

Date : 7 December 2022



MINISTRY OF INTERNATIONAL TRADE AND INDUSTRY  
DEPARTMENT OF STANDARDS MALAYSIA

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**Accreditation Division**  
**ACCREDITATION CIRCULAR 1/2022**  
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**CHANGE OF ACCREDITATION CYCLE**

**1. Introduction and scope**

Department of Standards Malaysia (JSM) is in the process of harmonising its management system across all the schemes offered as follows: :

- a) *Skim Akreditasi Makmal Malaysia* (SAMM)
- b) The Scheme of Accreditation of Certification Bodies (ACB)
- c) Malaysia Inspection Bodies Accreditation Scheme (MIBAS)
- d) Malaysia Proficiency Testing Provider Accreditation Scheme (MyPTP)
- e) Primary Healthcare Laboratory Accreditation Scheme (PHLAS)
- f) Scheme for the Accreditation of Validation and Verification (V&V)

Effective 1st January 2023, JSM will implement a five (5) year accreditation cycle.

**2. Objective**

This circular is aimed to inform JSM accredited conformity assessment bodies (CABs) on the transition process to the five (5) year accreditation cycle.

**3. Changes to the accreditation cycle:**

3.1 Changes to the accreditation cycle are as follows:

- a) For the SAMM, MIBAS, MyPTP and PHLAS schemes, the accreditation cycle will be changed from a three (3) year accreditation cycle to a five (5) year accreditation cycle; and
- b) For the ACB scheme, there is a change to the first accreditation cycle (first five (5) years after award of accreditation).

3.2 Changes to the accreditation cycle are as follows:

- a) First accreditation cycle (first five (5) years after award of accreditation):

Stage	Date
Surveillance 1	10 months after award of accreditation
Surveillance 2	15 months after scheduled Surveillance 1
Surveillance 3	15 months after scheduled Surveillance 2
Reassessment	15 months after scheduled Surveillance 3; or 5 months before accreditation expiry date

b) 2<sup>nd</sup> and subsequent accreditation cycle:

Stage	Date
Surveillance 1	15 months from the date of previous accreditation expiry date
Surveillance 2	20 months after scheduled Surveillance 1
Reassessment	20 months after scheduled Surveillance 2; or 5 months before accreditation expiry date

3.3 Illustration of the distribution of assessments over the new accreditation cycle is as per Annex 1. The assessment programme based on the new accreditation cycle is as per Annex 2.

3.4 For the ACB scheme, in addition of clause 3.2, the following applies:

- a. Witnessing assessment shall be conducted annually in accordance to ACB 4 - Policy on scope of accreditation and management of accredited scope by certification bodies.
- b. For Certification Bodies (CBs) with Medical Device Quality Management Systems (MDQMS), please refer to Annex 3.

3.5 However, JSM reserves the right to revert the accreditation cycle depending on the performance of the CAB arising from the performance of the CAB (e.g. Failure to resolve nonconformities in accordance with an AB's procedures, consequence of poor performance in Proficiency Testing (PT), negative outcome of a complaint investigation; etc.) during the accreditation cycle.

#### 4. JSM arrangement for the transition to the new accreditation cycles

##### 4.1 Accredited conformity assessment bodies

- i. The change to the new accreditation cycle will be carried out with CABs that accreditation expires on or after **1<sup>st</sup> January 2023**. The change will take effect after the renewal (i.e. reassessment) of accreditation .

#### **4.2 New Applicants:**

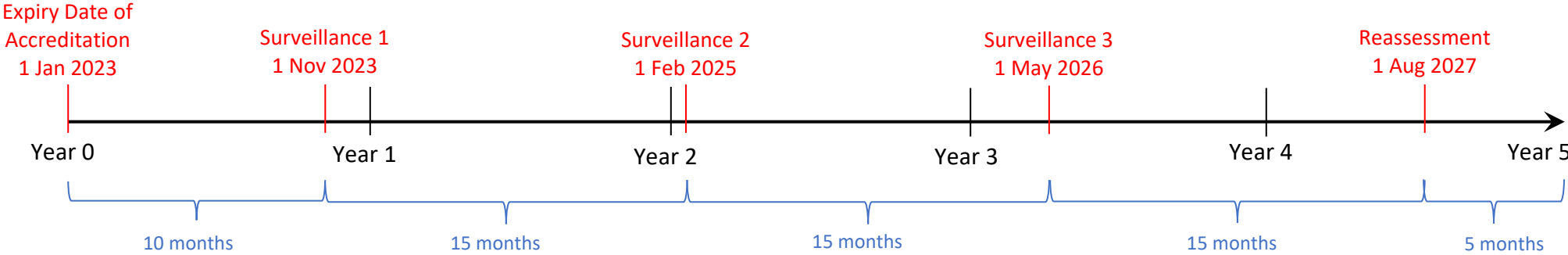
- i. All applicants whose accreditation is granted **after 1<sup>st</sup> January 2023** will be in accordance with the new five (5) year accreditation cycle.
- ii. For the ACB scheme, the following applies:
  - a. For new applicants without prior accreditation from JSM, the applicants will follow the first accreditation cycle; or
  - b. For new applicants with existing accreditation from JSM (i.e. addition of programme), the applicant may be recommended to the existing cycle of the accredited programme(s).

**THANK YOU**

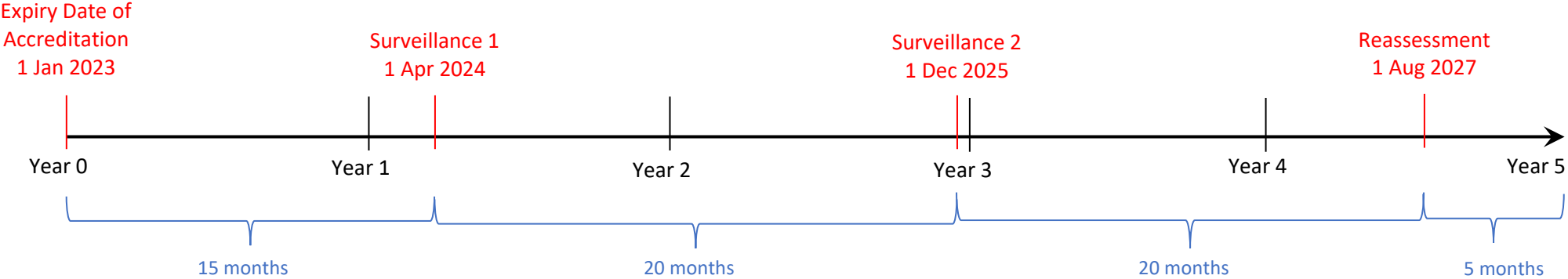
Director of Accreditation

# Illustration of distribution of assessments over the new accreditation cycle

## 1st accreditation cycle\*



## Second and subsequent accreditation cycle\*



\*For ACB, witnessing assessments, assessments are conducted annually as per the policy document, ACB 4.

**Assessment Programme based on New Accreditation Cycle**

**1<sup>st</sup> Accreditation Cycle (to edit include Year besides month & bottom example)**

AWARD/RENEWAL OF ACCREDITATION (YEAR 0)	SURVEILLANCE 1 (YEAR 0)	SURVEILLANCE 2 (YEAR 2)	SURVEILLANCE 3 (YEAR 3)	RE-ASSESSMENT (YEAR 4)
January	November	February	May	August
February	December	March	June	September
March	January	April	July	October
April	February	May	August	November
May	March	June	September	December
June	April	July	October	January
July	May	August	November	February
August	June	September	December	March
September	July	October	January	April
October	August	November	February	May
November	September	December	March	June
December	October	January	April	July

**Example of assessment dates based on 1<sup>st</sup> accreditation cycle**

1-Jan-2023	1-Nov-23	1-Feb-25	1-May-26	1-Aug-27
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**2<sup>nd</sup> and Subsequent Cycle**

AWARD/RENEWAL OF ACCREDITATION (YEAR 0)	SURVEILLANCE 1 (YEAR 1)	SURVEILLANCE 2 (YEAR 2)	RE-ASSESSMENT (YEAR 4)
January	April	December	August
February	May	January	September
March	June	February	October
April	July	March	November
May	August	April	December
June	September	May	January
July	October	June	February
August	November	July	March
September	December	August	April
October	January	September	May
November	February	October	June
December	March	November	December

**Example of assessment dates based on 2<sup>nd</sup> and Subsequent Accreditation Cycle**

1-Jan-23	1-Apr-24	1-Dec-25	1-Aug-27
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**CERTIFICATION BODIES ACCREDITED FOR MEDICAL DEVICE QUALITY  
MANAGEMENT SYSTEMS (MDQMS)**

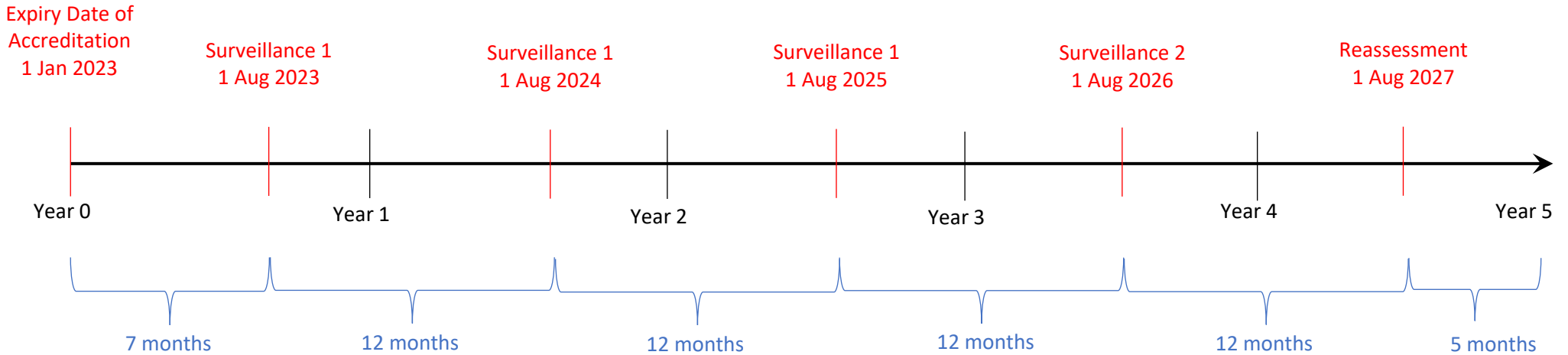
1. In line with IAF MD 8 - Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485), there will be annual surveillance throughout the five (5) year accreditation cycle as follows:

<b>Stage</b>	<b>Date</b>
Surveillance 1	7 months after award or accreditation / previous accreditation expiry date.
Surveillance 2	12 months after scheduled surveillance 1
Surveillance 3	12 months after scheduled surveillance 2
Surveillance 4	12 months after scheduled surveillance 3
Reassessment	12 months after scheduled surveillance 4; or 5 months before accreditation expiry date

2. CB's that are not just accredited for MDQMS but are also accredited for other programmes may choose to align the accreditation cycle of other programmes with the MDQMS accreditation cycle. However, please take note that the assessment fees remain as per the Standards of Malaysia (Fees) Regulation 2018 [P.U.(A) 75]. CB's wishing to do so shall inform JSM in order for JSM to issue the assessment programme accordingly.

3. An illustration of the MDQMS accreditation cycle is as follows:

**MDQMS Accreditation Cycle (Only applies to MDQMS CBs)**



4. The assessment programme for the MDQMS Accreditation Cycle is as follows:

<b>AWARD/RENEWAL OF ACCREDITATION (YEAR 0)</b>	<b>SURVEILLANCE 1 (YEAR 1)</b>	<b>SURVEILLANCE 2 (YEAR 2)</b>	<b>SURVEILLANCE 3 (YEAR 3)</b>	<b>SURVEILLANCE 4 (YEAR 4)</b>	<b>RE-ASSESSMENT (YEAR 5)</b>
January	August	August	August	August	August
February	September	September	September	September	September
March	October	October	October	October	October
April	November	November	November	November	November
May	December	December	December	December	December

<b>AWARD/RENEWAL OF ACCREDITATION (YEAR 0)</b>	<b>SURVEILLANCE 1 (YEAR 1)</b>	<b>SURVEILLANCE 2 (YEAR 2)</b>	<b>SURVEILLANCE 3 (YEAR 3)</b>	<b>SURVEILLANCE 4 (YEAR 4)</b>	<b>RE-ASSESSMENT (YEAR 5)</b>
June	January	January	January	January	January
July	February	February	February	February	February
August	March	March	March	March	March
September	April	April	April	April	April
October	May	May	May	May	May
November	June	June	June	June	June
December	July	July	July	July	December

**Example of assessment dates based on 2<sup>nd</sup> and Subsequent Accreditation Cycle**

1-Jan-23	1-Aug-23	1-Aug-24	1-Aug-25	1-Aug-26	1-Aug-27
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