Our mission: To ensure that the drugs, medical devices, and other therapeutic products available in Canada are safe, effective and of high quality.

NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

Management of Applications for Medical Device Licences and Investigational Testing Authorizations
Management of Applications for Medical Device Licences and Investigational Testing Authorizations

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Attachment 1 - Interim Target Performance Standards for Management of Applications for Medical Device Licences and Investigational Testing Authorizations
MANAGEMENT OF APPLICATIONS FOR MEDICAL DEVICE LICENCES 
AND INVESTIGATIONAL TESTING AUTHORIZATIONS

1. PURPOSE

The purpose of this policy is to outline the way the Medical Devices Bureau (MDB) will manage applications for medical device licences and applications for investigational testing authorizations submitted in accordance with the Medical Devices Regulations.

2. SCOPE

This policy applies to the following medical device application types:

- Licence Applications for Class II, III and IV medical devices;
- Licence Amendments for Class II medical devices, and Licence Amendments (significant changes)* for Class III and IV medical devices;
- Licence Amendment Fax-Back Forms (for minor changes)** for Class II, III and IV medical devices, and
- Applications for Investigational Testing Authorizations (for testing involving human subjects).

The same management principles will be applied consistently to all medical device application types and all applications will be examined for completeness and suitability for review. In addition, subsequent solicited or unsolicited information will be subjected to a screening process.

All information and data submitted in support of a medical device licence application or application for investigational testing authorization remains the property of Health Canada.

3. FILING OF MEDICAL DEVICE LICENCE APPLICATIONS

Manufacturers are requested to send all original applications, application amendments and responses to Additional Information Letters to:

Information Dissemination Unit
Licensing Services Division
Medical Devices Bureau
Room 1605, Main Statistics Building #3
Postal Locator 0301H1
Ottawa, Ontario K1A OL2

Clarifax requests should be returned to the sender at the facsimile number indicated in the request.


4. ADMINISTRATIVE PROCESSING

All application types will be examined for administrative completeness e.g., fee form, appropriate fee enclosure and requisite application form information as outlined in detail in “Guidance on How to Complete the Application for a New Medical Device Licence”. The Bureau will target to complete this examination within four (4) calendar days of receipt in the Bureau.

4.1 Acceptable Applications

Applications meeting the administrative requirements will be assigned an application number and forwarded for subsequent application validation.

4.2 Unacceptable Applications

Applications that are deficient with respect to administrative content will result in a request for outstanding information by facsimile. The manufacturer will be given ten (10) calendar days to provide a complete response. Failure to provide the requested information within the specified time-frame or provision of deficient or incomplete information will result in the issuance of a Rejection Letter-Administrative Processing.

Fee status: No fees will be levied as a result of application rejection at the administrative processing stage.

5. APPLICATION VALIDATION PROCESS

All applications will be subject to an examination for validity of regulatory information for the type of application in question e.g., risk class, application type, catalogue detail, device purpose, as defined in the Medical Devices Regulations and as described in various guidance documents.

5.1 Acceptable Original Information

1. Class II Licence applications, Class II Licence Amendments and Class II, III and IV Licence Amendment Fax-Back Forms (for minor changes)

The Bureau will target to have Class II Licence Applications and Class II Licence Amendments examined for application validity and a Licence issued within fifteen (15) calendar days of receipt of the application in the Bureau. For Class II, III and IV Licence Amendment Fax-Back Forms (for minor changes) the Bureau will target to have the applications examined and the Fax-Back Form signed and returned to the manufacturer within seven (7) calendar days of receipt of the application in the Bureau for acceptable amendments and a Licence issued within fifteen (15) calendar days.

2. Class III and Class IV Licence Applications and Class III and IV Licence
Amendments (significant changes)

The Bureau will target to have Class III and IV Licence Applications and Class III and IV Licence Amendments (significant changes) examined for application validity within four (4) calendar days of receipt following the application processing step. Acceptable applications will then undergo technical screening, as described under Section 6.

5.2 Unacceptable Original Information

a) Class II Licence Applications, Class II Licence Amendments, and Class II, III and IV Licence Amendment Fax-Back Forms

If deficiencies are identified during the examination for validity of a Class II Licence Application, a Class II Licence Amendment or Class II, III or IV Licence Amendment Fax-Back Form (for minor changes), an Application Validation Additional Information Request will be issued to the manufacturer by facsimile.

The manufacturer will then have ten (10) calendar days from the date of the Application Validation Additional Information Request to submit the identified information. A new fifteen (15) calendar day target will commence for Class II Licence Applications and Class II Licence Amendments, upon receipt in the Bureau of the requested information. For Class II, III or IV Licence Amendment Fax-Back Forms (for minor changes), a new seven (7) calendar day target will commence for the signed return of the Fax-Back Form and a new fifteen (15) calendar day target for issuance of the Licence after receipt of an acceptable response.

Failure to respond to the Application Validation Additional Information Request within the specified time-frame or provision of a deficient or incomplete response will result in the issuance of a Rejection Letter-Application Validation. If the manufacturer wishes to re-submit the application at a future time, it will be processed as a new application.

Fee status: In the case of a new Class II Application, a base fee (200$) will be levied upon issuance of a Rejection Letter-Application Validation.

b) Class III and IV Licence Applications and Class III and IV Licence Amendments (significant changes)

If deficiencies are identified during the examination for validity of a Class III or IV Licence Application or Class III or IV Licence Amendment (significant changes), an Application Validation Additional Information Request will be issued to the manufacturer by facsimile. A time-frame of ten (10) calendar days for filing a complete response will be stipulated. Failure to respond within the specified time-frame or provision of a deficient or incomplete response will result in the issuance of a Rejection Letter-Application Validation.
If the risk classification outlined in the application is incorrect and the actual classification according to the *Medical Device Regulations* is a higher risk classification, a **Rejection Letter-Device Classification** will be issued to the manufacturer.

Fee status: A fee (10% of fee submitted) will be levied upon issuance of a **Rejection Letter-Application Validation** or **Rejection Letter-Device Classification**. If an application is rejected, the manufacturer will be required to submit a new application with all the relevant information and fees.

6. **SCREENING**

All Class III, IV, and Class III, IV Licence Amendment (for significant changes) applications will be screened for technical completeness to ensure that the requisite information for the type of application in question, as defined in the *Medical Devices Regulations* and as described in various guidance documents, has been submitted.

Responses to **Additional Information Letters** should be provided in question and answer format with cross-referencing to original or replacement volumes as required. Manufacturers should clearly identify the Application Number of the relevant application. All subsequent information will be screened to ensure that it is complete for the purpose intended.

6.1 **Acceptable Original Information**

1. **Class III and Class IV Licence Applications and Class III and Class IV Licence Amendments (for significant changes)**

The Bureau will target to have Class III and IV Licence Applications and Class III and IV Licence Amendments (for significant changes) screened within fifteen (15) calendar days of receipt in the Bureau of an administratively complete and validated application. A **Screening Acceptance Letter** will be issued by Licensing Services Division when the information and material submitted is deemed acceptable for review.

2. **Applications for Investigational Testing Authorization, Class II, III, IV**

Applications for investigational testing authorizations will be screened prior to the commencement of review but the screening period will be included in the thirty (30) calendar day target review time. If the application is accepted for review, a **Screening Acceptance Letter** will be issued by Device Evaluation Division.

6.2 **Unacceptable Original Information**

1. **Screening Deficiency Letters**

If deficiencies are identified during the screening of a Class III or IV Licence Application
or Class III or IV Licence Amendment (for significant changes), a **Screening Deficiency Letter** (by facsimile and mail) will be issued by Licensing Services Division. Class III and Class IV device licence applications will be identified as deficient if the review components are not provided in sufficient detail as described in the Guidance Document, “Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications”.

The manufacturer will then have fifteen (15) calendar days from the date of the **Screening Deficiency Letter** to submit all of the requested information in a question and answer format. The Bureau will acknowledge receipt of the Screening Deficiency response from the applicant by facsimile. The response will then be subject to a new fifteen (15) calendar day screening period upon receipt in the Bureau. Provided that the application is now acceptable for review, a **Screening Acceptance Letter** will be issued to the manufacturer by Licensing Services Division.

If the original application is grossly deficient, a **Rejection Letter-Screening** will be issued as outlined in section 6.2.2.

For an unacceptable Application for Investigational Testing Authorization, a **Screening Deficiency Letter** will be issued by the Device Evaluation Division. The 30-day review target will stop upon issuance of the letter. Upon receipt in the Bureau of the requested information, a response will be issued by the Bureau and a new thirty (30) calendar day review target will commence. Further guidance on Investigational Testing application review components can be obtained from the document “Preparation of an Application for Investigational Testing - Medical Devices”.

If the original Application for Investigational Testing Authorization is grossly deficient, a **Rejection Letter - Screening** will be issued by the Device Evaluation Division as outlined in Section 6.2.2.

2. **Rejection Letters**

Failure to submit the information requested in a **Screening Deficiency Letter** within fifteen (15) calendar days from the date of the letter or submitted information which is incomplete or deficient will result in the application not being accepted for examination and the issuance of a **Rejection Letter-Screening** by Licensing Services Division for failure to provide a complete application.

If an original application is grossly deficient, it will not be accepted for examination. A **Rejection Letter - Screening** will be issued by Licensing Services Division for failure to provide a complete application. A Class III, IV application is considered grossly deficient when there is an omission of review components (as applicable) in the application as listed and described in the guidance document “Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications”.

All decisions to reject an application are without prejudice to re-filing. If the manufacturer
wishes to resubmit an application at a future time, it will be processed as a new application.

Fee status: A fee (10% of applicable fees) will be levied upon issuance of a Rejection Letter - Screening.

A manufacturer may appeal the Bureau’s decision to reject their application by following the Appeals process outlined in Section 12 of this document.

7. REVIEW

Upon issuance of a Screening Acceptance Letter, applications will enter the review queue of each Section in Device Evaluation Division. The Head of each Section is responsible for managing the Section’s workload and assigning new work items to their staff, taking into account performance targets.

The review target for Class III Licence Applications and Class III Licence Amendments (for significant changes) is sixty (60) calendar days from the date of the Screening Acceptance Letter.

The review target for Class IV Licence Applications and Class IV Licence Amendments (for significant changes) is seventy-five (75) calendar days from the date of the Screening Acceptance Letter.

7.1 Clarification Requests

At any point during the review process, manufacturers may be requested by facsimile to clarify or add precision to information or data within a Licence Application, Licence Amendment or Application for Investigational Testing Authorization. This information must be of a minor nature in order to be considered a clarification request.

Clarification requests do not contain requests for new data and manufacturers will have ten (10) calendar days to submit the requested information in question and answer format. The review clock does not stop during this time provided the faxed responses are considered acceptable.

There is no limitation on the number of such requests that may be issued for one application; however, the same request will not be repeated.

7.2 Requests for Additional Information

At any point in the review process, significant deficiencies or information omissions that preclude the ongoing review of a Licence Application, Licence Amendment or Application for Investigational Testing Authorization may be transmitted to the manufacturer in an Additional Information (AI) Letter. Such letters will be issued by Device Evaluation
Division and the manufacturer will be given sixty (60) calendar days from the date of the letter in which to submit the requested information in question and answer format. The Bureau will target to issue one AI letter. In certain situations a second AI letter may be issued.

The review clock is stopped from the date of the Additional Information Letter. Upon receipt of the response to the AI Letter, a facsimile acknowledging the receipt of the Additional Information will be issued to the manufacturer by Licensing Services Division, and a new ten (10) calendar day screening period begins, followed by a thirty (30) calendar day review period. Medical Devices Bureau reserves the right to request clarification of the information submitted as defined in Section 7.1.

7.3 Refusal Letters

A Refusal Letter will be issued by the Bureau Director in the following circumstances:

S failure to submit the requested information in response to an Additional Information Letter within the sixty (60) calendar days specified, or submission of an incomplete or deficient response;

S failure to meet the requirements of the Medical Devices Regulations or any provisions of the Act, after a comprehensive review by Device Evaluation Division; or

S the applicant has made a false or misleading statement in the application.

The Refusal Letter will contain the specific reasons or deficiencies that resulted in the decision to refuse issuance of a Medical Device Licence or Authorization for Investigational Testing.

All decisions to refuse an application are without prejudice to re-filing (see Section 10 below). If a manufacturer wishes to resubmit an application at a future time, the application will be processed as a new application. Information and data submitted to support the original application will not be returned to the manufacturer. Such data may be cross-referenced if re-filing occurs within six (6) months (see Section 10 below).

Fee status: Full application fees will be levied upon issuance of an application Refusal Letter.

A manufacturer may appeal the Bureau’s decision to refuse their application in accordance with the Appeals Process outlined in Section 12 of this document.

7.4 Withdrawal Letters

At any time during the review of their application, manufacturers may withdraw their application by informing the Bureau Director of their intent in a Withdrawal Letter. All Withdrawal Letters will be acknowledged in writing by the Bureau. The status of the application will be recorded as “withdrawn by manufacturer”.
Withdrawal of an application is without prejudice to re-filing. If a manufacturer wishes to resubmit an application at a future time, a new Application number will be assigned and the application will be processed as a new application. Information and data to support the original application remain the property of Health Canada. Such data may be cross-referenced if re-filing occurs within six (6) months of withdrawal (see Section 10 below).

Fee status: If an application has been accepted for review and is awaiting to be reviewed, a 10% fee will be levied upon withdrawal of the application. A full fee will be levied upon withdrawal of an application if the application is under review.

8. REVIEWERS’ REPORTS

Following receipt of a **Refusal Letter**, an applicant (manufacturer) may request reviewers’ reports by writing to the Bureau Director and referencing the Application number.

The Bureau will target to provide a copy of the requested reports to the applicant within fifteen (15) calendar days of receipt of the request.

9. UNSOLICITED INFORMATION

Manufacturers are encouraged to submit at any time during the review, updated information on the regulatory status of the device in other countries and safety information enhancing the safe use of the medical device, including updated safety-related labelling and problem reports submitted to other Regulatory Agencies. Such safety information does not include significant changes to the device under review, which should be filed as a new application.

Manufacturers are requested to clearly identify the relevant application in a cover letter so that the new information can be forwarded efficiently to the appropriate review team.

10. RE-FILED APPLICATIONS

Manufacturers may re-file previously withdrawn applications, rejected applications or applications for which a **Refusal Letter** was issued.

In all cases, a re-filed application is considered to be a new application and will be managed according to this policy. In addition, a re-filed application is subject to any new policies, procedures or guidance documents that may be in effect at the time of re-filing.

10.1 Re-filing within six (6) months

If an application is re-filed within six (6) months of a **Refusal Letter** or **Withdrawal Letter**, the manufacturer may submit only the material requested in the outstanding **Additional Information Letter** or listed in the **Refusal Letter** provided there is
appropriate cross-referencing to the original material submitted.

If the manufacturer chooses to cross-reference original material previously filed, certification that the original material pertaining to the device remains unchanged must be included with the re-filed application. Manufacturers must also clearly identify new and previously submitted information in the Table of Contents of the re-filed application.

Fee status: Fees will be levied on a re-filed application according to additional updated review components.

10.2 Re-filing after Six (6) months

If an application is re-filed after six (6) months of a Refusal Letter or Withdrawal Letter, the manufacturer must submit a completely new application, i.e. no cross-referencing to previously submitted material is allowed. This procedure reflects the dynamic nature in the development of a medical device. The manufacturer should indicate, however, the components that were previously filed and certify the information that has remained unchanged. Any revisions should be high-lighted to facilitate the review.

10.3 Re-filing of a Rejected Application

If an application has been rejected, the manufacturer must submit a completely new application, i.e., no cross-referencing to previously submitted material is allowed.

11. FEES

For information on issues related to application evaluation fees, refer to the “Guidance document on Cost Recovery Fees in Respect of Medical Devices Regulations”.

12. APPEAL PROCEDURES

The purpose of an appeal is to allow the Therapeutic Products Directorate (TPD) and an application manufacturer to discuss issues related to a Directorate decision on an application. The Parties may clarify and justify their positions using information available to the TPD when the decision was made. The appeal must be based on the same information and material as the original decision. Information and material not submitted at the time of the initial decision will not be accepted.

The appeal procedures do not apply to the challenge of existing policies, guidelines or standards. The Directorate maintains other mechanisms to review and revise these documents which involve input from and consultation with a broad range of stakeholders. The appeal procedures also do not apply to issues related to changes in requirements resulting from the evolution of regulatory policy that have resulted in other products reaching the market under less stringent or more favourable conditions. Where appeals involve these types of issues, the appeal will be denied.
There are two levels of appeal procedures. The first level of appeal is to the Bureau Director responsible for the original decision. The second level of appeal is to the Director General (DG) of the Directorate.

The first level of appeal involves review of the Directorate’s decision within a process that is managed by the review Bureau. This process provides for a fair re-assessment of the original decision. Although the original reviewer may be consulted to clarify the basis of the original decision, the review of the appeal is carried out by staff who did not undertake the original review. Exceptions may occur where the expertise related to the matter is highly specialized. This review may also involve external expertise related to the matter by a qualified expert. The results of the first level review are presented to the Director for re-consideration of the original decision. It is recognized that there will be considerable overlap between an administrative review and an “appeal” at this level.

The second level appeal involves review of the Directorate’s decision in a process managed through the Director General’s Office. This process provides for an independent review of the subject of the appeal under the direction of the DG or his/her delegate. Those involved at this level are operationally and administratively removed from the review Bureaux. The second level appeal process provides for the consultation, where appropriate, of an Appeal Committee, a small group of scientific or medical experts with expertise relevant to the contentious issues of the appeal. This Committee makes recommendations to the Directorate. The Directorate does not devolve its regulatory decision-making authority to the Committee and continues to make final application decisions.

12.1 First level of appeal: Bureau Director

A manufacturer may appeal a decision to the Bureau Director at the following stages during the application review process:

1. Rejection Letter
2. Refusal Letter
3. Additional Information Letter

Within ten (10) calendar days of the date of the letter with the Therapeutic Products Directorate decision, the manufacturer must submit, to the Bureau Director, a letter of intent to appeal, to the attention of the Manager, Licensing Services Division.

Within twenty (20) calendar days of the date of the letter of intent to appeal, or such time that the Bureau Director and the manufacturer may agree upon, the manufacturer must file a comprehensive document containing the manufacturer’s position and full supporting information, cross-referenced to previously submitted data, as applicable (an electronic copy of this document, if available, should be provided as well). Should the manufacturer wish to meet with Bureau officials, this should be indicated when filing the comprehensive document. The purpose of this meeting is to provide the manufacturer with an opportunity to reiterate the major aspects of their appeal as stated in their filed appeal document. There will not be a debate of the issues or an appeal decision made at this meeting.
The appeal will be based only on the information and material upon which the original decision was made. Any new information referenced or contained in the comprehensive document will result in its return to the manufacturer for appropriate severances. This may result in denial of the appeal.

The Bureau Director will inform the manufacturer of the outcome of the appeal and outline the basis for the decision within twenty (20) calendar days from the receipt of the manufacturer’s supporting information or from the date of the meeting if one is requested.

12.2 Second Level of Appeal: Director General or Delegate and Appeal Committee

A manufacturer may appeal the Bureau Director’s decision following a first level appeal to the Director General at only the following stages during the application review process:

1. Rejection Letter
2. Refusal Letter

Within thirty (30) calendar days of the date of the Bureau Director’s decision made on the first level appeal, the manufacturer must submit to the DG, a letter of intent to appeal to the attention of the Manager, Licensing Services Division.

The manufacturer’s letter should include only the following information:

- a copy of the comprehensive document submitted at the time of the first level appeal (an electronic copy of this document, if available, should be provided as well), and
- a copy of the Bureau Director’s letter of decision on the first level appeal and attachments if any.

Within fifteen (15) days of the receipt of the manufacturer's intent to appeal, the DG or his/her delegate will acknowledge the receipt of the appeal and extend an invitation to the manufacturer to define the specific outstanding issues with the application at an informal meeting with the Directorate. This meeting will be non-confrontational and no debate of the issues will take place. The meeting will provide to the manufacturer an opportunity to ensure the DG or his/her delegate and the Office of Science, Bureau of Policy and Coordination, are aware of the salient points of the application that support the manufacturer’s position. Members of the review Bureau responsible for the application may attend this meeting.

The DG or his/her delegate will forward to the Office of Science the request for the second level appeal and all of the attached information and will request the Office to make recommendations regarding the acceptability of the appeal submission at the second level, possible resolutions of the appeal, and the need for an Appeal Committee. In order to ensure a fresh look at the matter and in the interests of fairness and independent review, no one in the Directorate involved in the evaluation of the application or in making the original decision will be responsible for the review of the second level appeal. However,
both the manufacturer and the bureau officials involved in the original decision may be consulted to expedite the review.

Within ninety (90) calendar days from the receipt of the manufacturer's notice declining to meet with the Directorate or from the date of the meeting if one is requested, the DG or his/her delegate will inform the manufacturer, with reasons, in writing, of:

a) the Directorate’s decision to grant the appeal; or
b) the Directorate’s decision to create an Appeal Committee; or
c) the Directorate’s decision to uphold the original decision without consulting an appeal committee; or
d) any other regulatory options that result from the review of the matter.

The DG or his/her delegate may consider an appeal without referring to an Appeal Committee based on the review of the matter including the report of the Office of Science and the recommendations made therein.

Some of the issues that may be appropriate for Appeal Committee consultation include:

• interpretation of available data;
• disagreement in applied methodology;
• relative weights given to data impacting on the risk benefit assessment of the application information;
• where the Directorate is not unanimous in its opinion on the application;

Issues that generally are not appropriate for Appeal Committee consultation include those that involve:

• insufficient data;
• data quality;
• application of false information;
• allegations of intellectual or regulatory bias;
• matters in which regulatory policy or procedures are the dominant concern; and
• where the Directorate has available recent outside independent expert opinion on the issue.

Where the DG or his/her delegate decides to consult an Appeal committee, the Committee will be formed with membership determined by the manufacturer and by the Directorate as follows:

• one member selected by the DG or his/her delegate from nominations by the manufacturer,
• one member selected by the DG or his/her delegate from nominations by the relevant Bureau Director, and
• one member appointed by the DG or his/her delegate, who, when possible, is a member of an Expert Advisory Committee and who will chair the Appeal
The DG or his/her delegate will also appoint a member of the Office of Science as coordinator of the Committee who will be responsible for managing the operation of the Appeal Committee.

Members will be chosen based on their experience, expertise, or analytical skills relevant to the review of a particular disputed issue. All committee members have to meet conflict of interest and security clearance requirements. Any person who was previously involved with decisions related to the application or reviewed information related to the application on behalf of the Directorate or manufacturer will not be eligible as a member of the Appeal Committee. Detailed information on security requirements and the Conflict of Interest Policy (COI) (Annex 3, Policy Guide for the Management of Advisory Committees in Health Canada, March 1998) is available from the Office of Science.

The manufacturer of the application will be requested to provide nominations for one member of the Appeal Committee with expertise in areas identified by the Directorate as relevant to the resolution of the matter. The manufacturer is required to include the Curriculum Vitae of their candidates and written confirmation that the candidates can comply with the COI policy. To ensure that nominees can comply with COI requirements the manufacturer should not provide them with any material for review prior to the official appointment of the member by the DG or his/her delegate. The nominees should not have been involved with the manufacturer in the past and should not have expressed their views regarding the product in question. The coordinator of the Appeal Committee will be responsible for the material provided to the members for review. Costs incurred for all committee members will be paid by the Directorate.

The information considered by an Appeal Committee will be based on the same information contained in the application as that reviewed to arrive at the original decision. A Committee may receive oral representation from the manufacturer and/or the relevant review Bureau as considered to be necessary by a Committee member. The Committee will make recommendations to the DG. Each recommendation will be made on the concurrence of at least two of the three Committee members. Consistent with its advisory role, the Committee will not be asked to make a decision on the application. Rather, advice from the Committee will be solicited through one or more direct questions related to the specific outstanding issues that have been identified during the appeal processes.

Within fourteen (14) calendar days of the receipt of a Committee's recommendation the DG or his/her delegate will consider the recommendations of an Appeal Committee and inform the manufacturer of the Directorate’s decision.

12.3 Impact on Review Process

If the decision resulting from either the first or second level of the appeal process is in favour of the manufacturer, the review process will resume according to this policy and the Performance Targets (Attachment #2).
If the decision of the appeal process is not in favour of the manufacturer, the Directorate decision will be considered upheld and effective on the date of the original decision for application management purposes.

Final version: March 27, 2001
## INTERIM TARGET PERFORMANCE STANDARDS FOR MANAGEMENT OF APPLICATIONS FOR
MEDICAL DEVICE LICENSES AND INVESTIGATIONAL TESTING AUTHORIZATIONS

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<th>SCREENING 2</th>
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TARGET = 90% of the submissions in a category to be processed within the time shown.

(Screening 2 and Review 2: the screening and review of additional information requested during the review of an application or amendment).

August 18, 2000