ISTITUTO NAZIONALE PER L'ASSICURAZIONE CONTRO GLI INFORTUNI SUL LAVORO

Valutazione e gestione del rischio derivante da esposizione a nuove sorgenti di campo elettromagnetico per la tutela dei lavoratori portatori di dispositivi medici impiantabili attivi

Sessione 1 - Lavoratore con DMIA - come affrontare la valutazione dei rischi

15.05 La valutazione del rischio per lavoratori con DMIA: aggiornamento del quadro normativo

Ing. Giovanni Calcagnini - ISS

Inquadramento generale

Condizione di esposizione

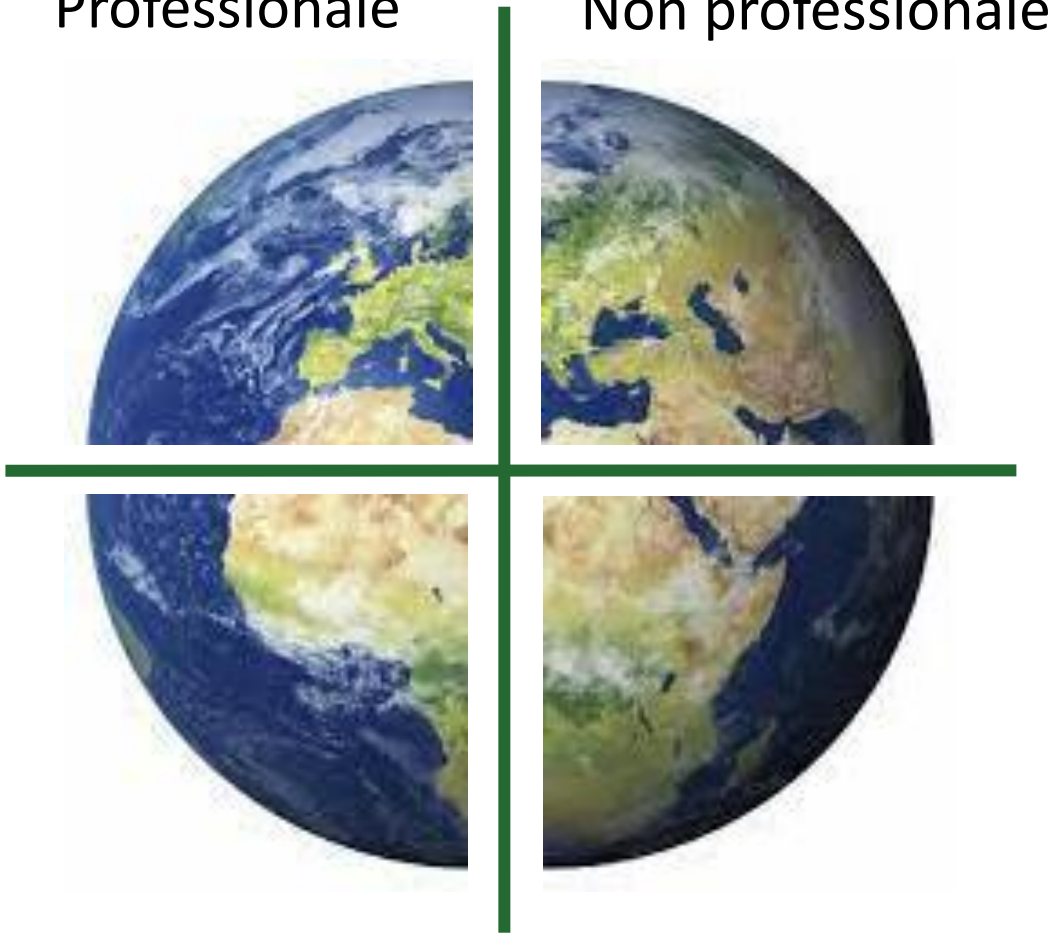
Professionale

Non professionale

Dispositivo Medico (DM)

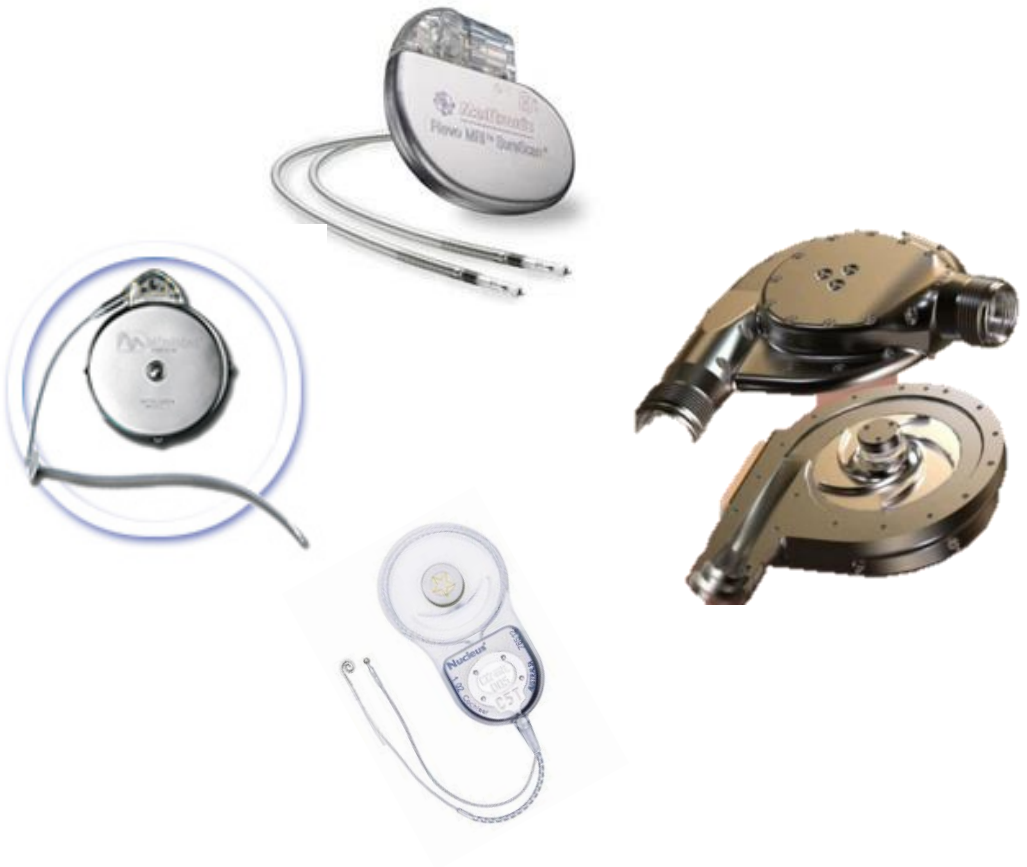
DM attivo, non impiantabile o indossabile

DM impiantabile attivo



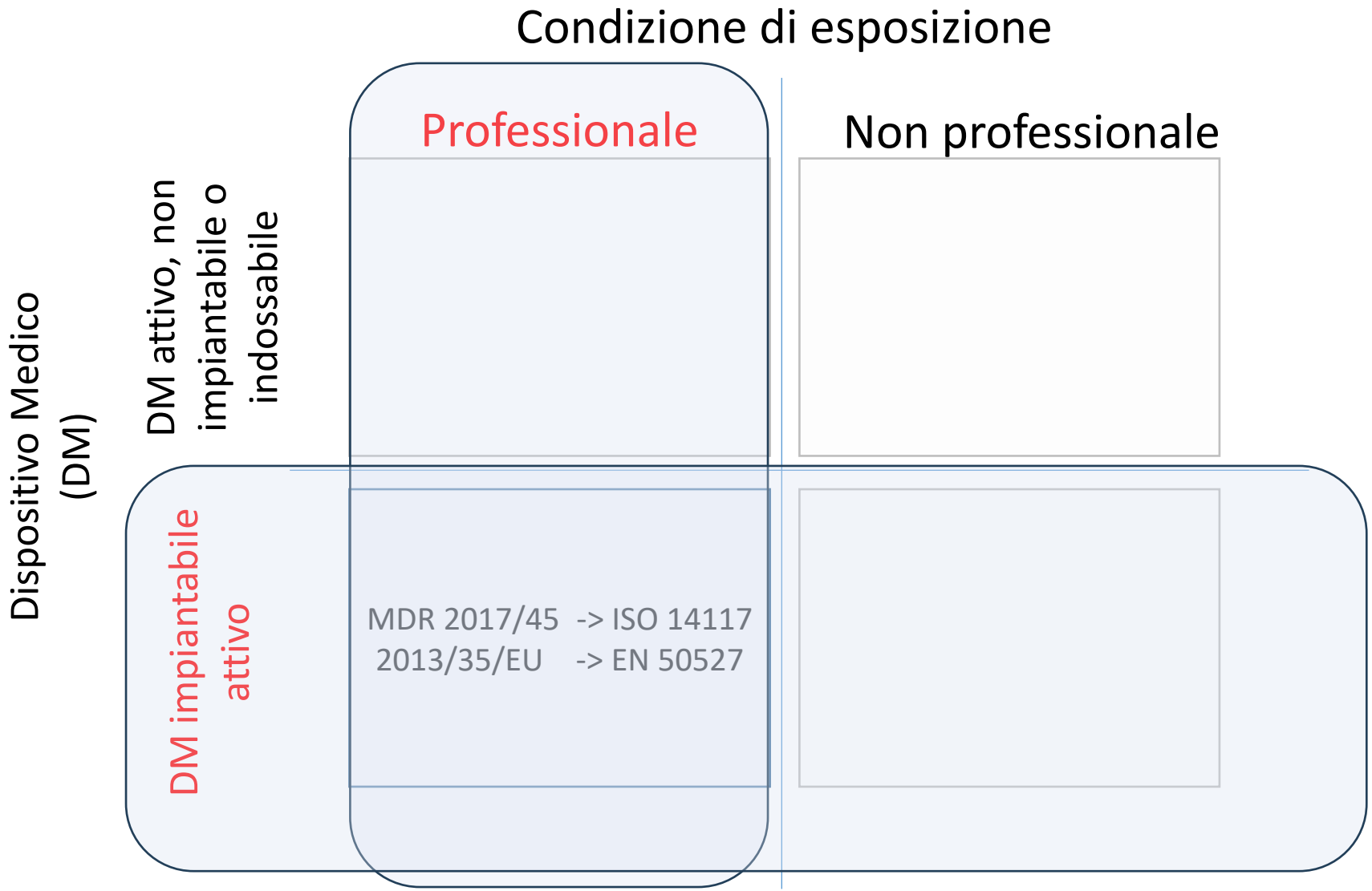
Dispositivi medici Impiantabili ed indossabili

Dispositivi Medici Impiantabili Attivi



Dispositivi Medici Attivi Indossabili

Inquadramento generale



La famiglia di norme CEI EN 50527

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-1 — **2017-09**

La seguente Norma è identica a: EN 50527-1:2016-12.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 1: Generalità

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-1 — **2017-09**

La seguente Norma è identica a: EN 50527-2-1:2016-12.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-1: Valutazione specifica per lavoratori con stimolatore cardiaco (pacemaker)

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-2 — **2018-11**

La seguente Norma è identica a: EN 50527-2-2:2018-05.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-2: Valutazione specifica per lavoratori con defibrillatori cardiaci impiantati (ICD)

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-3 — **2022-07**

La seguente Norma è identica a: EN 50527-2-3:2021-10.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori portatori di dispositivi medici impiantabili attivi
Parte 2-3: Valutazione specifica per lavoratori con neurostimolatori impiantabili

CEI EN 50527 – 1: razionale

The basis for the immunity limits set for AIMDs in their product standards is derived from the Reference Levels from Council Recommendation 1999/519/EC without any time averaging being included

The risk assessment is based on the approach that AIMDs are expected to function as described in their product standards as long as the General Public Reference levels of Council Recommendation 1999/519/EC (except for static magnetic fields) are not exceeded and where no specific warnings have been issued to the AIMD-Employee.

CEI EN 50527-1: procedura per la valutazione del rischio

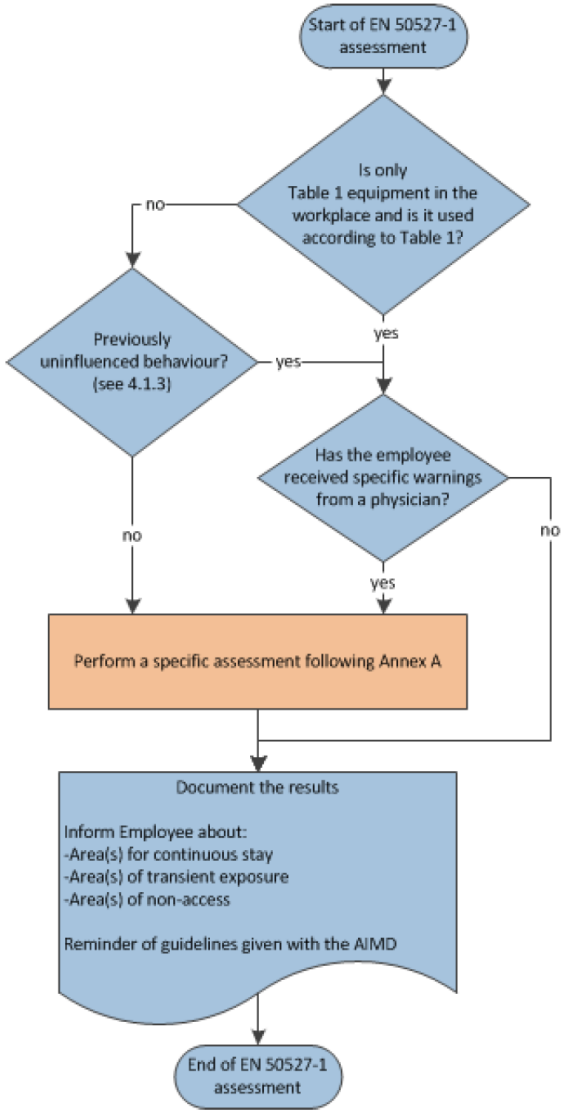


Figure 2 — Risk assessment process

Table 1

All places	Mobile phones, smart phones and cordless phones	See 5.2.1 As example for pacemakers and defibrillators the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.
All places	Two-way radios	See 5.2.1.
All places	Base stations for DECT cordless phones and WLAN (e.g. Wi-Fi)	See 5.2.1 As example for pacemakers and defibrillators the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.
Medical workplaces	All medical equipment not using electromagnetic field emitters for therapeutic or diagnostic purposes	If medical workplaces include static or time varying magnetic or electric fields, then operational precautions may be necessary. For equipment used at medical workplaces listed elsewhere in this table look at the appropriate section.
Workplaces open to the general public (as covered by Article 4.6 of Directive 2013/35/EU)	Places open to the public and in compliance with the exposure limits given in the European Council Recommendation 1999/519/EC are deemed to comply without further assessment provided that the compliance was made against the derived reference levels.	It is possible, under certain circumstances, to exceed the reference levels and still comply with the Recommendation basic restrictions. Such circumstances are usually in localized areas, close to EMF emitting equipment, so transient exposure in those areas may be permitted. In case of doubt further guidance may be obtained from device or emitter manufacturers, medical advisors or by the use of the appropriate device specific standard.

CEI EN 50527-1: Specific Risk Assessement

CEI EN 50527-1: Specific Risk Assessement

A.1 General

This annex provides a method for the specific assessment of AIMD-Employees where there is no particular standard. If there is a standard for a specific AIMD in the EN 50527-2-x series, then the provisions given in that standard take precedence over the methods in this annex.

The risk assessment should involve input from:

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

— AIMD-Employee and his responsible physician,

— experts (technical and medical), e.g. manufacturer of the AIMD.

La famiglia di norme CEI EN 50527

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-1 — **2017-09**

La seguente Norma è identica a: EN 50527-1:2016-12.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 1: Generalità

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-1 — **2017-09**

La seguente Norma è identica a: EN 50527-2-1:2016-12.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-1: Valutazione specifica per lavoratori con stimolatore cardiaco (pacemaker)

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-2 — **2018-11**

La seguente Norma è identica a: EN 50527-2-2:2018-05.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-2: Valutazione specifica per lavoratori con defibrillatori cardiaci impiantati (ICD)

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-3 — **2022-07**

La seguente Norma è identica a: EN 50527-2-3:2021-10.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori portatori di dispositivi medici impiantabili attivi
Parte 2-3: Valutazione specifica per lavoratori con neurostimolatori impiantabili

CEI EN 50527-2-1: Pacemaker

N O R M A I T A L I A N A C E I

Norma Italiana

CEI EN 50527-2-1

La seguente Norma è identica a: EN 50527-2-1:2016-12.

Data Pubblicazione

2017-09

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi Parte 2-1: Valutazione specifica per lavoratori con stimolatore cardiaco (pacemaker)

Under revision. Expected 2026

CEI EN 50527-2-1: Pacemaker

Recepita come CEI EN 50527-2-1:2017-09

EN 50527-2-1:2016 (E)

4 Specific assessment

4.1 Description of the assessment process

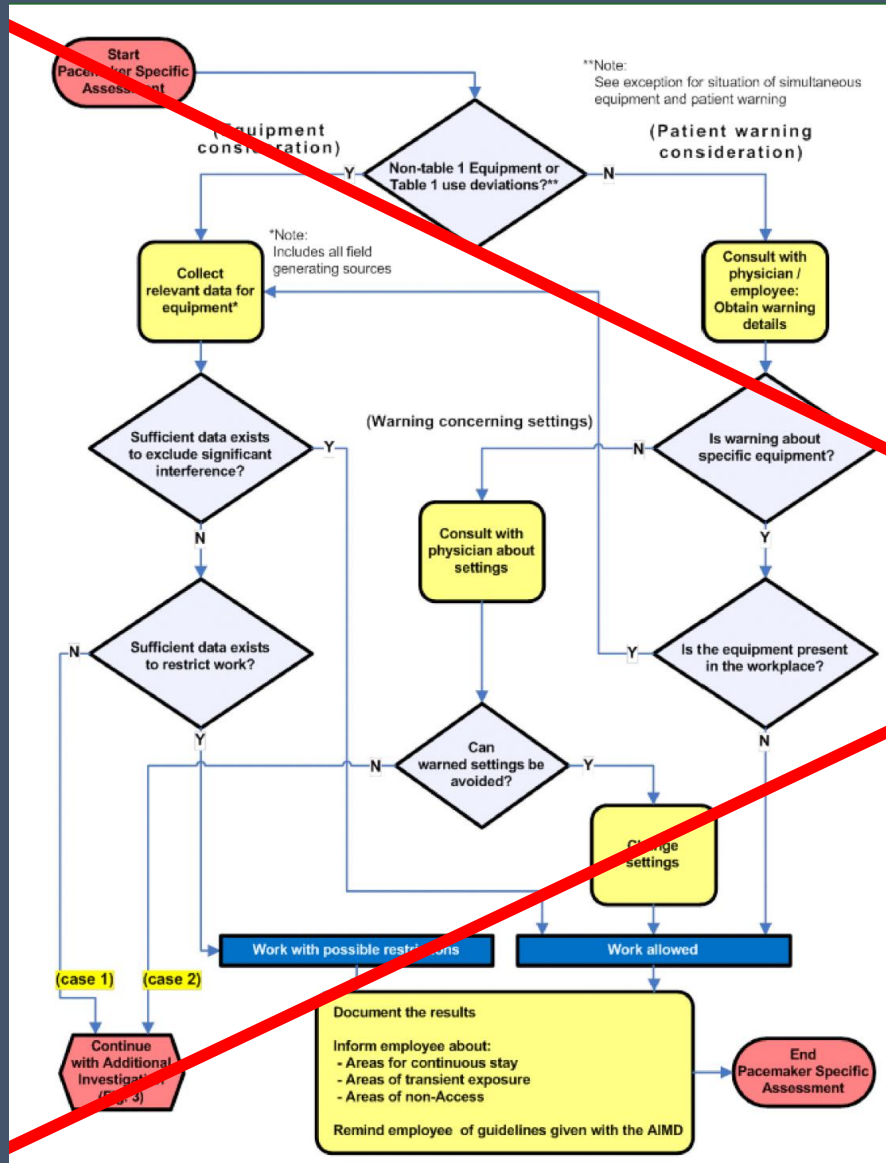
4.1.1 General

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.

CEI EN 50527-2-1: methods

50527-2-1 - DRAFT



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

CEI EN 50527-2-1: specific risk assessment: when?

50527-2-1 - DRAFT

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:

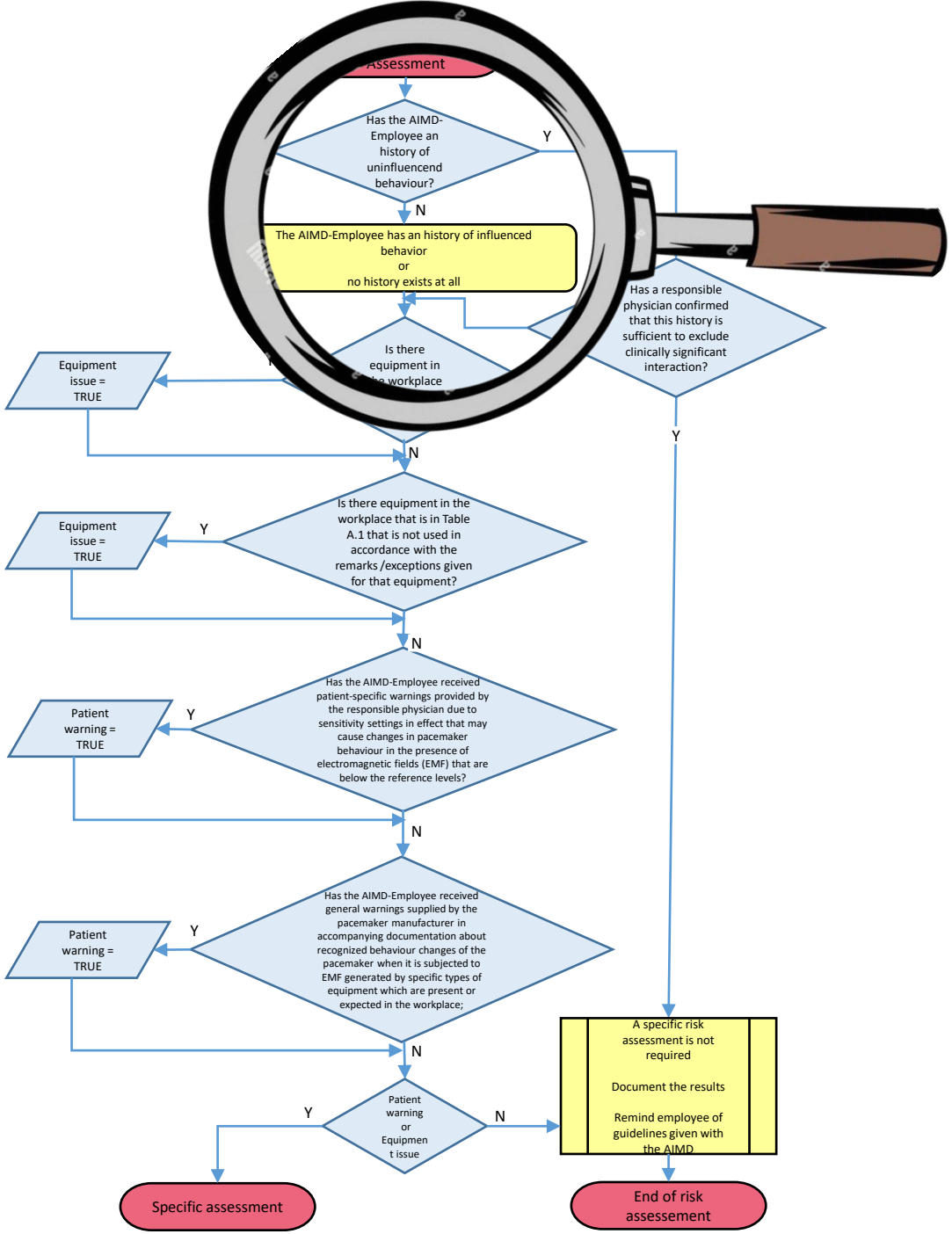
a) there is equipment present in the workplace that is neither included in, nor used in accordance with Table A.1;

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.



Start Risk Assessment

Has the AIMD-Employee an history of uninfluencend behaviour?

Y

N

The AIMD-Employee has an history of influenced behavior or no history exists at all

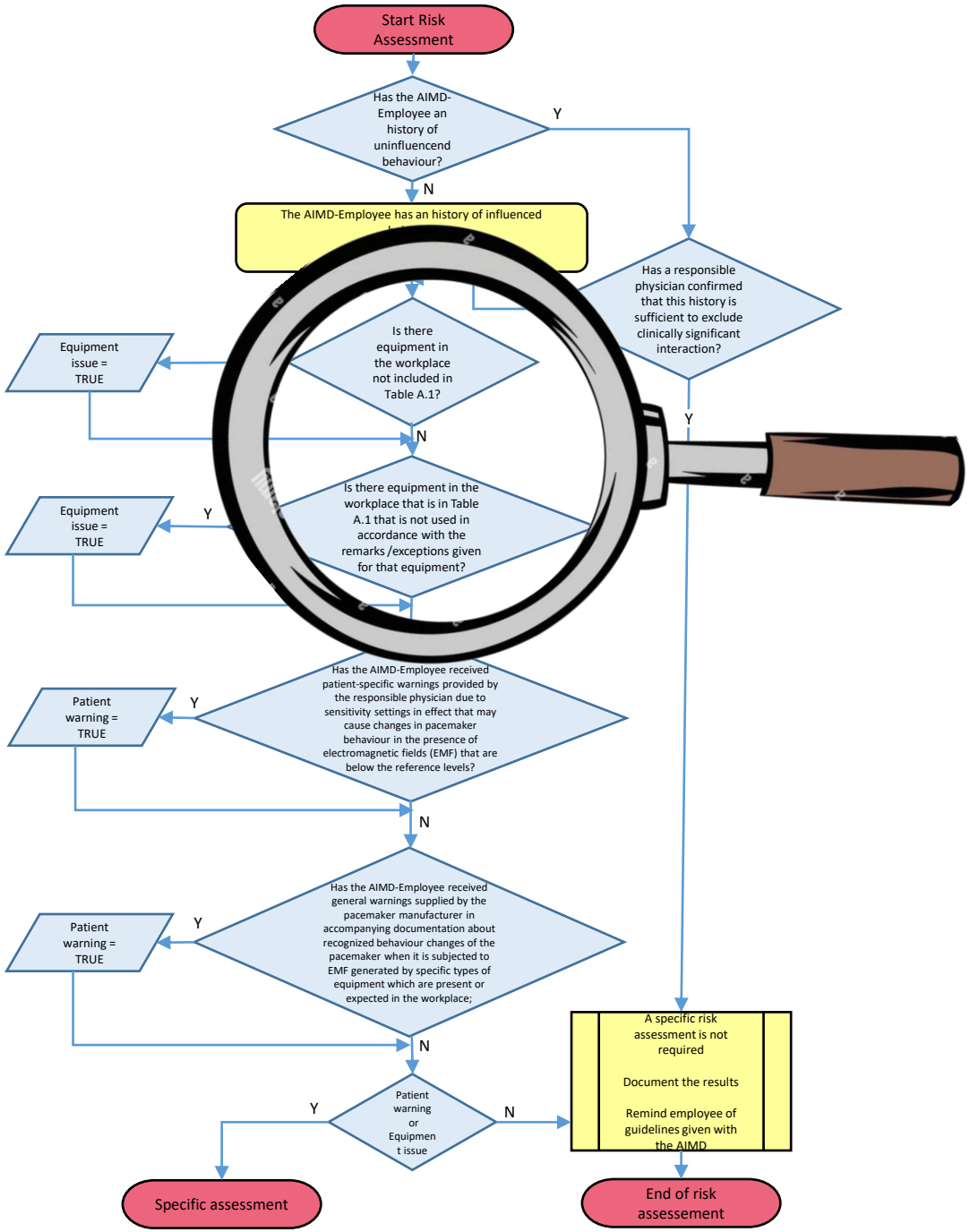
Has a responsible physician confirmed that this history is sufficient to exclude clinically significant interaction?

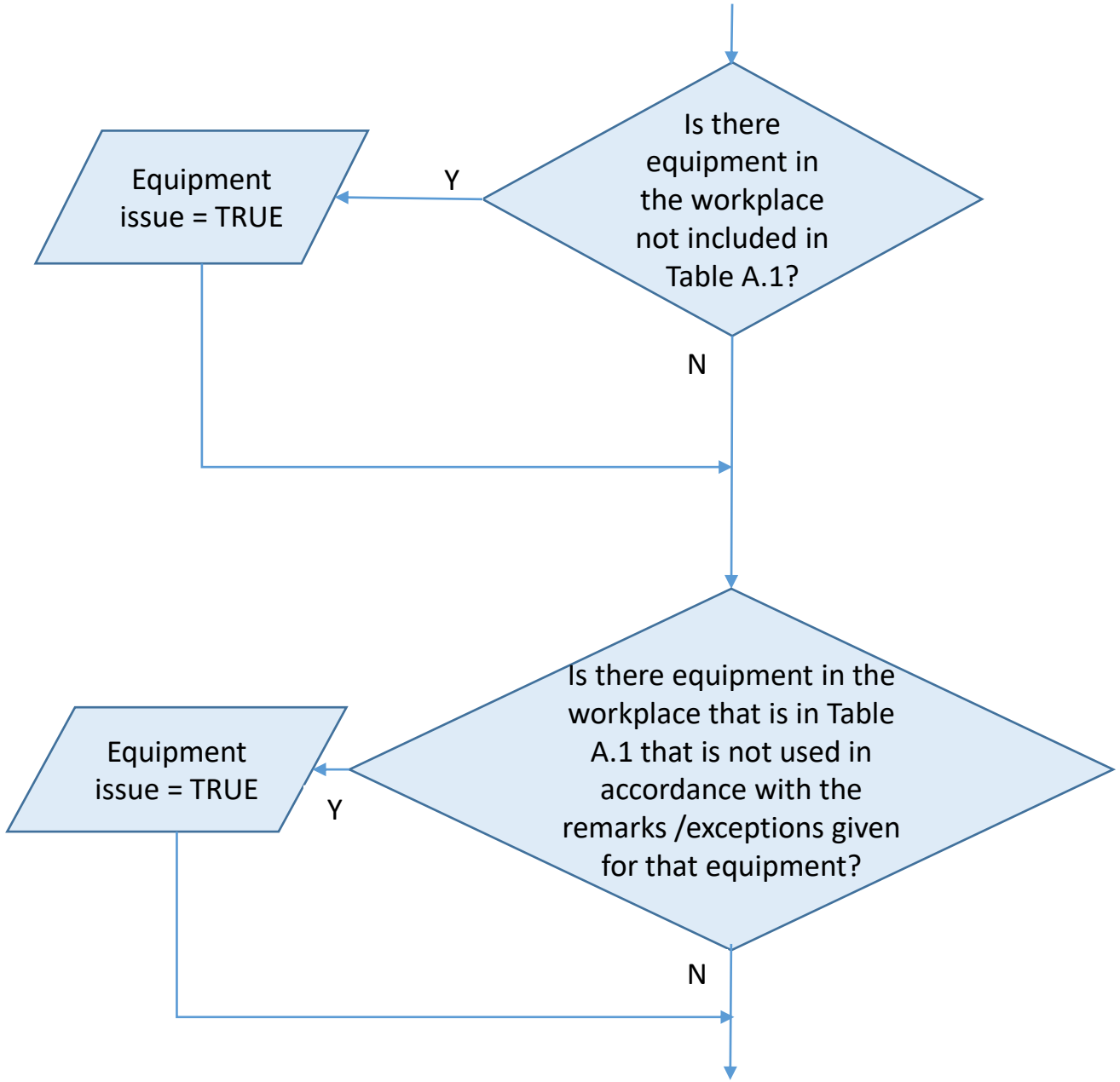
N

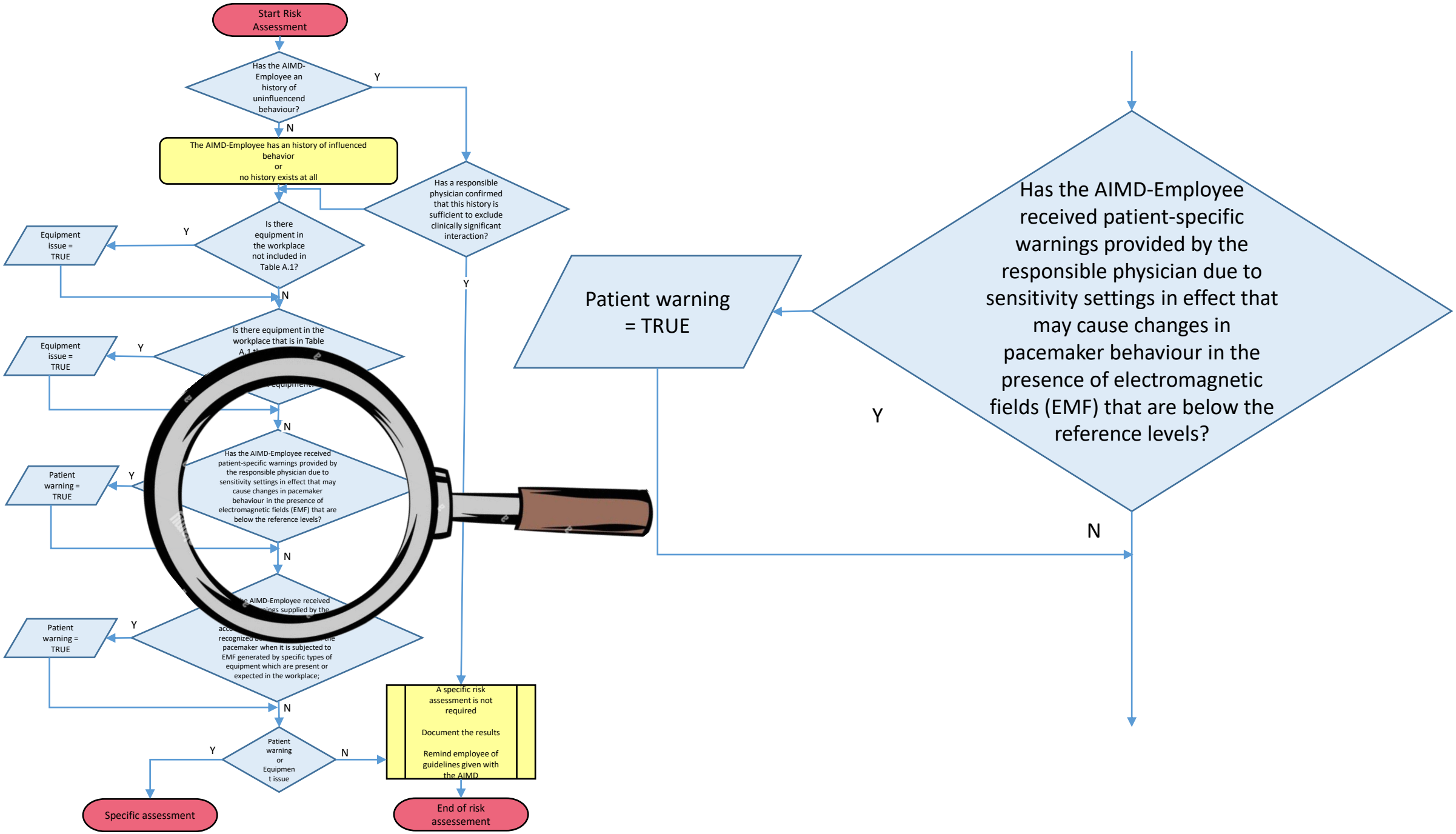
Y

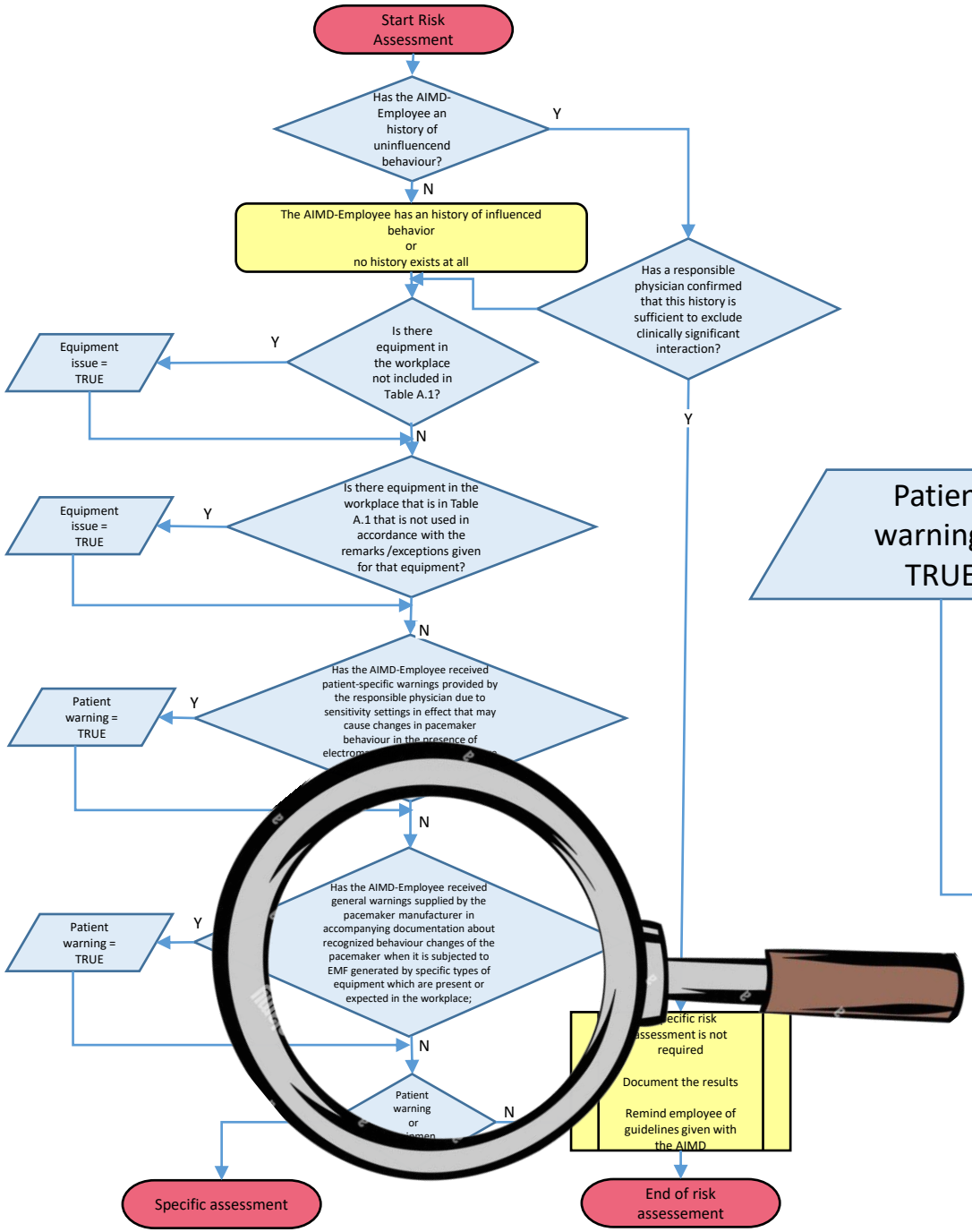
- A specific risk assessment is not required
- Document the results
- Remind employee of guidelines given with the AIMD

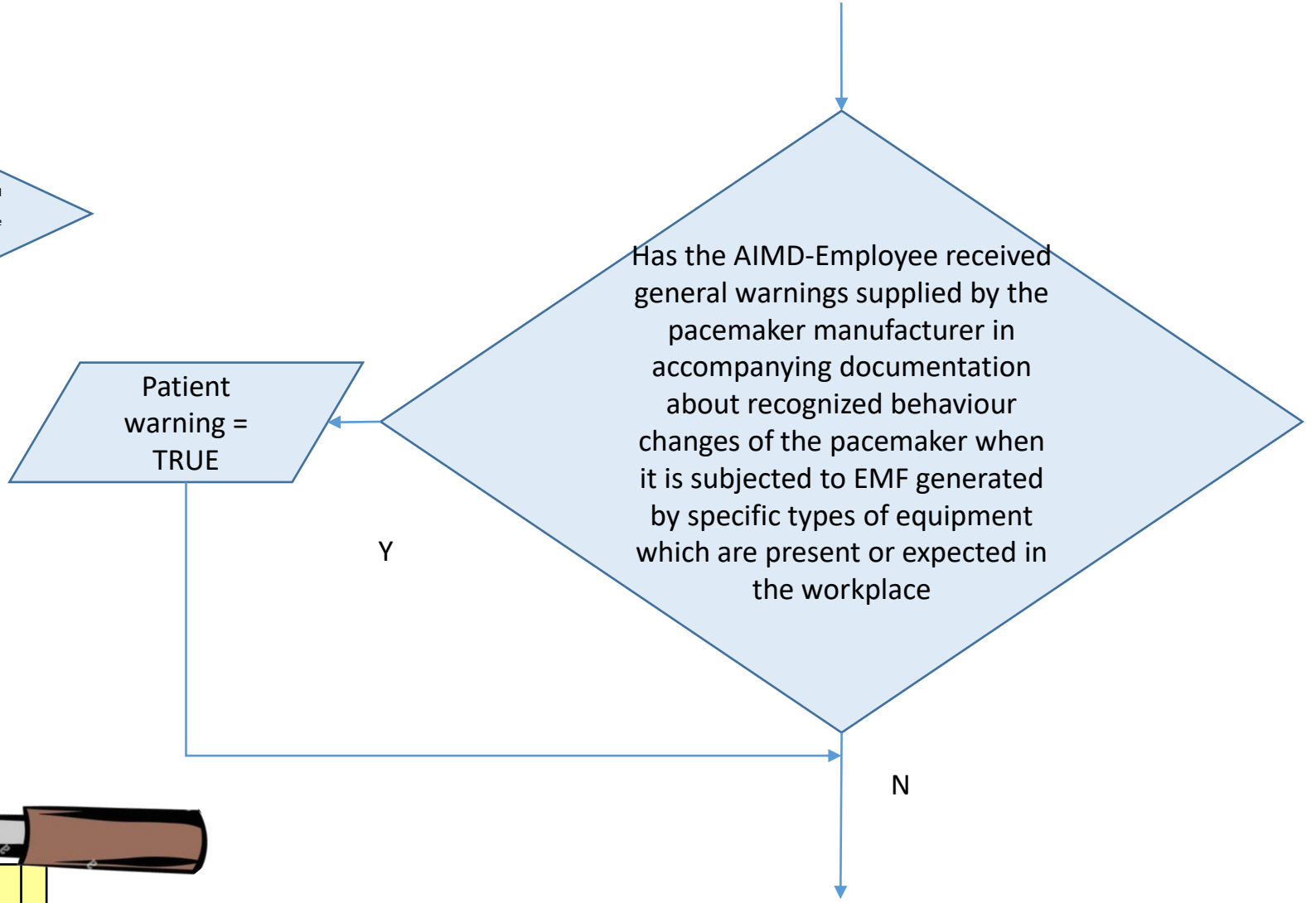
End of risk assessement


Start Risk Assessment
Has the AIMD-Employee an history of uninfluencend behaviour?
Y
N
The AIMD-Employee has an history of influenced
Has a responsible physician confirmed that this history is sufficient to exclude clinically significant interaction?
Y
Is there equipment in the workplace not included in Table A.1?
Equipment issue = TRUE
N
Is there equipment in the workplace that is in Table A.1 that is not used in accordance with the remarks /exceptions given for that equipment?
Equipment issue = TRUE
Y
Has the AIMD-Employee received patient-specific warnings provided by the responsible physician 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?
Patient warning = TRUE
Y
N
Has the AIMD-Employee received 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 which are present or expected in the workplace;
Patient warning = TRUE
Y
N
Patient warning or Equipmen t issue
Y
N
A specific risk assessment is not required
Document the results
Remind employee of guidelines given with the AIMD
Specific assessment
End of risk assessement

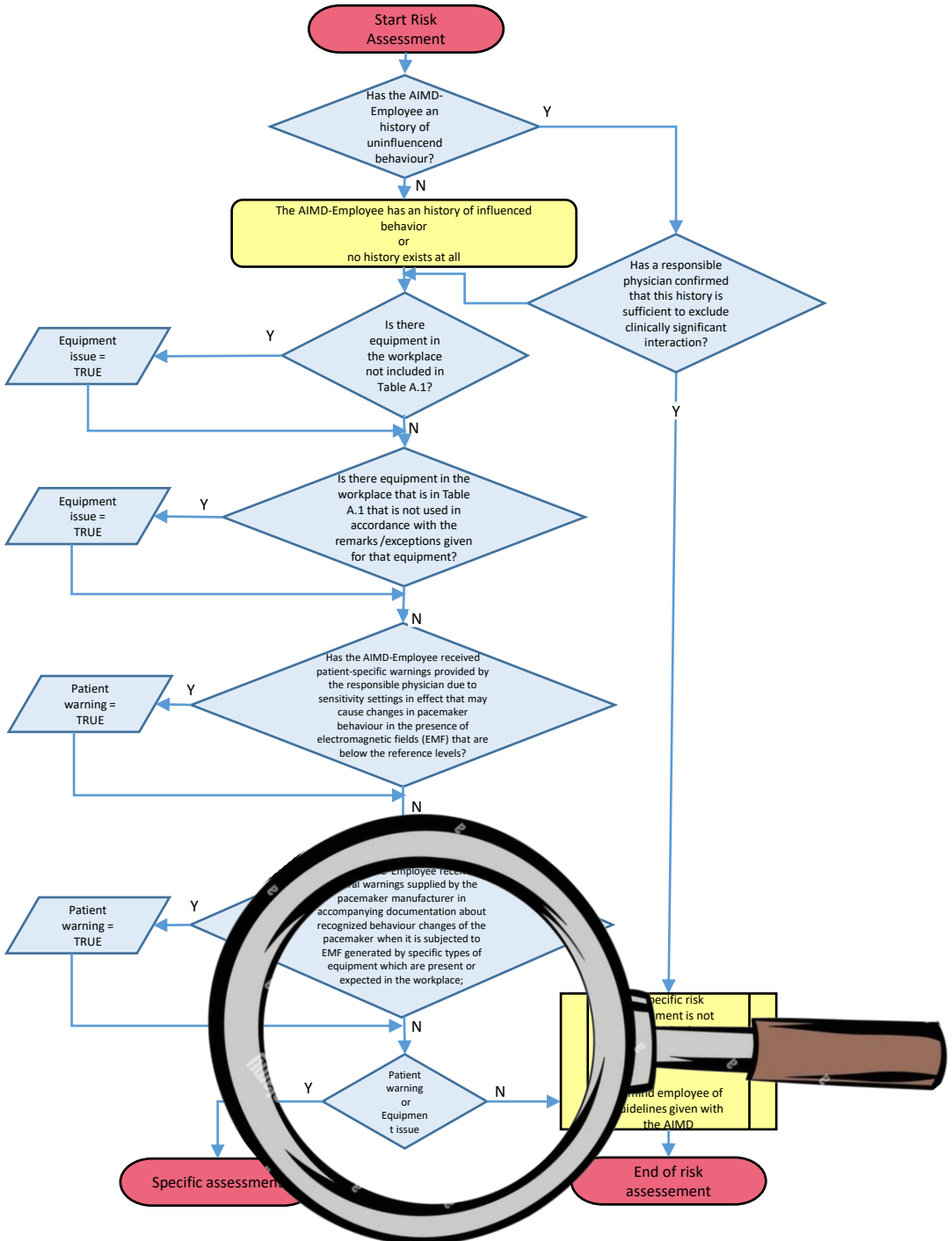

Is there equipment in the workplace not included in Table A.1?
Y
Equipment issue = TRUE
N
Is there equipment in the workplace that is in Table A.1 that is not used in accordance with the remarks /exceptions given for that equipment?
Y
Equipment issue = TRUE
N

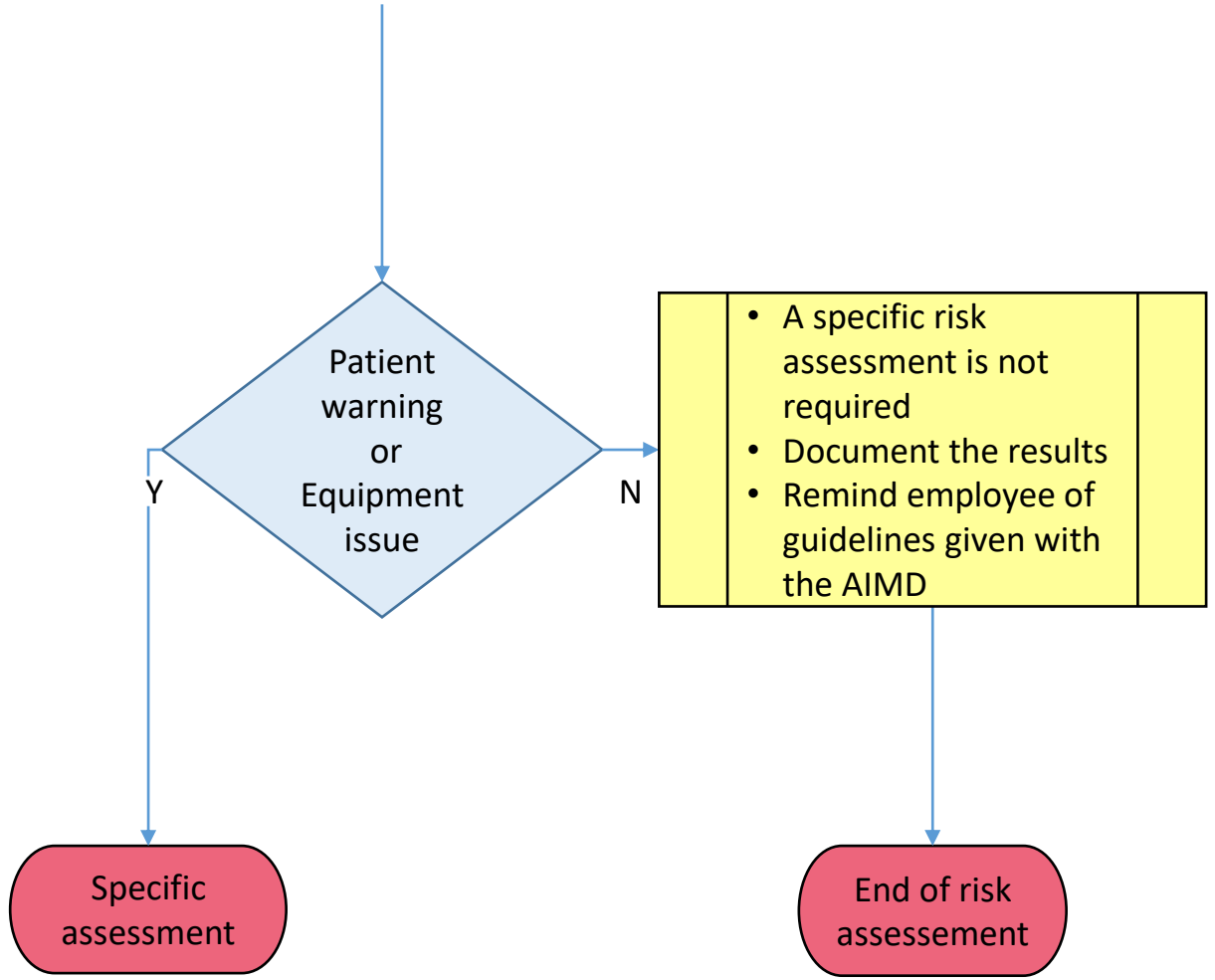

Start Risk Assessment
Has the AIMD-Employee an history of uninfluencend behaviour?
Y
N
The AIMD-Employee has an history of influenced behavior or no history exists at all
Has a responsible physician confirmed that this history is sufficient to exclude clinically significant interaction?
Y
Is there equipment in the workplace not included in Table A.1?
Y
Equipment issue = TRUE
N
Is there equipment in the workplace that is in Table
Y
Equipment issue = TRUE
N
Has the AIMD-Employee received patient-specific warnings provided by the responsible physician 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?
Y
Patient warning = TRUE
N
Y
Patient warning = TRUE
N
A specific risk assessment is not required
Document the results
Remind employee of guidelines given with the AIMD
Patient warning or Equipmen t issue
Y
N
Specific assessment
End of risk assessement
Patient warning = TRUE
Has the AIMD-Employee received patient-specific warnings provided by the responsible physician 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?
Y
N


Start Risk Assessment
Has the AIMD-Employee an history of uninfluencend behaviour?
Y
N
The AIMD-Employee has an history of influenced behavior or no history exists at all
Has a responsible physician confirmed that this history is sufficient to exclude clinically significant interaction?
Y
Is there equipment in the workplace not included in Table A.1?
Y
Equipment issue = TRUE
N
Is there equipment in the workplace that is in Table A.1 that is not used in accordance with the remarks /exceptions given for that equipment?
Y
Equipment issue = TRUE
N
Has the AIMD-Employee received patient-specific warnings provided by the responsible physician due to sensitivity settings in effect that may cause changes in pacemaker behaviour in the presence of
Y
Patient warning = TRUE
N
Has the AIMD-Employee received 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 which are present or expected in the workplace;
Y
Patient warning = TRUE
N
Patient warning or
N
ecific risk ssessment is not required
Document the results
Remind employee of guidelines given with the AIMD
Specific assessment
End of risk assessement


Has the AIMD-Employee received 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 which are present or expected in the workplace
Patient warning = TRUE
Y
N

50527-2-1 - DRAFT





CEI EN 50527-2-1: specific risk assessment: how?

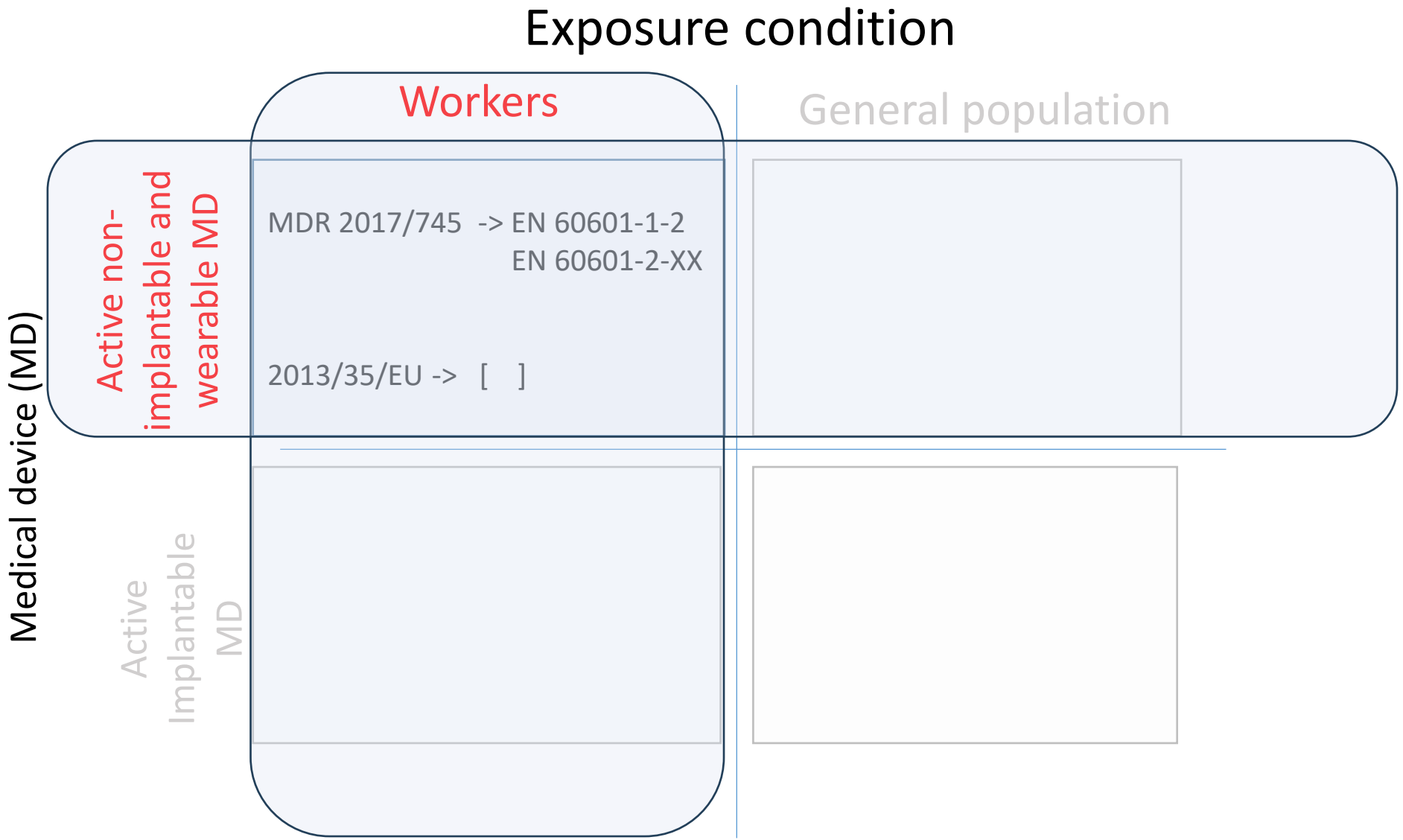
4.1.5.1 General

There are two alternative types of investigative methods that may be used:

- clinical (or *in vivo*) methods directly involving the pacemaker-Employee who is monitored for interference effects; or
- **non-clinical methods** based upon a choice of either ***in vitro*** or **comparative** study.

For leadless pacemaker systems only clinical and non-clinical *in vitro* methods shall be used as comparative study methods have not yet been established.
If a chosen method provides insufficient information for the risk assessment, further investigation is necessary.

Non-implantable active devices and wearables



Non-implantable active devices and wearables

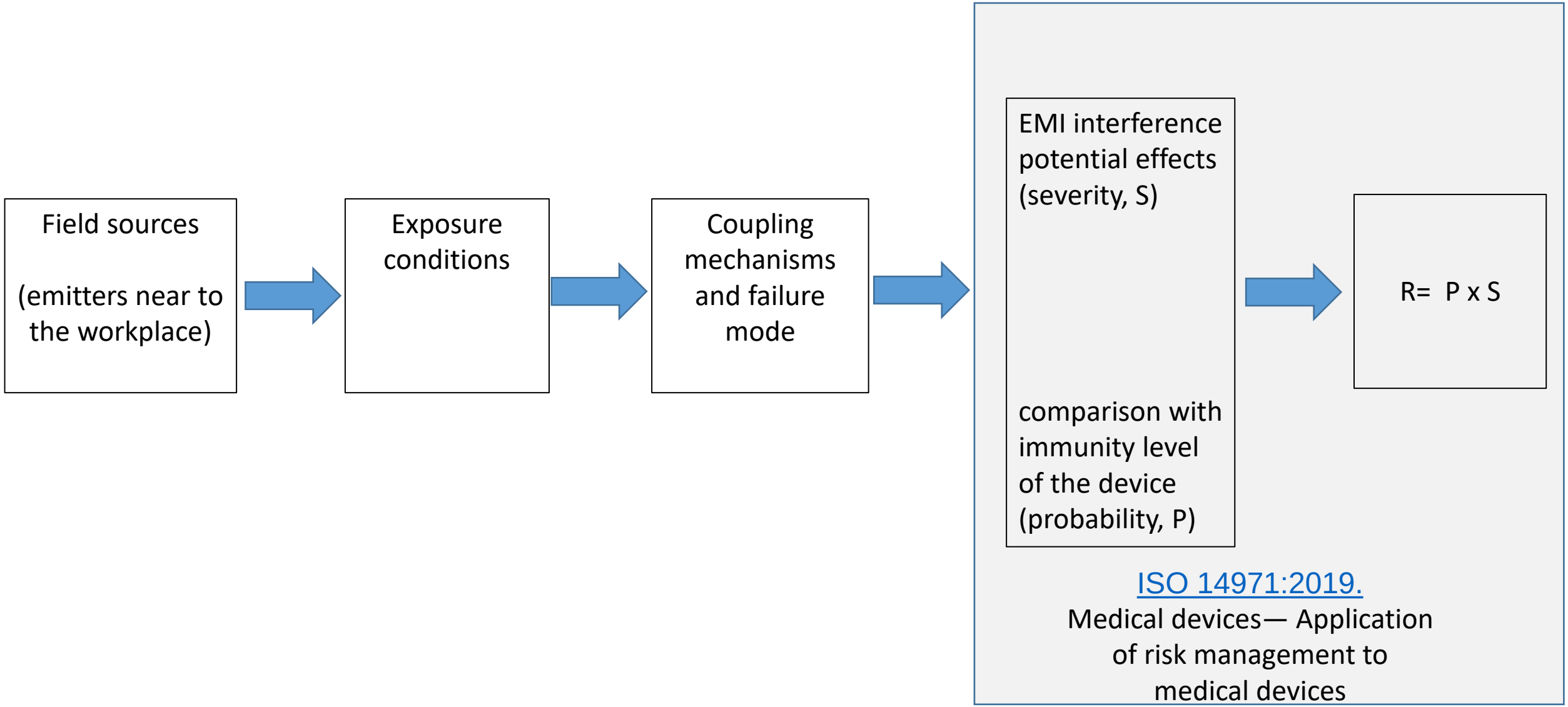
- Non esiste, al momento, una norma tecnica per la valutazione del rischio specifico di interferenze elettromagnetiche associato a lavoratori con dispositivi medici attivi non-impiantabili o indossabili*

- La norma sulla compatibilità elettromagnetica (EN 60601-1-2) demanda al fabbricante:
  - l'analisi dei rischi ed eventualmente l'esclusione di particolari ambienti o sorgenti
  - Le informazioni da riportare sui manuali dei dispositivi relativamente a livelli di immunità e/o distanze di sicurezza

NON ESISTE UN LEGAME FRA LIVELLI DI IMMUNITA' E «REFERENCE LEVEL»!

A maggio 2024 il CENELEC ha approvato la proposta di espandere il campo di applicazione della 50527 per includere i wearable devices

Modello concettuale per la valutazione del rischio



Aggiornamento del quadro normativo

summary and take –home message

Nuova versione della EN 50527-2-1 (expected late 2026):

- Inclusione dei dispositivi per la resincronizzazione cardiaca (CRT-P)
- Inclusione dei dispositivi leadless
- nuova flow-chart per l'analisi del rischio

Ampliamento dello scopo della EN 50527-1 per includere dispositivi medici attivi non-impiantabili ed indossabili (expected late 2027)