.

The ACA would not propose to set licence conditions on the use of MICS receivers, other than the advisory note that protection from interference will not be afforded. The key technical and operational conditions proposed for the use of MICS transmitters are:

- Band of operation: 402 - 405 MHz.
- Maximum EIRP: 25 µW – this limit to apply in any 300 kHz bandwidth.
- Operation on a no-interference basis.
- Transmitters in implanted devices to transmit only when commanded to do so by external programmers/controllers, except for medical implant events.
- programmer/controller devices to operate on a listen-before-transmit basis to identify and use the communication channel of lowest ambient noise.
- Frequency agility, to enable communication to occur on the lowest ambient noise channel determined to be available.

One-way Telemetry Implant Devices

The interference risk to receivers in other services from one-way telemetry devices is low, like the risk from MICS devices. However, the risk of interference to these one-way telemetry devices is significantly greater than that for MICS because of the absence of frequency agility and the associated interference avoidance techniques.

The particular one-way telemetry devices proposed for introduction into Australia, and known to be used at least in some parts of Europe, operate only on a single fixed radiocommunications channel that is in the heavily used mobile radio sub-band 403-403.9875 MHz in this country. This would increase substantially the likelihood of unavoidable interference to the operation of these devices should they be introduced. Additionally, the ACA observes that the introduction of specific and detailed technical requirements for two-way MICS devices in the band 402-405 MHz has decreased the certainty of continued regulatory support overseas for one-way telemetry implant devices. Accordingly, it does not seem appropriate to introduce regulatory arrangements that would support the use of these devices at this time. The ACA will continue to monitor overseas developments with this technology and within other regulatory bodies for changes that would address the above concerns, before support for these devices would be further considered.

Request for Comment

The ACA invites written comment on the above proposals.

Comment can be sent to:

The Manager
Spectrum Planning Team
Australian Communications Authority
PO Box 78
BELCONNEN ACT 2616

or

mailto:freqplan@aca.gov.au

Bibliography

1. European Radiocommunications Committee, *Relating to the Use of Short Range Devices (SRD)*, ERC Recommendation 70-03, April 2002.

2. European Radiocommunications Committee, *The European Table of Frequency Allocations and Utilisations Covering the Frequency Range 9 KHz To 275 GHz*, ERC Report 25, January 2002.

3. European Telecommunications Standard Institute, Electromagnetic compatibility and Radio spectrum Matters (ERM); *Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive*, ETSI EN 301 839-2 V1.1.1 (2002-06), June 2002.

4. FCC Rules and Regulations, Subparts E and I, Part 95, November 2002.

5. FCC Rules and Regulations, Table of Frequency Allocations, Part 2.106, November 2002.

6. Biotronik, Inc. Files Request for Waiver of Frequency Monitoring Rules for Cardiac Implant Device, *Public Notice*, ET Docket No. 03-92, DA 03-1778 (OET rel. May 27, 2003)

6. International Telecommunications Union, *ITU Radio Regulations*, Article 5, 2001.

7. International Telecommunications Union, *Sharing Between the Meteorological Aids Service and Medical Implant Communication Systems (MICS) Operating in the Mobile Service in the Frequency Band 401 – 406 MHz*, ITU-R SA.1346, 1998.

8. Ministry of Economic Development, *Radio Spectrum Policy*, Spectrum Band Plans, POLDOC 003, New Zealand, 26 September 2000.

9. Ministry of Economic Development, *Radio Spectrum Provision for Biomedical Telemetry Systems*, Engineering Consideration Document, Spectrum Planning Division, ECD 2000/1, New Zealand, March 2000.

10. Ministry of Economic Development, *Replanning of the Band 401 – 449 MHz*, Engineering Consideration Document, Spectrum Planning Division, ECD 2000/2, New Zealand, March 2000.

11. Radiocommunications Agency, *UK Radio Interface requirement 2030 Short range devices*, Version 1.2, 25 October 2002.

12. Radiocommunications Agency, *United Kingdom Table of Radio Frequency Allocations 9kHz – 105GHz*, RA 365, February 2000.

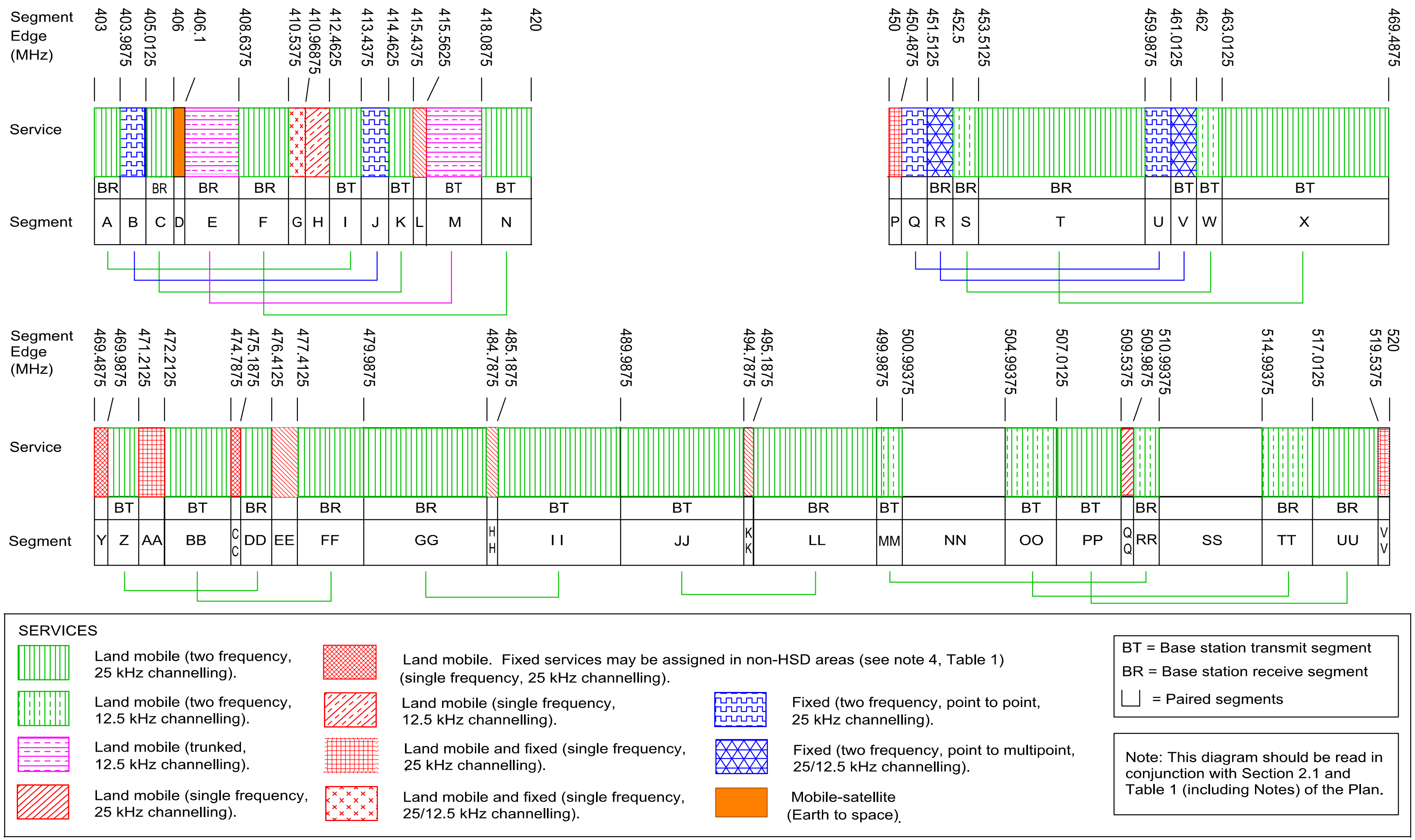
13. Australian Communications Authority, Australian Radiofrequency Spectrum Plan, January 2002.

Appendix 1 – Characteristics of MICS

ITU Supported Characteristics of MICS	
Programmer / Controller Unit	
Receiver noise bandwidth	200 kHz
Antenna Gain Tx/Rx	2 dBi
Power Into Antenna	-22 dBm
Tx Power	-20 dBm EIRP
Required SNR	14 dB
Noise Floor	-101 dBm
Ambient noise at receiver input	20 dB above kTB
Receiver noise figure	4 dB
Implanted Unit	
Receiver noise bandwidth	25 kHz
Antenna Gain Tx/Rx	-31.5 dBi
Power Into Antenna	-2 dBm
Tx Power at the surface of the skin	-33.5 dBm EIRP
Required SNR	14 dB
Noise Floor	-121 dBm
Ambient noise at receiver input	About kTB (due to tissue loss)
Receiver noise figure	9 dB
Transmission Losses	
Free space loss at 2 meters	30.5 dB
Fade margin (with diversity)	10 dB
Excess loss (polarisation, etc.)	15 dB
Building penetration loss	20 dB

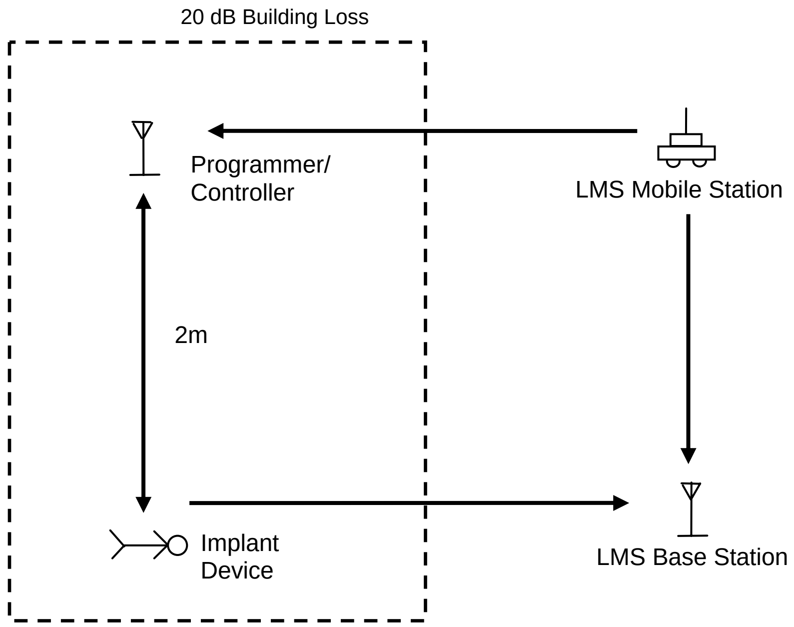
Appendix 2 – Extract from the 400 MHz Plan

Figure 1: 400 MHz Narrowband Services Diagram - December 2002



Appendix 3 - Interference Calculations

Interference Calculations



Minimum Separation Distance Required between the Programmer/Controller and a Mobile Transmitter

The minimum separation distance required to protect a MICS programmer/controller from interference caused by a mobile station transmitter is calculated below. The calculation assumes that the medical implant device is 2 metres from the programmer/controller. All values stated are from ITU-R SA 1346.

The radiated power from the implant device at the body surface

= -33.5 dBm EIRP

Free space propagation loss over 2 metres

= 30.5 dB

Other losses used in ITU-R SA 1346:

Fade margin = 10 dB
Excess loss = 15 dB (Patient orientation, antenna misalignment, obstructions and path loss)

The received power at the programmer/controller = -33.5 – 30.5 – 10 – 15 = -89 dBm

The programmer/controller requires a 14 dB protection ratio and therefore the maximum interference signal level at the programmer/controller = -89 – 14 = -103 dBm

If the maximum radiated power from the mobile transmitter is 46 dBm EIRP (RALI LM8) then, allowing for a 20 dB building attenuation (ITU-R SA 1346), the required propagation loss is:

= -129 dB

Using the Hata urban propagation model with a mobile transmitter height of 1.5 m and the programmer/controller height of 30 metres then the required minimum separation distance is:

= 2.2 km

Hata Urban Propagation Model (small to medium city)

Path loss = 69.55 + 26.16 * Log(Freq) - 13.82 * Log(Hbase) - A + [44.9 - 6.55 * Log(Hbase)] * Log(Dist)

A = [1.1 * Log(Freq) - 0.7] * Hmob - [1.56 * Log(Freq) - 0.8]

Minimum Separation Distance between the Land Mobile Base Station and MICS Transmitter

The minimum separation distance required to protect the LMS base station receiver from interference caused by a MICS transmitter is calculated below. All values stated below are from LM8.

Land mobile usable receiver sensitivity is:

= -116 dBm

The land mobile base station receiver requires a 5 dB protection ratio and therefore the maximum interference signal level into the land mobile receiver = -116 – 5 = -121 dBm

As the land mobile base station antenna gain is 6 dB (RALI LM8) then the maximum interference signal level at the land mobile receiver = -121 – 6 = -127 dBm

If the maximum radiated power from the MICS is -16 dBm EIRP then, allowing for 20 dB building attenuation (ITU-R SA 1346), the required loss is:

= -91 dB

Using the free space propagation model the required minimum separation distance is:

= 2.1 km

Free Space Propagation Model

Path loss = 32.45 + 20 * Log(Freq) + 20 * Log(Dist)