SLOVENSKI STANDARD
SIST EN 50527-2-1:2017

01-april-2017

Nadomešča:
SIST EN 50527-2-1:2011

Postopek ocenjevanja izpostavljenosti delavcev z aktivnimi medicinskimi vsadki elektromagnetnim poljem - 2-1. del: Specifično ocenjevanje delavcev s srčnimi spodbujevalniki

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-1: Specific assessment for workers with cardiac pacemakers

Verfahren zur Beurteilung der Exposition von Arbeitnehmern mit aktiven implantierbaren medizinischen Geräten (AIMD) gegenüber elektromagnetischen Feldern - Teil 2-1: Besondere Beurteilung für Arbeitnehmer mit Herzschrittmachern

Procédure pour l'évaluation de l'exposition des travailleurs porteurs de dispositifs médicaux implantables actifs aux champs électromagnétiques - Partie 2-1: Spécification d'évaluation pour les travailleurs avec un simulateur cardiaque

Ta slovenski standard je istoveten z: **EN 50527-2-1:2016**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
13.100	Varnost pri delu. Industrijska higiena	Occupational safety. Industrial hygiene
17.240	Merjenje sevanja	Radiation measurements

SIST EN 50527-2-1:2017 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 50527-2-1

December 2016

ICS 11.040.40; 17.240

Supersedes EN 50527-2-1:2011

English Version

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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European foreword

This document (EN 50527-2-1:2016) has been prepared by CLC/TC 106X “Electromagnetic fields in the human environment”.

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2017-07-04
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2019-07-04

This document supersedes EN 50527-2-1:2011.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

EN 50527 is currently composed with the following parts:

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

— EN 50527-2-1, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 2-1: Specific assessment for workers with cardiac pacemakers*;

— prEN 50527-2-2, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 2-2: Specific assessment for workers with implantable cardioverter defibrillators* [1].

1) Currently at drafting stage.

1 Scope

This European Standard provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted pacemakers. It offers different approaches for doing the risk assessment. The most suitable one will be used. If the worker has other Active Implantable Medical Devices (AIMDs) implanted additionally, they need to be assessed separately.

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

NOTE 1 This standard does not address risks from contact currents.

The techniques described in the different approaches may 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 pacemaker occurs when the exposure limits are not exceeded.

NOTE 2 The rationale for limiting the observation range to 3 GHz can be found in ISO 14117:2012, Clause 5.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 45502-2-1:2003[2)], *Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*

EN 50413, *Basic standard on measurement and calculation procedures for human exposure to electric, magnetic and electromagnetic fields (0 Hz - 300 GHz)*

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

3 Terms and definitions

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

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

Note 1 to entry: For the purposes of EN 50527–2–1, the term implantable pulse generator describes any active implantable medical device that incorporates functions intended to treat cardiac arrhythmias.

3.2
pacemaker
active implantable medical device intended to treat bradyarrhythmias, comprising an implantable pulse generator with or without lead(s)

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2) The EMC requirements within EN 45502–2-1 have been incorporated with updates into ISO 14117 and their use is recommended here.

Note 1 to entry: CRT-P devices (Cardiac resynchronization therapy pacemaker) by their nature behave similar and are covered by this standard. CRT-P devices are sometimes also called multi-channel pacemakers.

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
unipolar lead
lead with one electrode

3.5
bipolar lead
lead with two electrodes that are electrically isolated from each other

3.6
pacemaker-employee
worker with an implanted pacemaker

Note 1 to entry: For this worker, EN 50527–1 has revealed that a specific assessment following EN 50527–1:2016, Annex A needs to be done. If this worker bears additionally other AIMD, they need to be assessed separately.

3.7
assessment team
team consisting of:

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

— pacemaker-Employee and his responsible physician,

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

3.8
Holter monitor
Holter ECG monitor
device that continuously records the heart's rhythms

Note 1 to entry: The monitor is usually worn for 24 h – 48 h during normal activity.

Note 2 to entry: The above definition was adopted from NIH (US. National Institute of Health). The Holter monitor is named for Dr. Norman J. Holter, who invented telemetric cardiac monitoring in 1949. Clinical use started in the early 1960s. Numerous medical publications can be found referring to “Holter”, “Holter monitoring” or often also called “Holter ECG monitoring” (see e.g. PubMed at http://www.ncbi.nlm.nih.gov/pubmed).

3.9
EM phantom
physical model containing tissue-equivalent material used to simulate the body in an experimental dose measurement (from World Health Organization)

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

3.10
uninfluenced behaviour
behaviour for which conditions are provided in EN 50527-1:2016, 4.1.3

4 Specific assessment

4.1 Description of the assessment process

4.1.1 General

The risk assessment is based on the approach that, according to EN 45502-2-1 and ISO 14117, pacemakers are expected to work uninfluenced as long as the General Public Reference levels of Council Recommendation 1999/519/EC are not exceeded (except for static magnetic fields and for pulsed high frequency electromagnetic fields) (see also F.7).

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 severe (clinically significant) interaction.

A specific risk assessment for the pacemaker-Employee is required when there is history of influenced behaviour or one of the following three conditions is fulfilled:

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 pacemaker-Employee has received warning(s) from the responsible physician that the pacemaker may be susceptible to electromagnetic interference (EMI), thereby increasing the risk at the workplace. There are two types of warnings that may be given:

   1) patient specific warnings provided by the responsible physician to the pacemaker-Employee due to sensitivity settings in effect that may cause changes in pacemaker behaviour in the presence of electromagnetic fields (EMF) that are below the reference levels; or

   2) general warnings supplied by the pacemaker manufacturer in accompanying documentation about recognized behaviour changes of the pacemaker when it is subjected to EMF generated by specific types of equipment;

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 pacemaker-Employee does have a history of uninfluenced behaviour while in its presence, but the pacemaker-Employee has received a specific warning as described above.

In order to minimize the burden placed on the employer and pacemaker-Employee, the assessment should begin with the investigation steps shown in Figure 1. The steps to be taken are based upon whether the specific assessment is the result of an equipment issue or a patient warning issue.

When only condition (a) exists, then 4.1.2 shall apply. When only condition (b) exists, then 4.1.3 shall apply. When condition (c) exists, then both 4.1.2 and 4.1.3 shall apply.

When a pacemaker is tested according to EN 45502–2-1, the manufacturer is required to provide a warning to the implanting physician in the accompanying technical information as to any sensitivity 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.

For equipment included in and used per Table A.1				
		History		
		Influenced Behaviour	Un-influenced Behaviour	No History available
Warning from responsible Physician	**Yes**	**2**	**3**	**2**
	No	**2**	**1**	**1**

For Equipment not included in or not used per Table A.1
Specific risk assessment for the pacemaker-Employee is required

Legend	
1	Further risk assessment is not necessary
2	Specific risk assessment for the pacemaker-Employee is required
3	Further risk assessment unnecessary if responsible physician has confirmed that this history is sufficient to exclude clinically significant interaction

Figure 1 — Overview of the assessment process

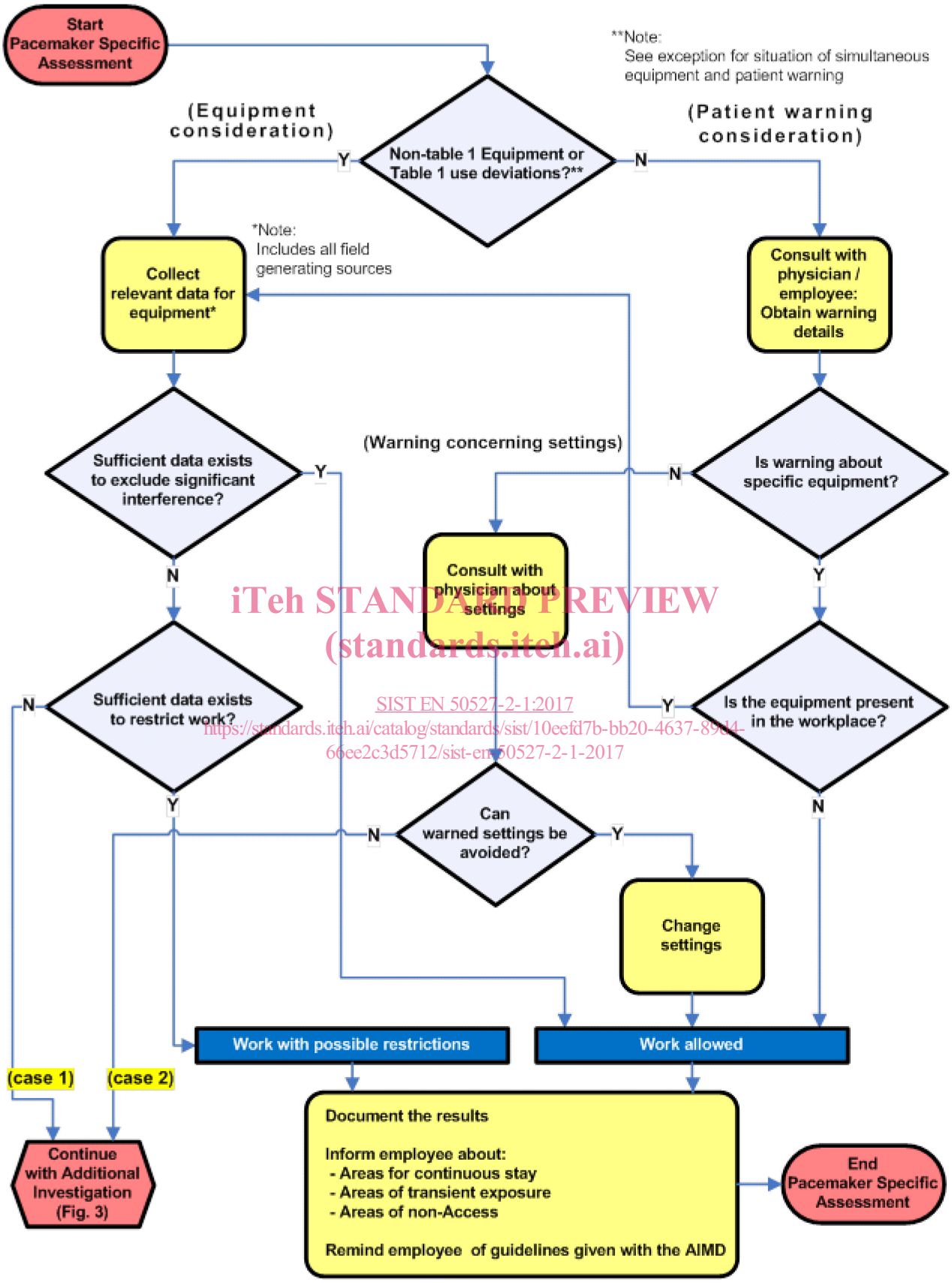

Figure 2 — Pacemaker specific assessment process

4.1.2 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 pacemaker 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 pacemaker-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, additional investigation, hereafter referred to as “Case 1”, is required as specified in 4.1.4.

The intent of this clause is to find and utilize information that may already exist and that allows the assessment to be completed without further, more costly and time consuming effort. It is recommended that experts who are likely to have such information be contacted. Examples of such experts are the pacemaker manufacturer, equipment manufacturer, employer’s technical department, consultants, or others skilled in EMI effects with implanted pacemakers.

4.1.3 Patient warning consideration

The responsible physician and pacemaker-Employee shall be consulted to determine the type of and details for any EMI warnings applicable to the pacemaker.

If the warning is about behaviour of the pacemaker due to interference from particular types of equipment (see 4.1 (b) (ii)) then it shall first be determined whether that equipment is actually present in the workplace:

- if the equipment is not present, the pacemaker-Employee is allowed to work without restrictions and the pacemaker specific assessment can be completed and documented as required in Clause 5;

- if the equipment subject to the warning is present, the steps given in 4.1.2 shall be taken.

If the warning is due to the applied settings of the pacemaker that may cause reduced immunity (see 4.1.1 b) 1)) to EMI that is at or below the reference levels, the responsible physician shall be consulted to determine whether the settings can be changed to avoid settings that are associated with the warning, thereby restoring standard immunity levels:

- if it is determined that such a change of settings can be made, the pacemaker-Employee shall be advised to arrange, through consultation with the responsible physician, for these changes of settings to be made prior to returning to work. When the change of setting has been completed, the pacemaker-Employee is allowed to work without restrictions; the results shall be documented as required in Clause 5 and the assessment is concluded;

- if the settings cannot be changed, then additional investigation, hereafter referred to as “Case 2” is required as discussed in 4.1.4.

4.1.4 Cases for additional investigation

When the investigation steps shown in Figure 2 have been followed but fail to mitigate or to dismiss risk to the pacemaker-Employee from the effects of workplace EMI, then an additional investigation shall be performed as shown in Figure 3 and described in 4.1.5. The goal of the investigation is to determine the likelihood of a clinically significant response of the pacemaker to the EMI at the workplace that is the result of the following:

a) **Case 1**: Equipment is used at the workplace that is:

   1) neither listed in, nor used in accordance with, Table A.1, and for which there is no information available that allows a pre-determination of safe or restricted work for the pacemaker-Employee, or

2) capable of emitting fields that may induce pacemaker lead voltages exceeding the immunity levels established by conformity with the pacemaker product standard, EN 45502-2-1,

3) known by the pacemaker manufacturer to potentially cause interference with the pacemaker and there is no applicable safe use guideline available from other sources.

b) **Case 2**: The responsible physician has prescribed settings of the pacemaker that make it susceptible to EMI even from equipment listed in Table A.1.

If one of these cases is valid, an additional investigation as shown in Figure 3 and described in 4.1.5 shall be performed.

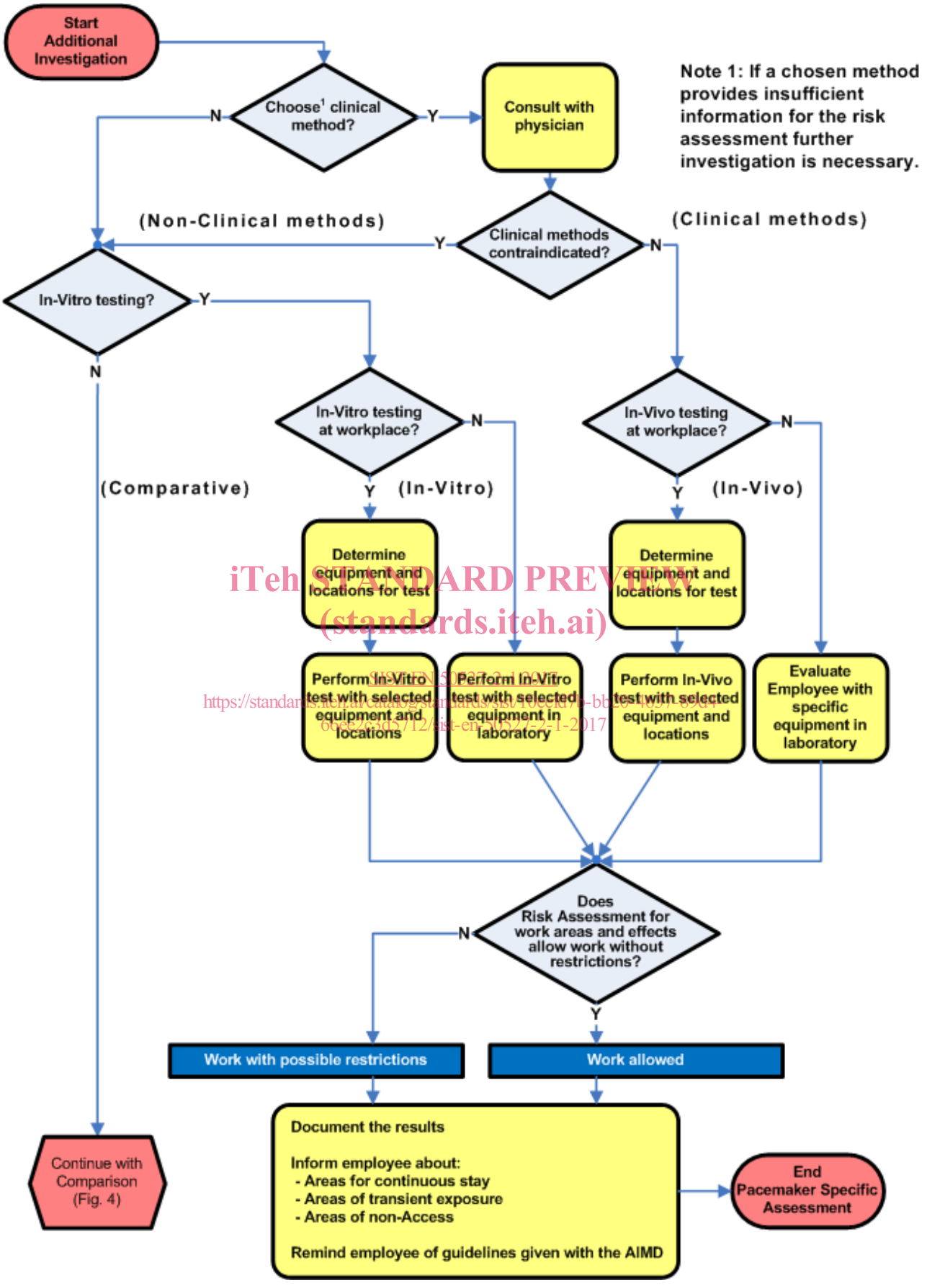

Figure 3 — Additional investigation process