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Postopek ocenjevanja izpostavljenosti delavcev z aktivnimi medicinskimi vsadki elektromagnetnim poljem - 2-3. del: Specifično ocenjevanje delavcev z vsadljivimi nevrostimulatorji

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-3: Specific assessment for workers with implantable neurostimulators

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ICS:

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Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-3: Specific assessment for workers with implantable neurostimulators

To be completed

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This draft European Standard is submitted to CENELEC members for enquiry.
Deadline for CENELEC: 2020-02-28.

It has been drawn up by CLC/TC 106X.

If this draft becomes a European Standard, CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 50527-2-3:2019) has been prepared by CLC/TC 106X “Electromagnetic fields in the human environment”.

This document is currently submitted to the Enquiry.

The following dates are proposed:

• latest date by which the existence of this document has to be announced at national level	(doa)	dor + 6 months
• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	dor + 12 months
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	dor + 36 months (to be confirmed or modified when voting)

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

1 Scope

This document provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted neurostimulator systems (NS), specifically of the type used for spinal cord stimulation (SCS).

It is recognized that implantable neurostimulators have been developed for a wide variety of clinical applications, however the SCS devices within the scope of this document represent the largest segment of the implantable neurostimulator applications thus far.

NOTE 1 If the worker has other Active Implantable Medical Devices (AIMDs) implanted additionally, they are assessed separately according to EN 50527-1 or other particular standards within the EN 50527 series.

The purpose of the specific assessment is to determine the risk for workers with implanted SCS devices arising from exposure to electromagnetic fields (EMF) at the workplace. The assessment includes the likelihood of clinically significant effects and takes both transient and long-term exposure within specific areas of the workplace into account.

NOTE 2 This document does not address risks from contact currents or the effects upon any associated external devices.

The techniques described in the different approaches can also be used for the assessment of publicly accessible areas.

The frequency range to be observed is from 0 Hz to 3 GHz. Above 3 GHz no interference with the devices within the scope of this document is expected to occur.

NOTE 3 The rationale for limiting the observation range to 3 GHz can be found in ISO 14708-3.

NOTE 4 Further information concerning the functions of neurostimulator systems can be found at https://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spinal-Cord-Stimulation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 50527-1:2016, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 1: General*

EN ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 50527-1:2016 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
implantable pulse generator
IPG
part of the active implantable medical device, including the power supply and electronic circuit that produces an electrical output

3.2
neurostimulator system
NS
active implantable medical device comprising an implantable pulse generator and includes therapy delivering electrodes usually part of implanted electrical leads that are intended to deliver therapy to a patient by electrically stimulating certain nerve structures, along with an associated external patient programming device

3.3
electrode
electrically conducting part (usually the termination of a lead) which is designed to form an interface with body tissue or body fluid

3.4
bipolar lead
lead with at least two electrodes that are electrically isolated from each other

3.5
AIMD-Employee
worker with an active implantable medical device

Note 1 to entry: For the purposes of this document, the term AIMD-Employee refers to the patient whose implant consists of a neurostimulator system of the type intended for spinal cord stimulation.

3.6
assessment team
team consisting of:

— employer and if applicable, his occupational health and safety experts and/or occupational physician;

— AIMD-Employee and his responsible physician;

— (technical and medical) experts as necessary, e.g. manufacturer of the device

3.7
unipolar stimulation
stimulation using a single electrode with reference to the outer shell of the implantable pulse generator

3.8
single lead bipolar stimulation
stimulation using two or more adjacent electrodes of a single lead structure

Note 1 to entry: Leads for use with SCS devices typically have a minimum of 8 electrodes.

3.9
two lead bipolar stimulation
stimulation using two electrodes located on two separate leads that are implanted in close proximity to one another

3.10
EM phantom
physical model containing tissue-equivalent material used to simulate the body in an experimental dose measurement

Note 1 to entry: EM phantoms are sometimes also referred to as torso simulator or phantom.

[SOURCE: World Health Organization]

3.11
uninfluenced behaviour
conditions for uninfluenced behaviour are provided in EN 50527-1:2016, 4.1.3

3.12
device
<in the context of this document> implanted spinal cord stimulator

3.13
electromagnetic field
EMF
<in the context of this document> alternating electric field, alternating magnetic field, or radio wave between 1 Hz and 3 GHz whether continuous, pulsed, or modulated in space or time

3.14
static field
SF
static magnetic field
SMF
static electric field
SEF
static (stationary) or quasi-static (below 1 Hz) electric field or magnetic field whether continuous, pulsed, or modulated in space or time

3.15
spinal cord stimulator
SCS
neurostimulator system designed specifically for stimulation of the human spinal cord to treat chronic pain by electrically stimulating the spinal cord but not the Dorsal Root Ganglion (DRG)

4 Specific assessment

4.1 Description of the assessment process

4.1.1 General

Spinal Cord Stimulation (SCS) is generally used for chronic pain reduction. The stimulation does not provide therapy in direct relation to AIMD-Employee safety, so changes to therapy, or turning therapy off, does not pose a specific risk to the AIMD-Employee. It is noted that an AIMD-Employee can also receive therapy changes which may appear as a “shock” or “jolt” due to abrupt movements such as coughing and laughing as well as from postural changes such as standing up from seating, or vice versa. These are not significant direct risk situations to the AIMD-Employee, but there may be indirect implications due to the nature of the occupation or positioning. A workplace risk assessment does not need to be based on an absence of risk or effect. It can be made using a balance of the benefits and the identified possible effects, both direct and indirect, due to the nature of the employment.

The risks to an AIMD-Employee resulting from to EMF or SF exposure in the workplace includes the following categories:

— that the implanted SCS may itself be influenced in a way that leads to temporary or permanent loss of therapy, or delivery of a corrupted form of therapy that might not meet the needs of the patient such that they might be unable to carry out their employee functions. ISO 14708-3 is the product standard that addresses the risks of malfunction and damage to the SCS NS when exposed to EMF or SF. The working group has deemed the risks to the AIMD-Employee related to malfunction and device damage to be acceptable, and they are therefore not addressed by this document. See C.2 for additional rationale.

— that the AIMD-Employee may experience additional effects upon their nervous system due to extrinsic stimulation arising from induced currents in their implanted lead system. These effects can include unpleasant sensations, up to and including “shocking” and “jolting”,

— that the induced currents are of sufficient magnitude to cause nerve tissue damage. This risk would occur at higher exposure levels and where the EMF frequencies are high enough that they would not be perceived by the AIMD-Employee.

To address these risks, this document describes a multi-phase risk assessment as summarized in Figure 1.

— Exclusion from further assessment based upon a consideration of prior history

— Exclusion from further assessment based upon a survey of the equipment in the workplace

— Exclusion from further assessment if the AIMD-Employee has a stimulator where outputs can be shut off in high-impedance mode and is able to work with the stimulator in this mode receiving no therapy while at the workplace.

— Assessment of the likelihood that the extrinsically induced current arising from the EMF environment of the workplace will exceed the stimulation threshold (i.e. limit of perceived stimulation) for the spinal cord portion of the human nervous system. Further assessment is prescribed where extrinsic stimulation cannot be ruled out.

— Assessment of the likelihood that the extrinsically induced current arising from the EMF environment of the workplace could cause damage to the tissues of the spinal cord. This risk is present when the characteristics of the extrinsically induced currents are such that they are not perceived by the AIMD-Employee, yet are of sufficient magnitude to result in a level of deposited power as to cause tissue damage as a result of tissue heating. . The underlying approach is first to allow work without restriction if it can be determined that no extrinsic stimulation and no tissue damage would occur,

— Where the risk of tissue damage has been ruled out, but extrinsic stimulation has not been ruled out, assessment of actual stimulation effects. Since the consequences of unintended stimulation vary widely from one individual to another the assessment necessarily involves *in vivo* testing.

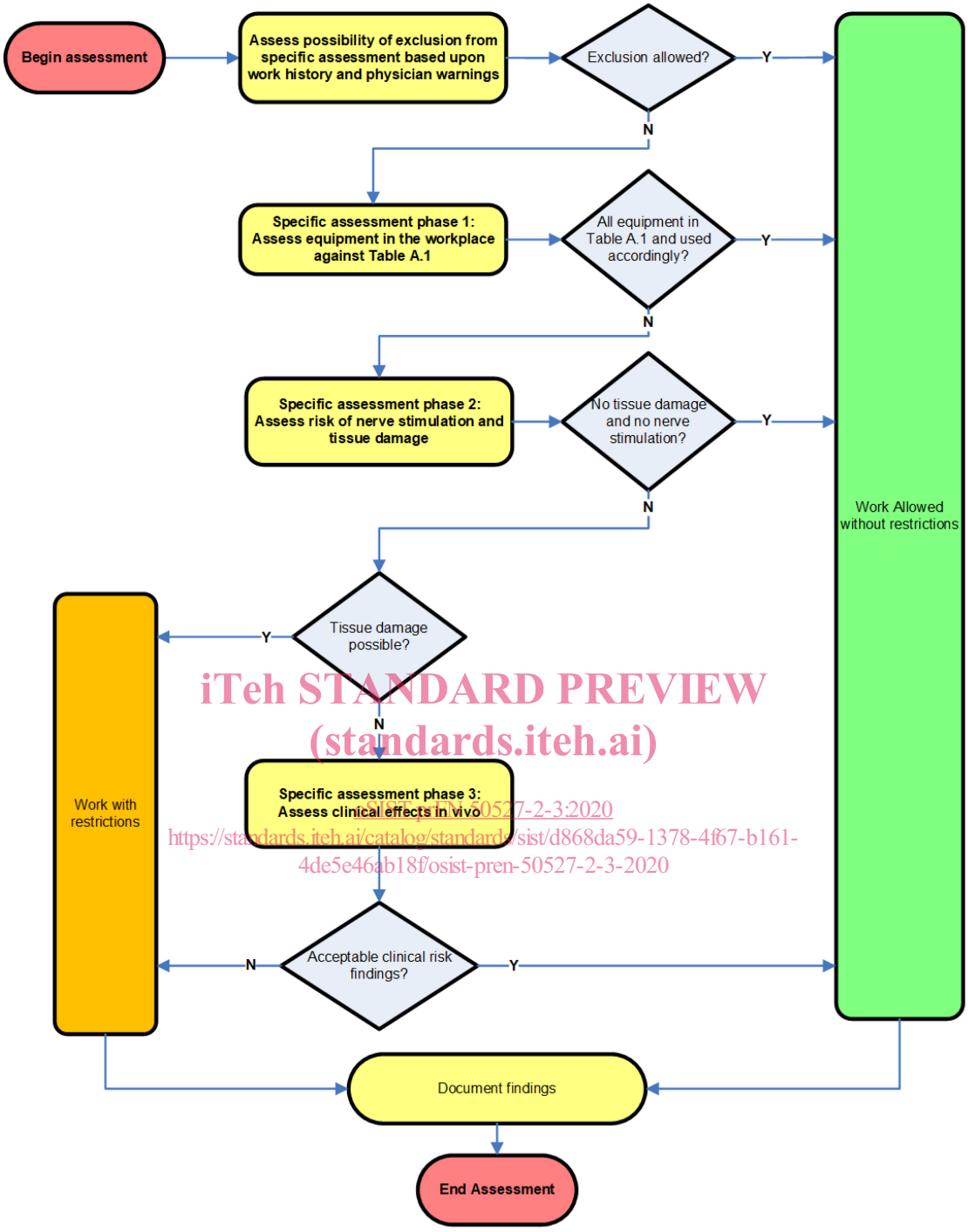

Figure 1 — Overview of the assessment process

4.1.2 Exclusion based on history and physician warnings

Further risk assessment is not necessary if a history of uninfluenced behaviour at the workplace exists and a responsible physician has confirmed that this history is sufficient to exclude clinically significant interaction.

When a SCS NS is tested according to ISO 14708-3, the manufacturer is required to provide a warning to the implanting physician in the accompanying technical information as to any settings available in the device that if used, afford the device with a reduced immunity to certain types of EMI. A specific warning would only be given to the patient receiving the implant if they were discharged with one of these settings in effect, or if at follow-up, a change to one of these settings was made for clinical reasons.

Figure 2 summarizes the situations where further risk assessment is unnecessary, and where a specific assessment (beginning with 4.1.3) is required.

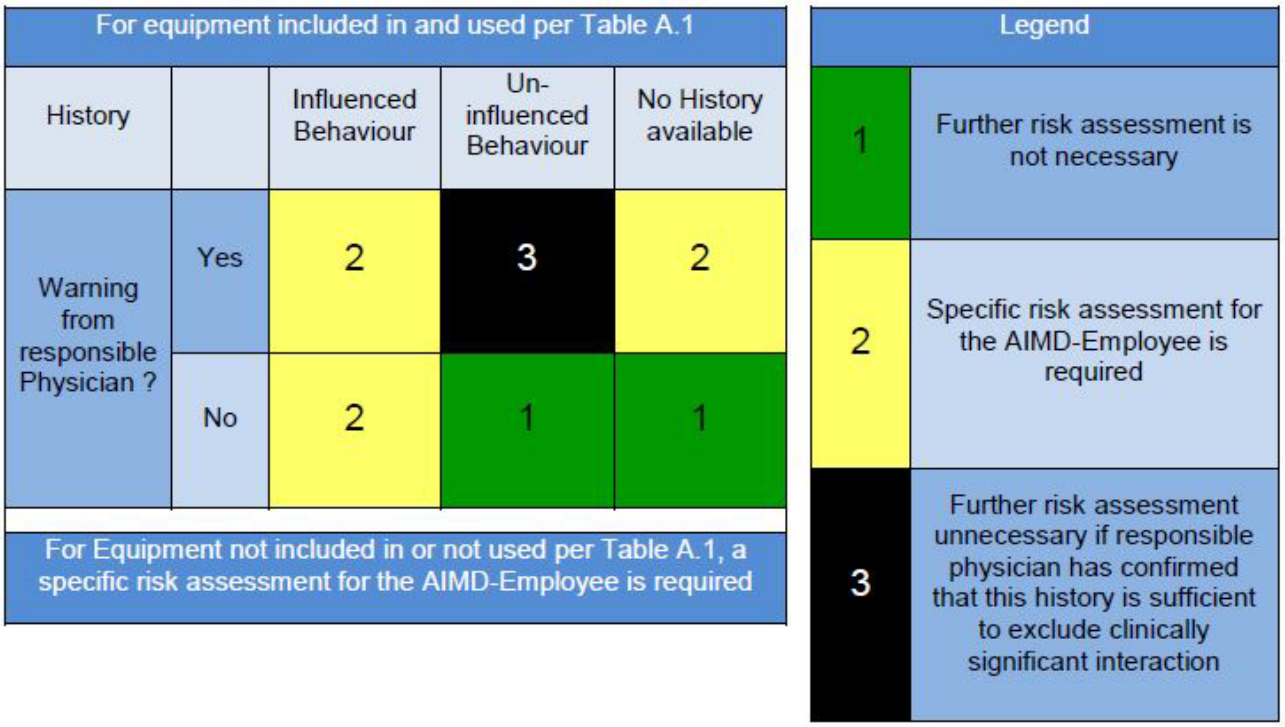

Figure 2 — Summary of assessment exclusion criteria

4.1.3 Specific assessment phase 1: Consideration of equipment and SCS therapy type

To minimize the burden on the employer and AIMD-employee, the specific assessment begins with a first phase in which it is determined if work can be allowed based upon considerations of equipment in the workplace.

A specific risk assessment for the AIMD-Employee is required when there is history of influenced behaviour or one of the following five conditions exists:

a) there is equipment present in the workplace that is neither included in, nor used in accordance with Table A.1;

b) all equipment at the workplace is listed in Table A.1 (see Annex A) and is used accordingly, but the AIMD-Employee has received warning(s) from the responsible physician that their device might be susceptible to static fields (SF) or electromagnetic fields (EMF) associated with particular types of equipment, thereby increasing the risk at the workplace.

c) there is equipment present in the workplace that is neither included in, nor used in accordance with Table A.1 and for which the AIMD-Employee does not have a history of device behaviour (uninfluenced or otherwise) while in its presence, but the AIMD-Employee has received a specific warning as described in 4.1.1 b).

Figure 3 depicts phase 1 of the specific assessment. The steps to be taken are based upon a consideration of equipment in the workplace and consultation with the responsible physician.

When any of the conditions a) through c) exist, 4.1.4 applies. Otherwise, no further assessment is required, and documentation of the assessment can proceed as required in Clause 5.

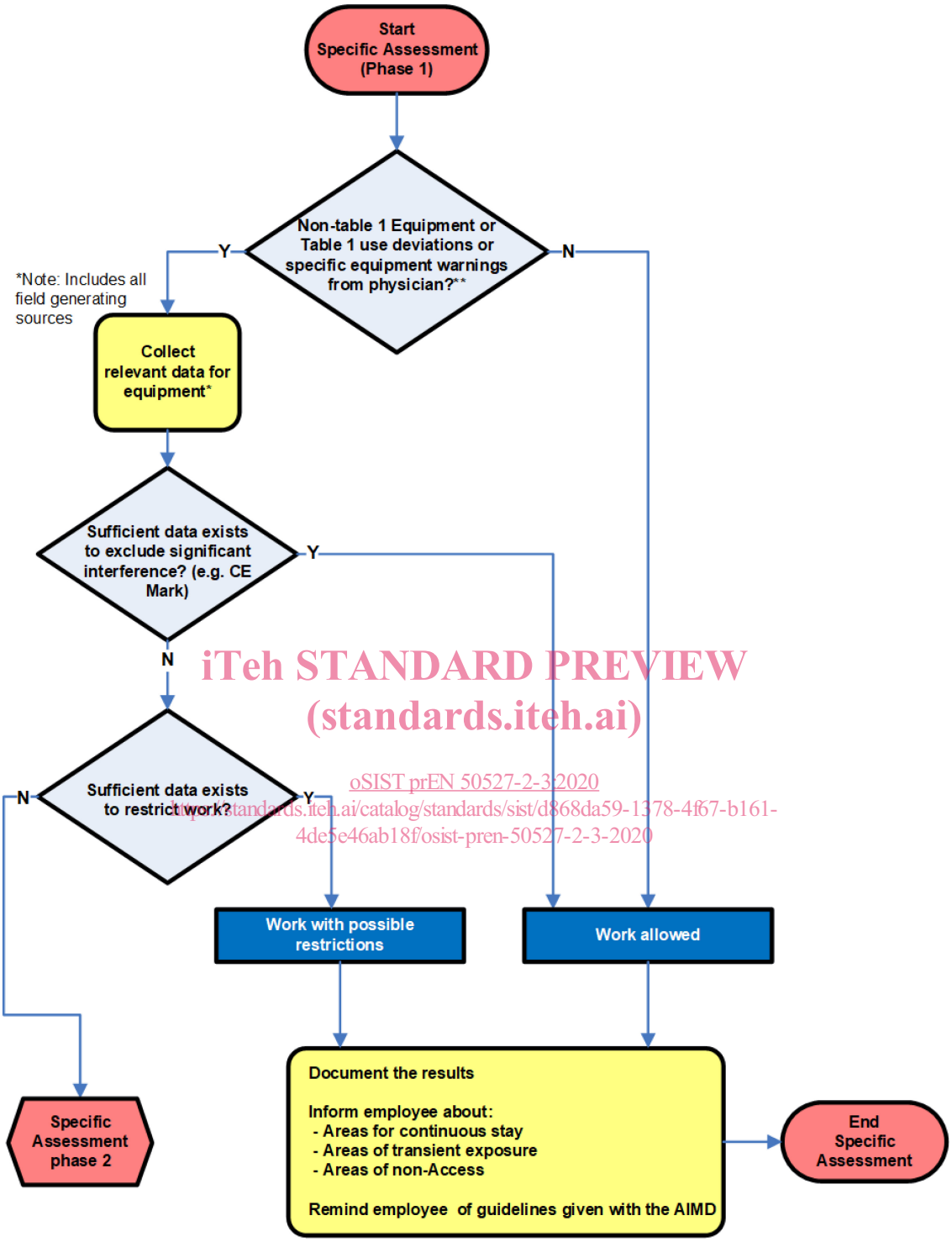

Figure 3 — Specific assessment phase 1

4.1.4 Equipment consideration

Information relevant to the equipment or other field generating sources under consideration shall be collected to answer sufficiently the following two questions:

— can it be determined that clinically significant interference with the device will not occur as a result of expected exposure to the equipment under consideration? If so, no further assessment is required, and documentation of the result can proceed, as required in Clause 5;

— can it be determined that the AIMD-Employee can return to the workplace only with restrictions placed on the work tasks or areas of access? If so, no further assessment is required, and documentation of the work restrictions can proceed as required in Clause 5.

When neither of these questions can be answered positively, the assessment continues to phase 2, as described in 4.1.5.

The intent of this subclause is to find and utilize information that might already exist and that allows the assessment to be completed without further, costlier and time-consuming effort. It is recommended that experts who are likely to have such information be contacted. Examples of such experts are the device manufacturer, equipment manufacturer, employer's technical department, consultants, or others skilled in EMF and SF effects with implanted devices.

4.1.5 Specific assessment phase 2: Ruling out extrinsic stimulation and tissue damage

When steps of the specific assessment phase 1 shown in Figure 3 have been followed but fail to mitigate or to dismiss risk to the AIMD-Employee from the effects of workplace EMF or SF, then additional investigation shall be performed as shown in Figure 4. The goal of Phase 2 investigation is to rule out the risk of extrinsic stimulation, and tissue damage.

The first step of phase 2 is to determine the levels of SF or EMF associated with the equipment in question. This is ordinarily done by performing an EMF site survey wherein the fields are measured directly in the workplace at the separation distances expected in daily exposure for the AIMD-Employee. Such measurements should account for seasonal variations (if any), as well as measurement at lesser distances to better understand the boundaries where higher exposures might occur. The results are then assessed using the methodology described in 4.2.

Coincident with the workplace site survey, it is necessary to collect information concerning the specific implant situation. As a minimum, it is necessary to know the type of stimulation in use (unipolar, bipolar or multipolar single lead, or bipolar two-lead). Additional information that is useful includes an approximation of the implanted loop area, proximity of lead electrodes to the spinal cord, the electrode area(s) for the specific leads implanted, and whether the implantable pulse generator carries an MRI conditional approval. These items of information might be available from the implanting physician. Otherwise, in the absence of such information, it should be assumed that the nominal conditions of implant as described in 4.2 apply.

Device "off" exclusion

If it is learned that the AIMD-employee is receiving unipolar stimulation and SCS device re-programming to bipolar stimulation is not possible, and the AIMD-Employee has a stimulator whose outputs can be shut off in high-impedance mode, and the AIMD-Employee is able to work with the stimulator in this mode receiving no therapy, the AIMD-employee is allowed to work with this restriction.

4.1.6 Specific assessment phase 3: Assessment of clinical effects using *in vivo* testing

There can exist situations where the results from 4.2 indicate that the risk of tissue damage is negligible, yet the EMF exposure levels are such that perception of them by the AIMD-Employee cannot be ruled out. In these situations, the specific assessment continues with the consideration of applying *in vivo* testing. The requirements for this phase of the assessment are described in 4.3.

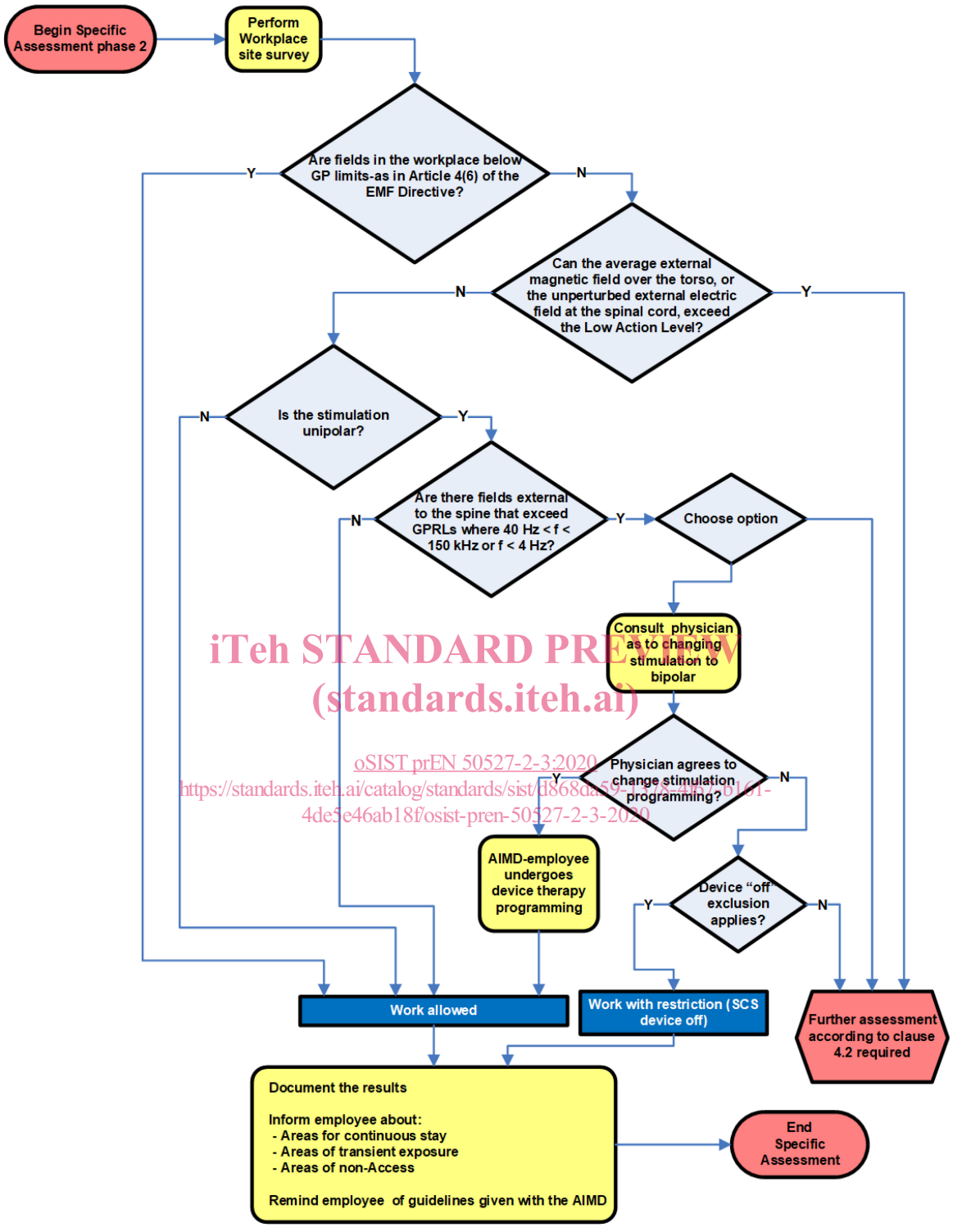

Figure 4 — Specific assessment phase 2 — Ruling out malfunction and extrinsic stimulation

4.2 Assessment of extrinsic stimulation and tissue damage risk

4.2.1 General

Assessment of the risk of extrinsic induced stimulation that might exceed the threshold of perception is a complex topic. Annex E together with Annex D, has been developed to provide an analysis methodology for determination of whether or not an external EMF will be of sufficient magnitude to result in stimulation of the spinal cord by way of induced currents and internal fields.

The risk of extrinsic induced voltages that might result in damage to tissue adjacent to the electrodes is also a developed in Annex E.

4.2.2 Overview of the Assessments Method given in Annexes D and E

Annex D introduces the SCS devices and important parameters associated with their use.

The SENN model (Spatially Extended Nonlinear Node model), which is used for modelling stimulation of nerves by internal electric fields in the body, is introduced in E.1 and E.2 and based on the work of J.P Reilly. The values of the ICNIRP internal electric field Basic Restriction for nerve stimulation is used for assessing nerve stimulation that may arise from external magnetic and electric fields. In E.3 the values of the ICNIRP internal electric field Basic Restriction for local heating in the body, are used in the assessment of whether or not tissue damage may occur.

The method for assessing whether nerve stimulation will be caused by external fields is based on evaluating the quantity which is referred to as the Nerve Stimulation Ratio (NSR). If the NSR is greater than 1 then nerve stimulation may occur, and if it is less than 1 nerve stimulation is not expected.

The stages of the method for assessing nerve stimulation are set out in E.5.1, and the results of the assessment are contained in the remainder of E.5.

The method for assessing whether tissue damage will be caused by external fields is based on evaluating the quantity which is referred to as the Tissue Damage Ratio (TDR). If the TDR is greater than one then nerve stimulation may occur, and if it is less than 1 tissue damage is not expected.

The stages of the method for assessing tissue damage are set out in E.6.1, and the results of the assessment are contained in the remainder of E.6.

The methods for assessing whether nerve stimulation and tissue damage occurs both depend on calculating the voltage induced by the external fields between the electrodes by the external fields (electric and magnetic), and the current flowing in the tissue between the electrodes. These are presented in E.4.

The assessments of E.5 and E.6 are brought together in 4.2.5 below and E.7.

In some situations, further assessment is required. The approach for this is given in E.8 and reproduced here.

4.2.3 Selection of Parameters Affecting the Assessment

The outcome of the assessment depends on many different parameters. To simplify this, assessments have been carried out for a few particular sets of parameters representative of worst cases.

Lead configuration

The leads between the IPG and electrode site form a loop in which voltages may be induced by magnetic fields. The lead configuration affects loop area which in turn affects the induced voltage. The areas used are as follows: 612 cm^2 for unipolar, 140 cm^2 for bipolar (using two leads) and 10 cm^2 for bipolar (using one lead).

Electrode spacing

The spacing of implanted electrodes affects the voltage induced between them. The spacings used are 50 cm for unipolar, 5,4 cm for percutaneous leads and 3,7 cm for paddle electrodes.

Electric and magnetic fields

Values of electric and magnetic fields for this assessment are shown in Figure 5 and Figure 6, respectively.

Two sets of values are used for frequencies between 1 Hz and 10 GHz. The two lines used are:

— the Low Action Level from the EU EMF Directive for exposure of worker;

— the Reference Level from the EU EMF Recommendation for exposures to the General Public.

These are representative of the higher fields that may be found in occupational environments and in environments accessible to the general public respectively, though they do not represent the highest fields that may be found in either of those environments arising from the detailed content of those documents.

These curves are derived from Guidance from ICNIRP as set out in Table 1.