2018/19 International Code of Practice for Telehealth Services

The Quality Benchmark for Digital Health and Care

- remote consultations
- telecare and social alarms (PRS)
- mHealth
- activity monitoring
- vital signs monitoring
- virtual coaching

incorporates ISO/TS 13131: Health Informatics – Quality Planning Guidelines for Telehealth Services

A Certifiable Code of Practice for the World

Developed by the Telehealth Quality Group (Europe) working in partnership with Global Community Resourcing (Australia)
Telehealth is the means by which technologies and related services concerned with health and well-being are accessed by people or provided for them irrespective of their location.

The International Code of Practice for Telehealth Services was developed and is wholly owned by the Telehealth Quality Group, TQG (see www.telehealth.global). Its antecedent European Code was developed within the European Commission funded TeleSCoPE project that ended in 2013 (EAHC 2009 11 11).

The TQG is an EEIG (European Economic Interest Group) incorporated at Companies House in Cardiff, United Kingdom (Registration Number GE000306). The IP for the Code is held by the TQG. The TQG operates in partnership with Global Community Resourcing (Australia).

PREAMBLE

To be successful, telehealth services need the trust of clinicians; health, social care and support practitioners; service users and both formal and informal carers. The International Code of Practice for Telehealth Services (hereafter ‘the Code’) provides a quality benchmark against which telehealth services (including telecare) can be assessed and certified. In so doing, it provides a basis for that trust.

The Code addresses health in both its clinical and well-being senses. It is positioned largely within a preventive and public health arena and is therefore very concerned with the benefits for service users as well as the way that services are provided.

The Code is relevant to us all, regardless of our age or any care or support need. In taking a strategic position the Code is able to act as an ‘umbrella’ that can link to a number of operational codes concerned with specific tasks undertaken by telehealth services.

CHANGES FROM THE 2017 CODE

Changes from the 2017 version of the Code are minor. These follow consultation with a key range of individuals and agencies. Those changes that are most notable are as follows:

Clause A7 Service Performance: Services are now required to honestly and openly display a range of performance measures on their website or in other publicly available material.

Clause A9 Cyber (Information) Security: In view of the importance of this issue to both the integrity of services and the safeguarding of personal data of service users and carers, further information is added to the guidelines within this clause.

Clause B6 Taking Account of User and Carer Views: A pointer is given in the guidelines for this clause that indicate the benefits that can be realised through co-production approaches with users and carers to e.g. service planning.

Clause I1 Fitness for Purpose and Interoperability of Technologies / Equipment and Related Software: The development of more secure digital communications networks means that the potential to further empower service users and carers is dramatically increased. Part of that power relates to people’s increased health literacy and ability to self-manage and exercise choices with regard to the technologies and services used. It follows that interoperability must be given greater emphasis when ‘fitness for purpose’ is considered. The guidelines are amended to reflect this.

GENERAL DATA PROTECTION REGULATION

For services that operate in the European Union or are bound by their legislation, careful attention must be made to the requirements that arise from the General Data Protection Regulation (www.eugdpr.org) and the absolute necessity for compliance with the same from May 2018. This Regulation impacts on many of the clauses within this Code, most especially Section D regarding Personal Information Management; but also for those that address cyber-security (e.g. A9) and the fitness for purpose of the technologies used within services (e.g. I1).
A. OVERVIEW

1. About the Code


Importantly the Code incorporates the quality planning guidelines set out in ISO/TS 13131 (2014). This means that a telehealth service that is certified to the Code also satisfies the requirement of the ISO Technical Specification 13131 (Health Informatics – Telehealth Services – Quality Planning Guidelines).

Other ISO standards are referenced within the Code and are noted in Appendix A.

Where telehealth services are certified to the Code, this gives reassurance to organisations that procure or commission services; service providers and their staff; service users and their carers; health insurers; and governments, and health and support agencies with an interest in telehealth.

Testimony to service quality can be provided for telehealth services that also operate in accordance with one or more ‘operational’ codes (for particular aspects of service provision such as video-consultations, social alarms and PRS). In this way the Code can be seen ‘strategic’ and acting as an umbrella that covers and can be supported by operational codes. A list of the operational codes that are recognised by the TQG is provided below.

- Code of Practice – Personal Emergency Response Services (2009, Australia PERSA)
- Telehealth Services – Standards (2014, Canada AC)
- Qualité de Service en Télésurveillance NF X50-520 (2013, France AFNOR)
- Staying at Home: Requirements for Suppliers of Combined Services VDE AR E 2757-2 (2011, Germany VDE)
- Supply Chain Quality Mark for Personal Alarm Services (2012, Netherlands QAEH)
- Code of Practice – Telecare Services (2011, New Zealand TSANZ)
- Servicios para la Promoción de la Autonomía Personal – Gestión del Servicio Asistencia UNE 158401 (2007, Spain UNE)
- Quality Standards Framework for Technology Enabled Care (TEC) Services (2017, UK TSA)
- International Code Of Practice for Planning, Commissioning and Providing Technology Enabled Care Services (2017, UK CECOPS)
- Code of Practice for Disability Equipment, Wheelchair and Seating Services (2015, UK CECOPS)
- TSA Integrated Telecare and Telehealth Code of Practice (2013, UK TSA)
- Core Operational Guidelines for Telehealth Services involving Provider-Patient Interactions (2014, US ATA)

The TQG is committed to ensuring compatibility of the Code with the outcome of work being undertaken by CEN (the European Standards Body) Technical Committee 431 ‘Service Chain for Social Alarms’. The TQG is, furthermore, monitoring work that is likely to lead to an ISO standard on Consumer Vulnerability. This is likely to be reference in a future iteration of the Code as requiring the attention of services.

The importance of the Code is increasing because of demographic, political and economic factors. More people are living with and managing long-term conditions. Others have shorter term needs (e.g. during a period of pregnancy and childbirth, recovery or rehabilitation). We can also expect more people to access and use telehealth services to help guide them in relation to their everyday health and fitness. This means that the Code is relevant to services provided for people of all ages – ranging from a 26 year old managing her diabetes; or a 46 year old challenged with his mental health; to an 86 year old supported with her dementia.

It must be recognised that telehealth services frequently operate alongside or are integrated with related health, care, housing and other support services. These ‘other’ services may include personal assistance and counselling;
provision of specific therapies and treatments; planning for transfers of care (e.g. hospital admissions and discharges); tenancy support; or be concerned with access to specialist assistive technologies (e.g. aids to vision or hearing) and community equipment. Many telehealth services may, therefore, play a part in care and support ‘packages’ and within ‘care pathways’ that are specific to certain (and sometimes multiple) health conditions.

The Code is not applicable to services that may carry the label ‘telehealth’ but which are solely focused on the gathering or exchange of ‘patient’ information (including that which relates to genomics) between clinicians.

2. Defining Telehealth

Telehealth is the means by which technologies and related services concerned with health and well-being are accessed by people or provided for them irrespective of their location. This means that telehealth services can operate locally (within relatively small communities) or internationally. The common feature is that the person accessing the service (sometimes referred to as the patient or client) is not physically in the location of service provision (whether or not provided by a health or social care practitioner).

3. The Purpose of the Code

The Code provides a quality benchmark for telehealth service providers; addresses the way that services, related procedures and practices are organised; and the way that risks are addressed. It also points to some of the skills, knowledge and competencies that are required by service staff. Service requirements that are addressed in the Code include the way in which communication takes place with users and carers. In addition the Code sets out requirements that will help to minimise the potential for people’s privacy or autonomy to be undermined.

4. Telehealth Domains

Domains for telehealth services range from pregnancy to palliative care. Services may focus on one or more of these domains and involve the use of a variety of technologies. The latter can include telephony devices, television and web-cams; video links and fixed or wireless telecommunication and computing devices (including smart phones and tablets); and therapeutic devices such as muscle stimulators or therapeutic pets. These may be provided directly by the services or by service users themselves. Services may also involve the use of environmental controllers, sensors, actuators and apps where these enable access to and/or the sharing of health, well-being or activity related information.

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It is important to recognise, in addition, that some of the technologies used within telehealth services can provide people with access to a wider range of different kinds of (non-telehealth) services such as information, social networks, email, training opportunities, etc. Telehealth services are, therefore, positioned to provide economic and social as well as health and well-being benefits for their users and carers.

5. Assessments for and Certification to the Code

Procedures whereby services can be certified to the Code are set out in Appendix B and on the TQG website at www.telehealth.global. To become certified, telehealth services shall satisfy the requirements of each clause that
applies to them. This includes all the clauses of ISO/TS 13131. Services may self-assess or be assessed for compliance by an independent organisation approved by the TQG. A self-assessment tool is available to TQG members that can help determine their readiness for certification as a prelude to either seeking independent assessment; or making a direct application (with supporting evidence) for certification. DNV GL (Healthcare) is the first independent organisation approved by the TQG to undertake such assessments. A range of charges apply. The level of the charge depends on the size and complexity of the service.

Services that either self-assess with a view to certification being conferred by the TQG or are certified (directly) through independent assessment to the Code:

- have an obligation to facilitate spot-checks or investigations of any part of their service (these can be undertaken without prior notice); and
- accept the manner in which certification can be suspended, renewed or revoked.

Services that are certified

- are included in listings on the TQG website; and
- have freedom to use a specific logo that indicates the type of certification on their websites and in their literature.

Certification in accordance with the requirements of the Code, as well as bearing testimony to service quality, gives services an advantage when competing with other providers.

Services should check the TQG website regarding any updated procedures around assessment for and certification to the Code.

6. ISO Certification

The Code incorporates ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services. It, therefore, offers a holistic framework that guides telehealth services in ways that respond sensitively to the range of people who can benefit; and provides a robust benchmark against which procedures around e.g. risk management can be assessed. The incorporation of ISO/TS 13131 provides significant added value and ensures that all key areas that relate to telehealth service provision are addressed.

7. Updating of the Code

The Code is reviewed and updated every two years. Updates may, however, be made at any time during the year. It is the responsibility of services to check that they (and their staff) are operating according with the latest version of the Code. Telehealth Quality Group members are consulted about the Code on an annual basis and are informed when changes are made.

8. The Code and its Structure

The Code has nine sections as shown in the figure below. The person who uses telehealth services is at the centre – this position symbolising their importance and their being able to:

- exercise choices about services and service options;
- give consent to the way in which their personal (including health) information is gathered, stored and used;
- have their views and opinions heard and taken into account; and
- have their human rights and dignity protected.
International Code of Practice for Telehealth Services: Framework
B. THE CODE

Notes

In general, the Code does not include clauses where the responsibilities of service providers are enshrined in the legislation or regulatory requirements of the countries in which they are based and/or operate. Certified telehealth services shall, however, comply with country-specific legislation or regulatory requirements as well as all applicable clauses in this Code.

The following notes apply:

1. Where reference is made to documents, policies, information or declarations that are placed on the website of the telehealth service; these shall be provided in the primary language or languages relevant to the areas of service operation and the nature of its service users.
2. Where reference is made to staff, this includes volunteers and other helpers, paid or unpaid, engaged by the service.
3. Where reference is made to users and carers it is the user that takes precedence in any matter relating to service provision and the conditions attaching to the same. The views and opinions of carers shall only be taken into account where they are authorised or where exceptional circumstances apply.
4. Where reference is made to consent this shall normally be informed and explicit. The increasing availability of software-based equipment / technologies that operate with complex algorithms and, in some cases, automated learning means that a more general level, albeit informed, is appropriate. Services shall, therefore, recognise their roles as trusted third parties in this context.
5. Where reference is made to the need for services to review documents, policies or strategies (etc.) this must be done at least every two years unless specifically stated otherwise.
6. There are 56 clauses. No service can be certified without being compliant with 40 of these. All 40 of the compulsory clauses are colour coded dark green (in the left panel). Certified services shall comply with all the clauses that are applicable to them. Those clauses which apply only when the activity is undertaken as part of the service are colour coded light green. There are 16 of these.
7. An attempt has been made in this Code to avoid the use of jargon. The need for the active involvement of users and carers together with the pursuit of goals that relate to service integration (as suggested by some such terms) are, however, endorsed.
8. The guidance provided in relation to each clause provides pointers to good practice. Some elements of such good practice may become requirements of the Code in the future.

The clauses that make up the Code are set out in the ensuing pages within sections as follows:

- A. General Considerations
- B. Ethical Perspectives
- C. Governance and Financial Issues
- D. Personal Information Management
- E. Staff and Staff Management
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**A1 Compliance with the Code**

**Requirement:**
Services shall be compliant with all clauses that relate to the telehealth service they provide.

**Applicability:**
Applicable to all services.

**Guidance:**
No telehealth functions that are undertaken by the service, its agents or sub-contractors shall be excluded from the requirement to comply. A clear and specific declaration regarding compliance shall be placed on the website. The declaration shall be dated and reviewed annually. If a service provides some telehealth functions which are not compliant with the code, the website shall make it clear which functions are not covered, so that there is no confusion.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

**A2 Availability of the Code**

**Requirement:**
Staff, users and carers (and any intermediary organisations) shall all be aware of this Code and as to where they can view and obtain copies.

**Applicability:**
Applicable to all services.

**Guidance:**
Making the Code fully available to staff and others helps to ensure the efficacy of service provision and to build trust in telehealth.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## A3 Service Website and Internet Presence

**Requirement:**
Services shall maintain a current website, or a readily accessible area within the website of the organisation of which they are part, that is specific to the telehealth service.

**Applicability:**
Applicable to all services.

**Guidance:**
Proper consideration shall be given to website accessibility with this being reflected in the content and format. The names of directors and senior management staff shall be posted on the website with it being made clear which (if any) individuals or organisations have a controlling interest in the service. Services might also wish to maintain their ‘internet presence’ through social media portals. The same principles regarding accessibility shall apply in those contexts.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
A4 Compliance with Statutory Requirements

**Requirement:**
Services shall be compliant with laws and regulatory requirements for all the countries or regions in which the service is provided or is incorporated. Services shall be prepared for and act in order to meet, in a timely fashion, any relevant legislative changes that arise in those countries or regions.

**Applicability:**
Applicable to all services. An exemption may be applied where telehealth services are provided for people who travel internationally for business or recreation purposes.

**Guidance:**
The laws, regulatory and licensing requirements that shall be considered by services include those that relate to health and safety, employment law, data protection, reimbursement; the registration and competencies of employees; and, where applicable, specific medical device regulatory frameworks.

The laws, regulatory and licensing requirement of countries, states, provinces or regions shall take precedence over the requirements of this Code; excepting where the requirements of this Code are more stringent.

This clause does not apply to the homes or other locations of users and carers over which services have no control - except with regard to installations, specific use, etc. of any technologies/equipment provided.

Services shall be guided by the principles set out in ISO 27001, 27017, 27799 and 13485 and, where services operate within the European Union, the European Commission Directives 2011/24/EU, 2009/136/EC and 95/46/EC.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
A5 Sustainability Strategy

Requirement:
Services shall have a current sustainability strategy.

Applicability:
Applicable to all services.

Guidance:
The importance of service sustainability cannot easily be overstated in view of the characteristics and needs of many users and carers.

A sustainability strategy will show, in service configuration and provision, how the economic / financial, social and environmental context is taken into account. It shall demonstrate an understanding of needs and markets specific to the service being provided and how this understanding impacts on planned changes to or the development of the service. It shall offer sufficient information, reflected in a business or financial plan, to show the sustainability of service funding.

In relation to environmental issues, consideration might be given in a sustainability strategy to the way that telehealth can reduce travel for staff, service users and carers.

Services shall be guided by the principles set out in ISO 14001, 26000 and 27001.

The sustainability policy shall be dated and reviewed at least annually.

ISO/TS 13131:
This clause together with C3, C5, H1 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### A6 Outcomes Focused Appraisal

**Requirement:**
Services shall undertake an annual outcome focused appraisal of their service as it relates to the health and well-being of service users and carers.

**Applicability:**
Applicable to all services.

**Guidance:**
The outcomes focused appraisal shall examine, drawing on information in an impartial manner, the extent to which the service has made progress towards or achieved its mission and related objectives. It shall provide pointers to potential changes in service provision having given attention, amongst other things to

- the health benefits that have or have not accrued to service users and carers;
- how the service has acted upon the complaints, compliments and suggestions received; and
- feedback from any surveys of users and carers.

It is recognised that, where intermediary organisations are involved, exploration of such outcomes to the desired extent, may not be possible.

In new services the outcomes focused appraisal shall put baselines in place and offer a framework against which future measurement of progress can be made.

The outcomes focused appraisal shall be dated and reviewed at least annually. It shall feed into the Quality Plan and carry the personal endorsement of a senior staff member.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
A7  Service Performance

Requirement:
Services shall record their performance in relation to a set of relevant measures.

Applicability:
Applicable to all services.

Guidance:
Services shall determine relevant measures of performance. These will in some cases include operational data. In any case a set of relevant measures shall be determined so that there is a framework against which future measurement of performance can be made. Operational measures might usefully include the time taken, number or frequency with regard to:
- provision, calibration, testing, installation or removal of devices and related technologies;
- examining data and/or responding to needs indicated through enquiries or device activation;
- verifying and updating user details, service choices and consents;
- viruses and malware identified, phishing attempts made and cyber-attacks thwarted; and
- complaints, compliments and suggestions.
Other measures might relate to the undertaking and outcomes of surveys undertaken with users and carers, mystery customer or ethical hacking exercises.
Services shall honestly and openly display a range of such measures on their website or in other publicly available material.
A clear declaration regarding compliance with this requirement, specific to the telehealth service, shall be placed on the website. The declaration shall be dated and reviewed annually.

ISO/TS 13131:
This clause together with A5, B2, C2, C3, C5, F1, H1 and H2 covers Clauses 5.3, 8.1 to 8.4 and 13.6 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
A8 Suitability and Physical Security of Service Locations

Requirement:
Services shall take preventive and responsive measures to ensure the suitability and physical security of the location or locations from which their service operates and the channels through which information flows.

Applicability:
Applicable to all services.

Guidance:
For physical locations there shall be
a) adequate facilities (in terms of physical space, comfort and privacy); and
b) a high level of security including such measures as motion activated or security lighting, controlled access and CCTV (closed circuit TV).

For communications channels procedures shall be in place that check, at least daily, their integrity and effective operation.

Where breaches of physical security take place these shall be reported to the appropriate authorities and the provisions of the service regarding such security shall be reviewed.

Services shall be guided by the principles set out in ISO 27001 and 27017.

ISO/TS 13131:
This requirement covers Clauses 12.1 and 12.2 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
A9 Cyber (Information) Security

Requirement:
Services shall ensure that a range of robust measures are in place to protect against and respond to cyber (information) security threats or breaches (including the theft of technologies/equipment and data).

Applicability:
Applicable to all services.

Guidance:
The threats that relate to cyber (information) security are growing. They demand action to secure all aspects the service (including e.g. billing and payment systems) and, crucially, to safeguard the personal data of service users and carers. The nature of the cyber (information) security threat is multi-faceted in that it relates not just to the technologies and the communications networks (wired and wire-less) but to the actions of service staff, agents, clients and subcontractors.

Other clauses within this Code include some specific requirements that relate to cyber (information) security. Action is, in any case, required on:

- perimeter security;
- reporting on and responding to cyber (information) security breaches;
- the robustness and testing and control (in relation to resistance to cyber threats) of technologies (including software) and equipment wherever located or installed;
- keeping systems ‘up to date’ through manufacturer updates and ‘patches’;
- provisions to prevent the theft of data and related technologies/equipment (and the ability to remotely delete data therefrom);
- controlled access to the system that underpins service operation (including management of passwords and screen-saver time-outs);
- tracking of access to data by staff including, where appropriate, ‘defined access policies’ that relate to time periods and locations;
- encryption of data / information (to an adequate level) that is gathered and shared; and
- updating of anti-virus software.

Services shall be able to demonstrate that they have clear policies relating to cloud computing – guided by the principles set out in ISO 27017.

Services shall report to the TQG all cyber security breaches and the remedial action taken. Such reporting shall include dates and times together with an assessment of the impact to the service. It shall also be clear when and how relevant information about such breaches is made known to users and carers.

Services can usefully take account of schemes and initiatives (operated by appropriate agencies) that support them in taking appropriate cyber (information) security measures (and for which certification or accreditation may be possible). The support of approved security consultants could be considered.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
Insurances

Requirement:
Services shall carry current insurances including, for example, buildings and equipment, public and product liability, professional indemnity, employer’s liability, information (cyber-) security and, where appropriate, clinical negligence and relevant health (including key person) insurances.

Applicability:
Applicable to all services.

Guidance:
Insurances shall be at levels commensurate with the nature of the service provided and the risks that pertain to staff, service users and carers. A clear declaration regarding insurances shall be placed on the website. The declaration shall be dated and reviewed annually.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### B: ETHICAL PERSPECTIVES

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**Requirement:**
Services shall have a current mission statement that includes attention to ethical principles.

**Applicability:**
Applicable to all services.

**Guidance:**
The mission statement shall set a clear direction for the service with regard to its objectives and modus operandi and which is in accordance with the ethical principles for service provision in the healthcare or related fields that apply. The service’s mission statement shall be posted on the website. It shall be dated and reviewed annually.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

| B2     | Quality Plan |

**Requirement:**
Services shall have a quality plan that defines the purpose of the service, how these purposes are achieved and how service progress in relation to the purposes are reviewed. It shall address for each quality objective, the procedure by which risks are mitigated in relation to the same.

**Applicability:**
Applicable to all services.

**Guidance:**
The quality plan contributes to service objectives associated with transparency, accountability, safety and effectiveness. It shall make clear who is responsible for its implementation, monitoring and review; and shall clearly reference the service’s resources and their usage / management. It shall show how it ensures that the quality and quantity of data collected or shared is sufficient for effective service operation.

The quality plan shall be included in a portfolio (or manual) of key policy and practice documents. It shall be dated and reviewed annually.

**ISO/TS 13131:**
This requirement, together with other clauses covers Clauses 6.1 to 6.8, 8.1, 8.4, 14.6 and 14.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
B3 Conflicts of Interest

Requirement:
Services shall ensure that all directors, staff, agents and sub-contractors are transparent about and manage conflicts or potential conflicts of interest that relate to their activities, involvement and/or shareholdings, in or outside the telehealth service.

Applicability:
Applicable to all services.

Guidance:
Conflicts of interest might include shareholdings or official positions held or previously held by the individual him/herself or other connected persons (including close family members) in bodies with which the telehealth service has significant dealings.

Such directors, staff, agents and sub-contractors or other connected persons shall not, in any case, acquire benefits from the telehealth service of such a magnitude that might impair his/her independence in the performance of his/her duties.

Service shall be aware of the potential for conflicts of interest for sub-contractors and intermediary organisations and seek to ensure that these are avoided or managed.

These conflicts or potential conflicts shall be included in an up to date register of interests held by the service.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
B4 Promotion and Marketing

Requirement:
Services shall not promote or market their wares by preying on fear, omitting important or giving misleading or unsubstantiated information.

Applicability:
Applicable to all services.

Guidance:
Some service users will be at higher risk than others in relation to their circumstances, health and well-being. Neither the extent of that risk, nor the anticipated benefits of telehealth, shall be exaggerated.

Misleading and/or unsubstantiated information might relate to e.g. claims regarding the medical credentials of the service and/or its staff or of the technologies used; or claims regarding service outcomes that are poorly evidenced.

Preying on fear includes the portrayal (in text, voice or images) of users or potential users (or those with whom it is intended that they might identify) in a way that is likely to create disproportionate worry or anxiety.

Good practice with regard to promotion and marketing might reference robust, validated and openly available research and/or evaluations that specifically relate to the service.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
B5 Providing Information for Users and Carers

Requirement:
Services shall make information about the service available to users and carers so they can exercise informed choices and give consent regarding their acceptance (or not) of the service and service options. An exception applies (see below).

Applicability:
Applicable to all services.

Guidance:
Informed choice means that users and carers shall receive information (whether in speech, written or printed material, in video, DVD or in apps) that is timely, clear and comprehensive. Through such information users and carers need to be made aware of service options; the risks and benefits pertaining to service operation; rights and responsibilities; arrangements for termination of or withdrawal from the service; and all applicable charges and costs (for different service options including those that apply when devices are supplied by users and carers themselves).

The information made available or provided shall normally be directly to users and carers but it is recognised that the contact may be indirect where intermediary organisations are involved. This does not obviate the need for timely information to be provided to users and carers whose primary contact is with an intermediary organisation.

Enabling the making of informed choices means that, in communicating information, proper attention is given by services to the needs of users and carers with e.g. hearing loss, sight loss, physical or cognitive impairments. Special considerations will normally apply where services are provided for the benefit of children.

Exceptionally, but only when authorised in law or applicable regulatory frameworks, the need for consent by users or carers may be overridden.

The provision of information does not extend to the marketing of products or services that do not relate to the purposes / objectives of the telehealth services. An opt-out shall be afforded to users and carers regarding such marketing.

ISO/TS 13131:
### B6 Taking Account of User and Carer Views

**Requirement:**
Services shall, in all aspects of their operation, give due consideration to the views, opinions and choices of their service users and carers.

**Applicability:**
Applicable to all services.

**Guidance:**
The views of the main beneficiary (user) shall take precedence over the views of carers except where the former are children without competence or adults with substantial dependency arising e.g. out of cognitive impairment or mental illness. Services may wish to demonstrate their willingness to take account of user and carer views through co-production approaches that facilitate their involvement in overall service planning; testing or trialling new products (with appropriate safeguards in place); making use of feedback (on-line or in other ways) in relation to service provision; or making follow-up calls after user or carer interactions with the service.

It is recognised that, where intermediary organisations are involved, obtaining the views of users and carers to the desired extent may not be possible.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### B7 Taking Account of Staff Views

**Requirement:**
Services shall give due consideration to the views, opinions and choices of their staff and consult with them wherever appropriate about relevant service plans or changes that impact on workflow, workloads, or required skills and training.

**Applicability:**
Applicable to all services.

**Guidance:**
The views of the staff are important to the effective operation of telehealth services and need to be taken into account. In some cases those views may be gathered through staff representatives. It is recognised that, where intermediary organisations are involved, obtaining the views of staff of those organisations would not be appropriate.

**ISO/TS 13131:**
This clause covers Clause 9.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## C: GOVERNANCE AND FINANCIAL ISSUES

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### C1 Governance Structure

**Requirement:**
Services shall have a clear governance structure (ensuring effective decision-making) that encourages good customer care.

**Applicability:**
Applicable to all services.

**Guidance:**
The operation of the governance structure shall be evidenced in the way that decisions are made, responsibilities assigned, accountability ensured, reporting processes practiced, and the way that staff are managed. The structure shall, where appropriate, include provision for clinical governance by which the needs of users with particular needs as ‘patients’ are taken into account.

The extent to which services satisfy the requirement of this clause takes account of other clauses elsewhere within the Code.

A clear declaration regarding the governance framework shall be placed on the website. It shall be dated and reviewed annually.

Services shall be guided by the principles set out in ISO 9001 and 22301.

**ISO/TS 13131:**
This clause covers Clauses 10.1 and 10.2 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
C2 Business Continuity Plan

Requirement:
Services shall have a business continuity plan.

Applicability:
Applicable to all services.

Guidance:
Services shall have a current business continuity plan that supports service dependability and determines the way in which disruption to the service will be dealt with or closure of the service achieved - whilst, at the same time, providing safeguards for users and carers (including those regarding their personal data).

Considerations around disruption might include (among other things) network failures, information (cyber-) security breaches (including DDoS, distributed denial of service attacks), extreme weather, employee illness, loss of a key sub-contractor or service insolvency.

If there are planned changes to the network supplier, careful consideration shall be given to ensure that any disruption to the service is minimised – with service users, carers and others being informed at least three months in advance.

The business continuity plan shall dated and key elements tested at an appropriate level, at least annually.

Services shall be guided by the principles set out in ISO 22301 and 27017.

ISO/TS 13131:
This clause covers Clauses 8.1, 8.3, 10.4, 10.6 and 13.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
C3  Risk Management

Requirement:
Services shall have a current risk management system that takes account of the outcomes of risk assessments and seeks to reduce the likelihood and impact of any adverse incidents for all elements of service provision.

Applicability:
Applicable to all services.

Guidance:
This system and related documents shall identify and follow a clear risk assessment process by which these are assessed and prioritised. It/they shall cover risks that relate to buildings, the communications infrastructure, information (cyber-) security, contamination of equipment/technologies and other matters relating to service provision. Specific and close attention shall be given to risks to staff including those that attach to in-person (home) visits where these are undertaken; and to the risks to users and carers relating to service provision and usage. The system and related documents shall (except for new services) set out, in summary, how adverse events or risks evident within or arising during the prior year have been dealt with or countered. Key information relating to the same shall be included within the Quality Plan.

Services shall be guided by the principles set out in ISO 27005.

ISO/TS 13131:
This clause together with C5, H1 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
C4 Maintaining Records

Requirement:
Services shall maintain comprehensive and up to date records for the service.

Applicability:
Applicable to all services.

Guidance:
Records shall document actions pertaining to service operation and service users stating the modes of such actions (extending from electronic communications to written information and involving data, images, video and voice information). They shall include matters such as

★ personal (health and related) information regarding service users and carers;
★ in-person (home) visits and tele-consultations;
★ other interactions with service users and carers;
★ interactions or consultations with health, social care and other professionals;
★ care and support ‘packages’; and
★ detail of consents given and related service protocols.

These records shall be held for the period of service (to or for a user) plus a minimum further two years or in accordance with country, state, province or region specific legislative or regulatory requirements.

Records shall also document information on

★ staff engaged; and the
★ qualifications, training and competencies of staff.

These records shall be held for the period of staff engagement/employment plus a minimum further two years or in accordance with country, state, province or region specific legislative or regulatory requirements.

Records shall also document information on

★ protection against cyber (information) security breaches; and the
★ nature and frequency of occurrence of such breaches.

These records shall be held for a minimum of four years or in accordance with country, state, province or region specific legislative or regulatory requirements.

Services shall be guided by the principles set out in ISO 9001, 22301 and 27001.

ISO/TS 13131:
This clause covers Clauses 10.7 and 14.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
C5 Back Up IT Arrangements

Requirement:
Services shall maintain procedures for real time or, at a minimum, daily transfer of information relating to service operation and the personal data of users and carers, to a secure environment.

Applicability:
Applicable to all services.

Guidance:
The back-up procedures shall relate to all core functions of the service. These shall enable the minimisation of any disruption following an ‘event’ and the continued operation (or prompt recommencement of operation) at a satisfactory level (i.e. with on-going monitoring of or for service users). The procedures shall take account of the potential for disruption that can arise due to IT failure or an cyber (information) security attacks, problems with the telecommunications network or staff shortages. In any event the procedures must ensure that personal information regarding service users and carers (and access to it) is safeguarded.

Services shall be guided by the principles set out in ISO 27005.

ISO/TS 13131:
This clause together with C3, H1 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
D: PERSONAL INFORMATION MANAGEMENT

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### D1 Protecting Personal Information

**Requirement:**

Services shall maintain current policies and procedures for the management and protection of personal information. An exception applies (see below).

**Applicability:**

Applicable to all services.

**Guidance:**

These policies and procedures shall ensure that services operate in a manner that is fully in accordance with country, state, province or region specific legislative or regulatory requirements. The policies and procedures shall give attention to the transfer of personal information over publicly accessible networks and the manner in which such information is accessed - whether via fixed or portable devices. Specific procedures for the protection of personal information shall be included.

Policies and procedures shall ensure that the manner of storage, management and sharing of personal information normally carries the consent of users and carers. It follows that such consent shall be renewed prior to any proposed change in arrangements for the transfer or storage of personal information. Staff shall be precluded from storing data on their personal technologies/equipment except in authorised circumstances (such as when on-site and alternatives are not possible).

In this context, services shall demonstrate an understanding that personal information is owned by the users and carers themselves. It is, therefore, entrusted, with their consent, by users and carers to the service for the contracted period and can only be retained by a service provider in certain circumstances.

Exceptionally, but only when authorised by law, the need for consent may be overridden.

Policies relating to the management and protection of personal information shall be posted on the website. They shall be dated and reviewed annually. Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**

D2 Staff Access to Personal Information

Requirement:
Services shall ensure that only authorised staff can input, amend or access personal information regarding users and carers and their service usage.

Applicability:
Applicable to all services.

Guidance:
Inputting of information shall only be undertaken by authorised staff (see below). An exception applies for users and carers when they upload information e.g. regarding measures of their vital signs. Alteration of personal information shall only be undertaken for the correction of errors or the making of clarifications. A clear record (i.e. providing an audit trail) shall be maintained of where, when, by whom and for what purpose access, inputting, addition, correction or alteration to personal information was made.

The accessing and use of personal data or any wider data harvesting shall only be undertaken with the consent of users and carers.

Authorised staff may include those from partner agencies, sub-contractors or intermediary organisations where there are clear contractual arrangements in place (and, exceptionally, other authorised persons).

Exceptionally, but only when authorised by law, the need for consent may be overridden.

Services shall be guided by the principles set out in ISO 27001.

ISO/TS 13131:
D3 User and Carer Access to Personal Information

Requirement:
Services shall make provision for users and carers to access their personal information.

Applicability:
Applicable to all services.

Guidance:
Full access to personal information (including audit trails relating to access to and usage of the same) shall be available to users and carers. They shall not be able to alter or add to such information except in respect of updating their circumstances or service choices (including making or changing appointments); and when uploading information e.g. regarding measures of their vital signs. Their right to request corrections and, in certain circumstances, to object to the processing of their personal data shall be recognised. It follows that services shall respond favourably to reasonable user and carer requests on such matters (including amendments to and corrections of their personal information).

This right of access extends to users and carers where the service is provided through a contracted arrangement with an intermediary organisation.


ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

D4 Further Usage of Personal Information

Requirement:
Services shall ensure that users and carers are aware of whether, how and in what circumstances their personal information is shared with other bodies (opt-outs shall apply).

Applicability:
Applicable where part of the service.

Guidance:
Wherever data is made available to a third party there shall be a legally binding agreement regarding its use and safeguarding.

Sharing may or may not be subject to anonymisation or pseudo-anonymisation. In the case of the latter, the procedure selected shall ensure that reasonable steps are taken to remove the possibility that individuals can be identified from the information in question.


ISO/TS:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
Dealing with Personal Information after Service Cessation

**Requirement:**
Services shall, after service cessation, keep the personal information of users and carers securely pending its transfer, deletion and/or anonymisation.

**Applicability:**
Applicable to all services.

**Guidance:**
After service cessation, full access to personal information shall be available to users and carers and authorised others for a minimum period of six years or in accordance with country, state, province or region specific legislative or regulatory requirements. Users and carers shall retain the right for such data to be released, transferred (e.g. to an alternative service) or erased by the service when formally requested to do so by them (or by their heirs or legal representatives). Copies of such data can only be retained by a service provider in certain circumstances that will normally require the consent of users and carers.

Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**
This clause together with D1 covers Clauses 14.1, 14.2 and 14.4 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### E: STAFF AND STAFF MANAGEMENT

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#### E1 Sufficiency of Staff for Service Provision

**Requirement:**
Services shall engage a sufficient range and number of staff, agents and sub-contractors with skills, knowledge and competencies that are commensurate with safe, effective and sustained operation of the service.

**Applicability:**
Applicable to all services.

**Guidance:**
Services shall be able to demonstrate how they determine and monitor, on an ongoing basis, the appropriate number of staff (and their skills, knowledge and competencies) in relation to each aspect of the service; how they respond where there are deficiencies (including dealing with high volumes of calls or incoming information and/or situations that may threaten business continuity); the extent to which staff roles and functions are supported by or, in part, replaced through automated elements of the service; and how they plan for their staff resource in the context of service maintenance, growth or development.

**ISO/TS 13131:**
This clause together with E5 covers Clauses 9.1, 9.2 and 14.6 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
E2 Staff Recruitment and Leaving Policies

Requirement:
Services shall have staff recruitment and leaving policies that are relevant to the nature of their service.

Applicability:
Applicable to all services.

Guidance:
The recruitment policies (or policy) shall seek to ensure that staff are of good character and demonstrate informed and empathetic approaches. Services shall normally employ staff with the relevant health, social care and/or related expertise and/or have ready access to such expertise during the contracted hours of service provision.

Staff who have contact with users and carers shall be issued with appropriate identification documents, badges and, where appropriate, uniforms. When a member of staff leaves, these documents together with all IT equipment held by him/her, and all other information relating to the service that is held by him/her shall be recovered with due speed; and passwords, etc. that permit access to databases, non-public parts of any websites, etc. immediately cancelled.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
E3 Providing for the Support and Well-being of Staff

Requirement:
Services shall make provision for the support, well-being, comfort and security of their staff.

Applicability:
Applicable to all services.

Guidance:
In seeking to ensure the well-being and comfort of staff, services shall give consideration to the way in which staff are managed and their performance reviewed; and also to their places of work and to the travel undertaken in the course of their work.

For staff who may undertake work from home they shall have sole and secure access (i.e. not shared with co-residents, family members or others) to technologies, equipment or software used for the service; and there shall be reasonable precautions taken by staff to preclude access to or viewing by any other person; and to avoid damage by children, pets, etc.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

E4 Safeguarding Staff when Travelling and Visiting

Requirement:
Services shall have procedures and practices that help to safeguard staff when travelling and visiting in the course of their work.

Applicability:
Applicable to all services.

Guidance:
Travel may be to/from in-person (home) visits to users and carers or for other work related reasons (including training). The procedures and practices shall ensure that staff are clear about their shared responsibility with the telehealth service provider for their personal safety and shall follow these.

The risks associated with lone working and/or of travel in insecure areas shall be taken account of and suitable precautionary or ‘alert’ procedures put in place where warranted. The latter may include precluding unaccompanied entry to certain geographical areas or properties and/or the usage/operation of (lone) worker monitoring procedures.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
**E5 Staff Training and Development**

**Requirement:**
Services shall provide staff with (or support them in accessing) training and opportunities for personal development.

**Applicability:**
Applicable to all services.

**Guidance:**
Training shall ensure that staff acquire, maintain and develop relevant knowledge, skills and competencies. The content of the training shall address, where applicable, appropriate communications methods that e.g. take account of the needs of users and carers who may have communication difficulties because of cognitive, physical or sensory impairments (including those who may be deaf or hard of hearing). It shall include thorough attention to cyber (information) security issues and the shared responsibility that they carry with regard to such matters.

**ISO/TS 13131:**
This clause together with E1 covers Clause 9.2 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

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**E6 Special Skills and Knowledge**

**Requirement:**
Services shall ensure that staff, agents and sub-contractors have skills and knowledge commensurate with service provision in relation to all specialist areas for which they claim expertise.

**Applicability:**
Applicable where part of the service.

**Guidance:**
This substantial breadth of telehealth services in relation to the ‘markets’ served and the associated needs of service users and carers means that some will focus on particular groups. Indeed the whole rationale for some services will relate to some such needs. Examples of such groups could include services for people with (or who experience) one or more of depression and/or mental health problems; seizures relating to epilepsy or other conditions; falls; a dementia; pregnancy or post natal needs.

The consequence will frequently be service configurations (and accompanying operational procedures) that demand particular skills and knowledge to be in place.

Hence where services make special claims with regard to the merits of their service for particular groups of beneficiaries, this must be supported by evidence of specialist skills and knowledge being in place.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
E7 Whistle-blowing Policy

Requirement:
Services shall have a whistle-blowing policy by which staff can report any concerns.

Applicability:
Applicable to all services.

Guidance:
This policy shall ensure that all staff are fully aware of their responsibility to, and the avenues by which they can (in confidence and without prejudice to themselves) report if elements of the service may have fallen or be at risk of falling below the required standards.

It follows that contracts for staff shall contain a suitable ‘whistle-blower’ clause and that procedures for reporting their concerns shall be set out. Reporting that may be construed as ‘whistle-blowing’ shall, in normal circumstances, be to a more senior (or a designated) staff member. But an alternative option, e.g. reporting to the certification body (i.e. the TQG or its agents) or the main national body responsible for quality of health and/or social care services, shall also be clearly pointed to. In either circumstance, any concerns reported by staff shall be treated in confidence, properly documented and held securely. Provision shall, in addition, be made to protect, where appropriate, the anonymity of the informant.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F: CONTACT WITH USERS AND CARERS

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**Agreements with Users and Carers**

**Requirement:**
Services shall have an agreement with users and carers regarding the manner of service provision (including supply of technologies/equipment), selected payment option(s) where they apply, arrangements for gathering personal information, response protocols, and procedures for service discontinuation.

**Applicability:**
Applicable to all services.

**Guidance:**
Agreements shall clearly set out details of the service (including the technologies/equipment supplied/used and any applicable costs) and the rights and obligations of the parties concerned. They shall include attention to processes that relate to consent; protocols for handling personal information; the following of clinical guidelines and protocols where applicable; charges for different service options (including when users/carers supply their own devices); and the process by which users and carers can withdraw from the service (and any penalties that apply).

Agreements shall enable early termination, without any charge or penalty, where this is initiated by users or carers because of a significant deterioration in health/medical need; or in the availability of (formal or informal) carer support; or because of the necessity to move to a specialised care institution; or end of life. Such agreements may be within the context of personal service plans and will normally be referenced in applicable formal contracts.

Where appropriate, agreements may include encouragement for users and carers to periodically test their telehealth equipment. Service provision shall not, however, depend on such action being undertaken.

Where re-cycled technologies/equipment are provided, users and carers shall be clearly informed of this.

It is recognised that some agreements may be given effect through sub-contractors and/or intermediary organisations.

Services shall be guided by the principles set out in ISO 9001.

**ISO/TS 13131:**
This clause covers Clauses 8.1, 8.2, 10.5 and 11.1 to 11.4 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F2  In-person Visits by Staff (including Mobile Responders)

Requirement:
Services shall have policies, where included as part of the contracted service, for in-person (home) visits by authorised staff (including those staff who may be designated as mobile responders) to users and carers.

Applicability:
Applicable where part of the service.

Guidance:
In-person (home) visits shall only be undertaken by authorised staff and shall follow clear procedures. These shall include

 ★ agreement with users and carers or other relevant persons for the visits and/or due advance notice being given;
 ★ a record being made of the visit, its purpose and its outcome; and
 ★ any special considerations regarding e.g. access to property.

As well as relating to those aspects of the service concerned with health and well-being, the above applies to visits made for the purpose of delivery, installation, removal, replacement, etc. of technologies/equipment.

Specific procedures for in-person visits shall apply when responses are made by services to known or suspected urgent or necessitous circumstances (e.g. by mobile responders). These shall include the manner in which clear endeavours are made to contact users and carers or other relevant persons (e.g. key-holders, relatives); and the means by which the identity of all persons involved is readily verified.

Authorised staff making in-person (home) visits shall carry identification, including a photo, to be proffered to (potential) users and carers (and other persons) on arrival. Staff shall, where not explicit (or in the case of any doubt), make it clear to users and carers the reason for their visit.

Where planned visits are delayed, notification shall be made to users and carers and/or other relevant persons of the same.

ISO/TS 13131:
This clause covers Clause 14.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F3 Tele-consultations (including Video-consultations)

Requirement:
Services shall have policies, where included as part of the contracted service, for tele-consultations with users and carers (via telephone, video-links, Skype, VSee, etc.).

Applicability:
Applicable where part of the service.

Guidance:
Tele-consultations (including video-consultations) shall only be undertaken by authorised staff and shall follow clear procedures. These shall include

★ agreement with users and carers or other relevant persons for the visits and/or due advance notice being given;
★ a record being made of the visit, its purpose and its outcome;
★ how interaction with users and/or carers is afforded the necessary level of privacy e.g. taking account of the potential presence of others;
★ audible and/or visual signals given to the user and/or carer; and
★ the adequacy for the consultation of the location (accommodation) in terms of space, comfort and privacy.

Authorised staff undertaking such consultations shall clearly identify themselves on-line at the beginning of the encounter. There shall be the means in place by which the identity of all persons involved is readily verified. Authorised staff shall, where not explicit, make it clear the reason for their ‘visit’. No opening of video or audio channels shall take place until the ‘call’ has been accepted by the user or carer (or an authorised member of staff on their behalf who is at the location of the user/carer) and the service provider.

Provision shall be made for tele-consultations (including video-consultations) to be initiated by or organised for users and/or carers as well as by the service provider. Provision shall also be made for users and/or carers to easily terminate such consultations. It shall, in either case, be clear to them when video and/or audio links have been closed.

It shall be borne in mind that inherent within such consultations is the transmission of personal information. Therefore services shall make it clear to users and carers when such consultations operate via non-encrypted public networks and systems.

Where tele-consultations (including video-consultations) initiated by services are delayed, notification shall be made to users and carers and/or other relevant persons.

ISO/TS 13131:
This clause covers Clauses 12.2, 12.3 and 14.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
**F4 Guidance (and Training) for Users and Carers**

**Requirement:**
Services shall provide guidance (and, where appropriate, training) to service users and carers.

**Applicability:**
Applicable to all services.

**Guidance:**
Guidance and (where appropriate, training) shall be provided in order to enhance the understanding of users and carers (and relevant others if necessary) of the service and the technologies/equipment concerned. This with a view to ensuring a sufficient level of competency in relation to their use of the service. It shall be recognised that guidance and training may be required periodically for some service users and carers. Services shall endeavour to meet such requirements (including through any sub-contractors and/or intermediary organisation).

Media options (including social media) could, in part, be used (e.g. via YouTube clips) for both guidance and training but with consideration requiring to be given to the extent to which users and carers can access the same.

**ISO/TS 13131:**
This clause covers Clause 11.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

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**F5 Personal Service Plans or Healthcare Plans with Users and Carers**

**Requirement:**
Services shall ensure that only authorised persons engage with users and carers to develop, agree and review personal service or healthcare plans.

**Applicability:**
Applicable where part of the service.

**Guidance:**
Personal service plans or healthcare plans, where they are used, shall take proper account of the needs, views and choices of users and carers. In some cases (where there are particular circumstances) such plans will necessarily be developed in collaboration with specialist staff, some of whom may be employed by partner (or other) agencies. Where appropriate they shall follow clinical guidelines and protocols that are determined by recognised professional bodies.

Personal service or healthcare plans shall be reviewed with users and carers as necessary (e.g. because of a change of circumstances) and at least annually.

**ISO/TS 13131:**
This clause together with F8 covers Clauses 10.3, 11.6 and 11.8 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F6 Prompts to Users and Carers with regard to Service Needs

**Requirement:**
Services shall ensure that service users and carers (including those who pay privately for the service or receive the service free of charge) are prompted, where appropriate, at least annually, to reconsider their service needs.

**Applicability:**
Applicable where part of the service.

**Guidance:**
Prompting in relation to service needs shall enable review with users and carers of service protocols, consents for the same and the merits (in light of any changing needs or preferences) of service options for users and carers. Where appropriate, amendments shall then be made to any personal service plans or healthcare plans and/or consideration given to where users or carers might benefit from complementary or different services.

It is recognised that, where intermediary organisations are involved, such prompting may require to be given effect by those organisations.

Services shall be guided by the principles set out in ISO 9001.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F7  Service Discontinuation by the Provider to Individual Users and Carers

Requirement:
Services shall be able to discontinue service provision to individual users and carers only where they are clearly in breach of their contractual obligations and/or are abusing the service. An exception applies (see below).

Applicability:
Applicable to all services.

Guidance:
Such discontinuation shall not take place without careful consideration being given of any potential consequential increased risk to users or carers. Where appropriate, services shall inform in advance and with reasonable notice (and, where necessary engage in a dialogue with) relevant health, social care or other agencies (including intermediary organisations). An exception applies in the event of service closure - where other provisions apply.

Discontinuation may be considered in the event of what may be considered as ‘abuse’ of the service – subject to this, and its definition, being included in the service contract. Circumstances that constitute abuse of the service by users or carers may, it is considered, include its repeated and ongoing and inappropriate non-use or use in ways that are outside those which have been agreed; which do not relate to the health or well-being of the user and/or carer; and/or are not commensurate with the purpose of the service.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

F8  Complaints and Suggestions

Requirement:
Services shall keep a record of complaints and suggestions made to them.

Applicability:
Applicable to all services.

Guidance:
This shall include and date all complaints and suggestions where these are made in writing (or other form of text). Services shall incorporate in their Outcomes Focused Appraisal how they have acted upon the complaints and suggestions received - together with the feedback from surveys of users and carers.

Services shall be guided by the principles set out in ISO 9001.

ISO/TS 13131:
This clause together with F5 covers Clause 11.8 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
**User and Carer Fault Reporting**

**Requirement:**
Services shall provide service users and carers with an easy means of reporting faults or failures of the technologies/equipment.

**Applicability:**
Applicable to all services.

**Guidance:**
There shall be a facility for users and carers to report faults via the service web-site and/or via telephone. Faults reported in this and other ways shall be dealt with promptly. Clear information about the facility to report faults shall be posted on the website. This shall be dated and reviewed annually.

Services should recognise that good practice in relation to such matters may include the use of technologies and communications systems that incorporate the ability to self-test and/or some level of redundancy whereby alternative communication routes may be used.

Services shall be guided by the principles set out in ISO 9001.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

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**User and Carer Changes to Network Supplier**

**Requirement:**
Where appropriate, services shall, in their contract agreements and supporting documents, make users and carers (and any sub-contractors and/or intermediary organisations) aware of the requirement to inform them of any intention (or desire) to make changes in their network supplier where this could affect access to or provision of the service.

**Applicability:**
Applicable where part of the service.

**Guidance:**
Reporting on any intended change by users and carers of their network supplier is important in view of the potential affect on service provision. A clause to this effect shall, where appropriate, be included within service contracts with users and carers or intermediary organisations.

Services should recognise that good practice in relation to this matter includes periodic prompting or reminders to users and carers to inform of any intention (or desire) to make changes.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### Abuse

**Requirement:**
Where appropriate, services, where there is contact with service users in their homes (whether face to face or through tele-consultations), shall have a policy relating to identification and the manner of dealing with abuse/potential abuse of users and/or carers.

**Applicability:**
Applicable where part of the service.

**Guidance:**
Training for staff shall ensure that they are aware of the potential for users and carers to be the victims of abuse (or neglect, itself a form of abuse). Procedures shall be in place for dealing with actual or suspected abuse by any person who has contact (whether face to face or through tele-consultations) with users or carers of the service; or of abuse that can take place between users and carers.

Such procedures shall include, where appropriate, making contact with or working in collaboration with relevant health, social care or law enforcement agencies.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## G: INTERPRETATION OF AND RESPONSES TO INFORMATION (OR ALERTS)

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<th>G1</th>
<th>Responding to Information Gathered through Remote Monitoring or ‘Alerts’</th>
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**Requirement:**
Services that provide remote monitoring shall ensure that timely action is taken where there is a known or indicated change in health, well-being and/or personal circumstances of users or carers.

**Applicability:**
Applicable where part of the service

**Guidance:**
Timely action may be immediate (e.g. in the event of falls, seizures or other necessitous circumstances) and is required regardless of whether there is a personal service plan in place. The nature of that action is such that it will normally require contact to be made with the user and/or carer; and may result in an in-person (home) or tele-consultation visit being made by a staff member. There may also be a need to review (sometimes with urgency) the way in which service operation responds to such changes or events. The action and its outcome shall be documented.

Some services will, in supporting users to self-manage, give automated information, advice or prompts to them that respond to changes in their health, well-being and/or personal circumstances. The limitations of such automated information shall be absolutely clear to users and carers and set out in contract documents and/or the advisory information provided to them.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
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<tr>
<th>G2</th>
<th>Handover After an Event or Change of Circumstances</th>
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<tr>
<td>Requirement:</td>
<td>Services shall follow procedures and protocols agreed with and configured for the specific benefit of individual users and carers relating to events or changes of circumstances.</td>
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<td>Applicability:</td>
<td>Applicable where part of the service</td>
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<tr>
<td>Guidance:</td>
<td>Procedures and protocols shall be in place that have been determined where necessary with the guidance of a clinician or other authorised health or social care practitioner or in accordance with the requirements of a service procurer or commissioner. They shall ensure that after actions have been taken that relate to the remit of the service (responding e.g. to an event or change of circumstances) that responsibility for user and carer health and wellbeing is satisfactorily handed over - unless it is already absolutely clear that any adverse change in (or specific threat to) health and well-being has been fully countered. This includes procedures and protocols that relate to the needs of users and carers at the end of a period of reablement (or rehabilitation). Services shall be guided by the principles set out in ISO 9001.</td>
</tr>
<tr>
<td>ISO/TS 13131:</td>
<td>This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.</td>
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**H: COMMUNICATIONS NETWORKS**

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<td>H1</td>
<td>Agreements between Services and Telecommunications Providers</td>
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**Requirement:**
Services shall maintain agreements with relevant telecommunications providers, companies or their agents by which use of the communications networks used is safeguarded.

**Applicability:**
Applicable to all services.

**Guidance:**
Agreements shall make clear (to users, carers, intermediary organisations and applicable others) the networks used and specify any guarantees (or the absence of any guarantees) regarding the integrity of the communications links.

Services shall be guided by the principles set out in ISO 22301 and 27001.

**ISO/TS 13131:**
This clause together with A5, C3, C5 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

| H2     | Monitoring of the Communications Networks |

**Requirement:**
Services shall monitor the communications networks used to ensure that they are operational and that faults are speedily identified and remedied.

**Applicability:**
Applicable to all services.

**Guidance:**
Reliability of the communications networks shall be a factor considered by services when selecting the network provider.

The outcomes of monitoring shall be recorded. The monitoring shall ensure that the integrity of communications networks is maintained in accordance with guarantees given. This shall include monitoring for cyber attacks.

Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**
This clause together with C3, C5 and H1 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
I: HARDWARE & TECHNOLOGICAL CONSIDERATIONS

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**Fitness for Purpose and Interoperability of Technologies/Equipment and Related Software**

**Requirement:**
Services shall operate using technologies/equipment (including operational software and apps) that are ‘fit for purpose’ and conform to relevant standards.

**Applicability:**
Applicable where part of the service

**Guidance:**
Fitness for purpose includes consideration of

★ the acceptability, accessibility and usability of the technologies/equipment to users and carers who may have physical (including dexterity) and sensory impairments;

★ the reliability of the technologies/equipment (e.g. their electro-magnetic compatibility with other devices);

★ the suitability of platforms for data handling;

★ the interoperability of the technologies/equipment;

★ the interoperability of health and personal information (e.g. where linking to electronic and/or personal health records);

★ the extent to which the technologies/equipment are designed to counter cyber (information) security threats;

★ their conformity with appropriate technical standards; and

★ the extent to which management of the technologies/equipment may be assisted through their capacity to automatically report their location and configuration.

Consideration of platforms for data handling might usefully consider the merits of FIHR (Fast Health Interoperability Resources) by which greater assurance might be gained with regard to the security, etc. of data related to personal (including health) data.

Appropriate testing of devices (including resistance to cyber attacks) can help in the process of determining fitness for purpose.

Medical devices, where included, shall be marked with their classification which, in the context of telehealth, will testify to their satisfying regulatory and licensing requirements of the relevant countries, states, provinces or regions. Some medical and other technologies/equipment and software will carry a CE (pertaining to the European Union) and/or an FCC (Federal Communications Commission, United States) mark that testifies to their safety.

Continues to next page
Where technologies/equipment are sourced or owned directly by users and carers (or any intermediary organisations), these will normally need to satisfy the same requirements. But subject to the integrity of communications systems or service operation not being compromised and personal information remaining protected, other devices may be linked. Note that where medical devices are linked to e.g. telecare or PRS services, specific requirements may consequentially apply to the whole ‘system’.

A clear **declaration** regarding the fitness for purpose of the technologies/equipment used shall be placed on the website. The declaration shall be dated and reviewed annually.

Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**
This clause together with I2, I3 and I6 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

## Database of Technologies/Equipment

**Requirement:**
Services shall maintain a contemporaneous and accurate database of technologies/equipment that is stored or supplied to users and carers.

**Applicability:**
Applicable where part of the service

**Guidance:**
Services shall be able to track the history and have full knowledge of the location of the technologies/equipment supplied by the service. This shall also include, where supplied by the service, a record of faults and repairs to the devices in question. At least annual stock audits shall be undertaken to assist in this.

The necessity for accuracy arises on account of cyber (information) security considerations such as those relating to the programmability of or isolation (in e.g. the case of infection) of devices.

A record shall also be made of technologies/equipment supplied by users and carers.

Services shall be guided by the principles set out in ISO 22301 and 27001.

**ISO/TS 13131:**
This clause together with I1, I3 and I6 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### Equipment Recall, Removal and Disconnection Procedures

**Requirement:**
Services shall have procedures for the recall, removal and/or disconnection of faulty or contaminated equipment from users and carers.

**Applicability:**
Applicable where part of the service

**Guidance:**
These procedures shall include, where appropriate, of the disconnection of technologies/equipment supplied by users and carers themselves. They shall ensure, wherever appropriate, timely replacement and/or provision of relevant advice or guidance to ensure that users and carers are safeguarded.

It is recognised that for some services such procedures may be given effect through intermediary organisations.

Services shall be guided by the principles set out in ISO 27017.

**ISO/TS 13131:**
This clause together with I1, I2 and I6 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### Protection and Safe-keeping of Technologies/Equipment

**Requirement:**
Services shall make provision for the protection, safe-keeping and storage of technologies/equipment.

**Applicability:**
Applicable where part of the service

**Guidance:**
The requirement for the protection and safekeeping of technologies/equipment shall be satisfied either directly by services or via arrangements with sub-contractors. It is recognised that such protection and safekeeping will, in some cases, be undertaken by intermediary organisations.

Responsibility for protection and safe-keeping of technologies / equipment that are supplied to users and carers will normally reside with them.

Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
Installation, Programming and Demonstrating of Technologies/Equipment

Requirement:
Services shall ensure that the installation, programming, calibration, initial testing and demonstrating of technologies/equipment, are undertaken in accordance with manufacturer’s or supplier’s guidance.

Applicability:
Applicable where part of the service

Guidance:
Installation and related work shall only be undertaken by people who have the required skills, knowledge and expertise. It follows that services shall make reasonable checks on the quality and effectiveness of the work undertaken to complete the tasks in question. In planning for installations or establishing the suitability of particular technologies/equipment, consideration shall be given to the effect on communications links that may arise because of the configuration of buildings (or the manner of their construction); to Internet speeds and/or the ‘coverage’ of mobile networks.

Where technologies/equipment are supplied by users and carers, these remain their responsibility but services need to be satisfied that installation, programming and calibration is undertaken in a way that meets the same requirements.

Services shall be guided by the principles set out in ISO 27001.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## 16 Maintenance, Servicing, Repair and Replacement of Technologies/Equipment

**Requirement:**
Services shall have robust procedures in place to enable maintenance, servicing, repair or replacement of technologies/equipment where supplied by the service.

**Applicability:**
Applicable where part of the service.

**Guidance:**
- Maintenance, servicing, repair or replacement shall be undertaken within contracted timescales, in accordance with manufacturer’s or supplier’s guidance only by people who have required skills, knowledge and expertise.
- Determining the maximum timescales for repairs and maintenance (within e.g. any contracted arrangement) will have involved consideration, by services, of the risks to users and carers. Required action may, for some services, be given effect through intermediary organisations.
- Maintenance shall include, wherever appropriate, cleansing and decontamination, (re)calibration, battery replacement (or re-charging) and functional checks.
- Separate quality assurance checks may be necessary for devices that measure vital signs or are used for testing at the point of care.

ISO/TS 13131:
This clause together with I1, I2 and I3 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## Recovery, Recycling and Re-Use of Technologies/Equipment

### Requirement:
Services shall have robust procedures in place for any technologies/equipment that is removed, recovered, returned, re-cycled or re-used (e.g. after service cessation for a prior user).

### Applicability:
Applicable where part of the service

### Guidance:
Procedures shall include attention to cleaning, disinfecting and decontamination, re-calibration, functional checks, battery replacement and full erasure of any personal data stored on the technologies/equipment concerned.

No previously used equipment shall be re-supplied to users and carers where there is significant wear and tear; including where casings are broken or cracked. There shall be no missing pieces. The process of cleaning, disinfecting and decontamination, as well as safeguarding users and carers, shall take account of the need to minimise the risk to staff who undertake such tasks or who transport the technologies/equipment.

Erasure of data held by any device shall only be undertaken after any requirement for submission to a health record has been satisfied. The process of erasure shall be double checked and the process recorded.

Where equipment is re-issued this shall be properly documented and made known in writing to users and carers for whom it is provided.

For recycling, the regulatory and licensing requirements of the relevant countries, states, provinces or regions shall be satisfied.

Services shall be guided by the principles set out in ISO 14001 and 27001.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
Appendix A:
Some Relevant ISO Standards

Where mentioned in specific clauses of the Code, services shall give attention to the International Organization for Standardization (ISO) standards mentioned. Services do not, however, need to be fully compliant with them with the exception of ISO/TS 13131. The summary descriptions below, excepting for ISO/TS 13131, are drawn from the ISO website (www.iso.org).

**ISO 9001: Quality Management Systems - Requirements**

ISO 9001 sets out the criteria for a quality management system. It is based on a number of quality management principles including strong customer focus, motivation and implication of top management, the process approach and continual improvement. The standard helps ensure customers get consistent, good quality products and services, which in turn brings many business benefits.

**ISO/TS 13131: Health Informatics – Telehealth Services – Quality Planning Guidelines**

ISO/TS 13131 provides ‘generally applicable’ quality planning guidelines for telehealth services – with telehealth being recognised as ‘the use of information technologies to deliver healthcare and transmit health information over both long and short distances.’ It strongly emphasises issues around risk management.

**ISO 13485: Medical devices – Quality Management Systems – Requirements for Regulatory Purposes**

ISO 13485 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

**ISO 14001: Environmental Management**

ISO 14001 specifies requirements for the development and implementation of an environmental management system. It relates to significant environmental matters over which organisations may have control or influence.

**ISO 22301: Societal Security – Business Continuity Management Systems - Requirements**

ISO 22301 specifies requirements to plan, establish, implement, operate, monitor, review, maintain and continually improve a documented management system to protect against, reduce the likelihood of occurrence, prepare for, respond to, and recover from disruptive incidents when they arise.

**ISO 27001: Information Security Management**

ISO 27001 specifies the requirements for establishing, implementing, operating, monitoring, reviewing, maintaining and improving an information security management system within the context of an organisation’s overall business risks.


ISO/IEC 27005 and 27017 provide guidelines for information security risk management. They support the general concepts specified in ISO/IEC 27001 and are designed to assist the satisfactory implementation of information security based on a risk management approach. ISO 27799 links to ISO/IEC 27017 and supports the interpretation and implementation in health informatics, whether words and numbers, sound recordings, drawings, video or medical images; and the means of their storage or transmission.
Appendix B:  
Guidelines for Services Seeking Certification

Introduction
The International Code of Practice for Telehealth Services provides a framework against which services can become certified. Certification provides an important level of assurance to service users and others. The most robust route to certification (see below) is through the use of an authorised body. This route is, therefore, highly recommended.

Before seeking certification through self-assessment or an authorised body, services must be current members of the Telehealth Quality Group (TQG). **No service is permitted to claim that they are certified against the International Code or to display the relevant logo without the specific written authority of the TQG.**

All certified services are listed on the TQG website at [www.telehealth.global](http://www.telehealth.global). Such services will have satisfied the requirements of all clauses within the Code that apply to their service.

Levels of Certification
Services can either self-assess or choose to be assessed by an authorised external, independent expert body. The route taken determines, after certification is achieved, which logo the service is able to display. The logos that apply in the case of successful assessment and certification are indicated below. The routes to certification are set out in the flow diagram overleaf.

Wherever a service is independently assessed by an authorised body it is a requirement that they are clear which body undertook the assessment. Publicity material, etc. must carry the logo of that authorised body as well as the relevant TQG (Telehealth Quality Group) logo. With regard to assessments through an authorised body, the TQG works with DNVGL Healthcare ([www.dnvgl.co.uk/assurance/healthcare](http://www.dnvgl.co.uk/assurance/healthcare)). DNVGL is an international certification organisation operating in over 100 countries – providing assessment and certification services that cover a wide range of fields. With regard to the work undertaken, DNVGL collaborates with TQG with regard to spot-checks or investigations for services that are certified via either route.

These guidelines offer an overview of procedures for services self-assessing or seeking assessment through an authorised body - and, then, seeking certification. Where assessment is sought through an authorised body, further specific conditions will apply.

The International Code and ISO/TS 13131
The Code incorporates the quality planning guidelines set out in ISO/TS 13131 (2014). This means that a telehealth service that is certified to this Code also meets the requirement of this Technical Specification (TS). Note, however, that the TS states (Para 4) that it ‘is not intended to be used for certification, regulatory or contractual purposes’. Services cannot, therefore, be certified specifically in relation to its requirements.
**Routes to Certification**

### Self-Assessment (undertaken by service)

1. **Application submitted with payment; checked by TQG.**
   - Major non-conformities identified.
   - Minor non-conformities identified.
   - Conditional Correction Notice is issued to service.
   - Service makes corrections; submits evidence within agreed timescale.
   - Service is not eligible for certification. Resubmission with payment required.

### Assessment by Independent Body

1. **Assessment undertaken by authorised independent body**
   - Major or minor non-conformities identified.
   - Findings issued to service. May require ‘Corrective Action Plan’
   - Service makes corrections; submits evidence within agreed timescale.
   - Service does not make corrections; fails to submit evidence within agreed timescale.
   - Service is not eligible for certification.
   - No non-conformities identified. Recommendation for certification made to TQG Certification Board.
   - Service certified subject to payment. Certification issued. Feedback sent to service.
Certification

Certification gives reassurance to:

- service providers and their staff;
- users of the services and their carers;
- organisations that procure or commission services;
- health insurers; and
- governments, health and support agencies with an interest in telehealth.

Certification can be retained for either one or three years depending on the route taken. This is subject to it being clearly and continuously evidenced by the service that it satisfies all relevant clauses of the Code. This means that services must be alert on an ongoing basis to:

a) the requirements of the relevant clauses - including any changes or adjustments that are incorporated in each year’s or biennial (every two years) version (normally released between December and January).

b) the fact that spot checks of the service can take place at any time and that, if significant shortcomings are identified, certification can be suspended or withdrawn.

Services must also be aware that changes in the nature of their service may mean that their ability to meet the requirements of some clauses may be compromised, or that ‘other’ clauses may require to be met. Such changes in the nature of services that impact on their conformity with Code requirements must be notified to the TQG and will require to be clearly evidenced.

Self-Assessment

Services that wish to self-assess must very carefully examine the relevance of and the extent of their conformity in relation to the requirements of each clause within the current version of the Code. An up to date version of the Code will always be available to download from the website at www.telehealth.global.

A thorough and honest self-assessment will enable the necessary evidence regarding conformity with the requirements of the Code to be gathered. It will also enable the identification of any gaps, shortcomings or omissions that need to be remedied. A Self-Assessment Tool has been developed to assist services that plan to seek certification. This can be obtained by application to the TQG.

Services that self-assess can either directly seek certification via the TQG or opt for assessment by an approved body. In the event of directly seeking certification through the TQG (following self-assessment), the application is considered by the TQG Certification Board. If approved by the TQG Certification Board the certification conferred lasts for one year. Services are then required to undertake a specific fresh self-assessment exercise and re-apply for approval (as a certified service) in order to continue to be permitted to use the approved logo. The logo is only issued on payment of the requisite fee to the TQG.

Assessment by Authorised Independent Body

DNVGL (www.dnvgl.co.uk/assurance/healthcare) is the first authorised body able to undertake assessments and spot-checks in relation to the Code. It is recommended that services seeking certification consider the added value that assessment via this route to certification confers.

When a service is ready to seek assessment (perhaps after using the Self-Assessment Tool) by which they can then apply for certification, they are required to complete the Certification Application Form (available on the Telehealth Quality Group website) and send it to the authorised body with a copy to the TQG. Once the contract for assessment with the authorised body has been agreed, that body will contact the service to agree a date for what will be a Foundation Assessment. A Foundation Assessment is undertaken at the outset of the three-year assessment cycle.
(see diagram overleaf). It is a thorough and robust assessment of the whole service. And unless otherwise agreed, Foundation Assessments always involve on-site visits (to one or more sites of service provision) by the approved body. The assessment includes a review of documentation; of systems, processes and procedures; and involves meetings with staff with different kinds and levels of responsibility.

The service will be issued (by the approved body) with contact details for a lead assessor who will be able to assist with queries relating to the assessment (and subsequent certification) process. The approved body can also clarify the expectations that are set out in the guidelines provided for each clause in the Code.

The three year cycle that relates to certification, following assessment by an authorised body, includes Interim Assessments and Spot-Checks (the nature of which is outlined below).

The authorised body will decide on the duration of assessments undertaken. The TQG and/or the authorised body will decide on the nature and duration of any spot-checks. Key factors in determining the structure and length of assessments are the:

- the complexity of services provided (taking account of different service ‘models’);
- number of service users and the extent of service user needs; and the
- number of staff working at the service, including relevant subcontractors.

In advance of the on-site visit, the lead assessor/auditor or his/her staff will review the website and relevant documents provided by the service as part of the assessment process. If such documents and declarations are not on the website such information / declarations must be provided or signposted a minimum one week prior to any assessment date.

Undertaking a thorough and honest self-assessment (perhaps using the Self-Assessment Tool) against the requirements of the Code will enable services to collate the necessary material and ensure readiness for assessment by an authorised body.

The assessment team from the authorised body will include one or more professionals from a range of health, social care and related disciplines. Where appropriate these will have undergone additional training from leading experts. They will have extensive experience of inspections, assessments and audits for health and social care organisations – public and private, local and national.
This is not, however, just a top-down process. The assessors work in partnership with services in order to help them achieve their goals. All the assessors are, in addition, committed to maintaining the utmost confidentiality when undertaken assessments.

Upon receipt of the completed Certification Application Form, the authorised body will review the information and provide a clear and transparent cost for undertaking the assessment. Those costs are directly payable to the authorised body in question. At 2018, for small (non-complex) services with clear operational procedures, there is a modest cost (not less than €3500) for a Foundation Assessment. The cost is higher for larger and more complex services. The agreed sum must be paid to the authorised body.

The cost of the Foundation Assessment is normally followed by lower costs for Interim Assessments in the ensuing two years. Note, however, that some ‘pass-porting’ can assist Foundation Assessments and may be permitted where a service is currently certified or accredited to another code. This can result in a lower cost being incurred. The other codes and quality marks that the TQG will consider for such pass-porting are listed in the main document. Some consideration may also be given where a service has been certified to ISO9000 or ISO9001.

After the Foundation Assessment, the TQG Certification Board will be given a recommendation by the authorised body and will (normally quickly) award certification and issue, subject to appropriate fees having been paid, a special logo for use by the service (for a three year period).

Interim Assessments are undertaken where initial certification has taken place after assessment through an authorised independent body. They occur at twelve month intervals between the Foundation Assessment and the expiry of the period of certification (three years). They can be on- or off-site. The reviews are risk based in their approach but also explore other areas, on a sampled basis, for different areas of service provision.

Spot Checks

Note that all services, whether certified after self-assessment or an assessment by an authorised independent body, are liable to spot-checks by that body or by the TQG (or both, acting in concert). They may include on-site visits and/or reviews of publicly available information on the service website.

There is an absolute obligation for service to facilitate spot-checks at any time (including, night-time, weekends and national holidays where services operate on this basis). This requires that a process must be in place to facilitate access to the premises of service providers (and management and operational staff) by TQG nominated persons (that may be of an authorised independent body). The process must include the means by which the identity of nominated persons and service staff can be verified. The very essence of spot-checks is that there may be no prior notice. Their nature and duration is determined by the TQG and/or the assessment body.

Certified services, as well as having an obligation to facilitate spot-checks (and, if necessary, further investigations if these are necessary) must accept the fact that the outcome of a spot-check (or an Interim or Foundation Assessment) can mean certification being suspended or revoked (see below).

Use of Logos

Certified services are free to use the relevant logo (indicating certification) on websites, literature, and business cards; also in publicity and promotional material.

Appeals Procedure

If there are concerns about the conduct of the assessors/auditors, assessment process and/or the conduct of spot-checks, these should be notified directly with the authorised body whenever they are involved; otherwise with the TQG. Such notification should be sent by a secure means within 20 working days of the matter arising (including if this relates to concerns or disagreements about the outcome of an assessment).
Service Reviews and Support Visits

Service reviews or support visits from the TQG or an authorised independent body can be conducted at the request of services (whether or not certified) at any point in order to provide further guidance on how to seek or maintain certification, and/or how to conform to the requirements of the Code. The approach is a supportive one; to share experience and good practice from other services (but with confidentiality being maintained) and to draw from the assessment teams’ extensive experience. Undertaking support visits cannot, of course, guarantee successful certification. Such service reviews or support visits will normally carry a charge.

Non Conformities

It must always be borne in mind that the assessment and certification process is concerned with the setting and maintaining of a quality service benchmark. The assessment process and that which relates to spot-checks is, therefore, robust. But a helpful part of the assessment process is the way in which prompt feedback is given to services regarding any non-conformity with the requirements of the Code. This feedback may be provided either separate to or within reports produced relating to Foundation or Interim Assessments and/or spot-checks.

Feedback that indicates a minor non-conformity would relate to a single shortcoming in relation to a particular clause requirement – but where there is no significant detriment to the service. Such a failure would not incur any additional risk to staff, service users or others, but nevertheless would require remedy with due speed. A minor non-conformity can become a major non-conformity if not remedied within an agreed timescale.

A major non-conformity would relate to one or more failures in relation to clause requirements – where there is an actual or potential additional risk to staff, service users or others and/or other significant detriment to the service. Urgent remediying of such major non-conformities may be required; failure to make such remedies in a timely way is likely to lead to certification not being given; or an existing certification being suspended or revoked (see below).

The flow chart earlier in this Appendix shows the process of assessment.

Suspension or Revocation of Certification

The Telehealth Quality Group may suspend or terminate certification in cases where:

- it becomes aware through assessments, spot-checks, independent investigations, or other activities, that the service poses an immediate and unacceptable risk to the safety of service users, staff or others;
- a service fails to submit required information for assessment or certification purposes;
- a service does not seek timely renewal of its certification through the required processes;
- the service is in breach of contract arrangements with an authorised assessment body;
- the service has not paid necessary fees;
- the service does not give access for assessors or authorised others as part of the assessment process or for spot-checks; or
- the service has made false public claims regarding its certification.

The Telehealth Quality Group will liaise with authorised bodies with regard to suspension or revocation of certification wherever appropriate, and will normally provide the service with a warning that suspension is being considered. Suspension of certification will be notified in writing – making clear the situation that has led to suspension as well as setting out the requirements and timelines that must be met if reinstatement of certification is to be considered.

Revocation of certification requires immediate termination of the use of the certification logo and references to such certification on the website, on letterheads, marketing material, etc. The listing of the service on the Telehealth Quality Group website (as one that is certified to the Code) will be removed. If the failings are such that they are considered a risk to the reputation of the TQG, then suspension from or expulsion from membership will be considered.

End