Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation of Health and Social Care Services

Making a Submission on a Stage-2 Inspection Report to the Director of Regulation

Standard Operating Procedure (SOP)

Effective June 2019

Safer Better Care

1. Procedure

This standard operating procedure (procedure) outlines the process for a service provider (the "provider") to make a formal submission to the Director of Regulation on a regulatory judgment in a stage-2 inspection report.

2. Scope

This procedure only applies to **stage-2 inspection reports** which contain regulatory judgments following inspection of children and healthcare services.[1]

The following areas are outside the scope of a submission and will not be considered:

- any matter which is the subject of an independent inquiry or legal proceedings
- any commentary on Parts 2 or 8 of the Health Act 2007 (as amended)
- any submission made without completing the compliance plan or action plan[2] and or feedback form as referred to in section 3.1 of this procedure
- any commentary not related to the regulatory judgments contained within the stage-2 inspection report
- stage-3 inspection report and published reports
- any submission from a provider's representative body on an issue of general concern
- any matter relating to a third party who believes they are adversely mentioned in an inspection report, for example, a visiting health professional[3]
- any matter relating to the conduct of inspectors or authorised person

[1] 'Services' as used in this document includes, detention school, children's residential centres, healthcare facilities, hospitals, medical radiological installations, child protection and welfare services and foster care services.
[2] Where applicable
[3] Any person who believes himself or herself affected in this way should raise the matter directly with the inspector who is responsible for compiling the report.

(inspectors)[4]

- any matter previously dealt with under the HIQA's complaints policy.
- any matter considered to be vexatious in nature.

3. Stages of inspection report

Inspection reports outline the compliance of the provider with relevant regulations and nationally mandated standards as set under the Health Act 2007 (as amended); the Child Care Act, 1991; the Children Act, 2001; and the Child Care (Amendment) Act 2011. Inspectors may look at any aspect of the service in order to assess compliance with the standards.

In the course of their regulatory and inspection work, inspectors make judgments on an ongoing basis regarding the governance, leadership and management,[5] the quality and safety of services and the degree to which a provider and persons in charge comply with relevant national standards.

Inspectors base their professional regulatory judgment on all the available relevant information in relation to the service. Inspections can often take place over one to two days, and it is therefore not possible for an inspector to reference, in the inspection report, all of the information obtained.

An inspection report may go through three stages of development. This procedure references the inspection report at each stage of development.

3.1 Stage-1 inspection report

A stage-1 inspection report is issued to the provider following an inspection of the service. Preliminary findings will have been given verbally by the inspector or inspectors during the close-out meeting at the end of the inspection. When the stage-1 report is issued to the provider, it will also include a feedback form and

[4] These matters will be dealt with under HIQA's complaints policy.
[5] Capacity and capability of the provider to deliver a safe quality service.

compliance plan template or action plan template[6].

At this point, the provider should engage with the inspector to discuss any specific concerns or queries they may have regarding the inspection report and or regulatory judgments in the stage-1 inspection report. This can be done by phone and or email with the inspector.

The provider may submit a completed feedback form. This should include any factual accuracy detail and feedback on the regulatory judgments made by the inspector in the stage-1 inspection report. Completed feedback forms must be returned within **15 working days** from the date of issue of the stage-1 inspection report to the provider.

Notwithstanding the feedback process, the provider is required to submit a compliance plan or action plan to the inspector at this stage. The completed plan must be returned to the Director of Regulation within **15 working days** from the issuing of the stage-1 report.

3.2 Stage-2 inspection report

A stage-2 inspection report includes any changes made by the inspector following the feedback process. The stage-2 inspection report will only be issued to the provider on completion of the feedback process outlined in section 3.1 of this procedure. If the provider does not engage in the feedback process, a stage-2 inspection report will not be issued to the provider.

[6] Where applicable

3.3 Stage-3 inspection report (final report)

A stage-3 inspection report is the final report which is issued to the provider.

4. How to make a submission on a regulatory judgment or judgments — procedure steps

Once the provider has completed the feedback process and has been issued with the stage-2 inspection report, the provider has **10 working days** to submit a formal submission[7] using the submission form available on HIQA's website.

A submission may be made by the provider in the following circumstances:

- Where the provider has fully engaged with the feedback process and believes that the judgment or judgments[8] contained in the stage-2 inspection report are disproportionate to the evidence provided to, reviewed and observed by the inspector on the inspection and through the feedback process.

Valid submission

A submission will be considered to be valid once it has been fully completed on the prescribed form as set out above and contains no areas that are out of scope (see section 2 of this procedure) or personal data.

4.1 Registered provider submission

Submission form

The submission should be made by completing the submission form available on HIQA's website and sending it by email to the Director of Regulation at directorofregulation@hiqa.ie.

[7] The making of a submission does not impact on HIQA's function to monitor compliance with standards or repond to risk.
[8] Judgments descriptors include – compliant, substantially compliant or not compliant and the associated risk rating. A submission on regulatory judgments does not include feedback on the body of the report or factual accuracies. These matters should be dealt with during the stage-1 inspection report feedback process.

Review of regulatory judgments

The provider must outline the particular regulatory judgment or judgments contained in the stage-2 inspection report that it wishes to have reviewed. Providers may submit contemporaneous evidence or descriptors of circumstances that support its case.

Personal data

The Director of Regulation[9] will not accept submission forms and associated documents from providers which include personal data.[10] If personal data is included in the submission and or any supporting documentation, the submission will be deemed to be invalid and all documentation received will be destroyed.

In this case, the provider will be given an opportunity to make a valid submission without personal data within **five working days** of being issued notice of the destruction of its previous submission. If no valid submission is received after five working days, the inspection report will be progressed to a stage-3 inspection report. If a valid submission is received within five working days, the timelines in this procedure for decision will apply.

4.2 Director of Regulation Review

Once a valid submission is received, the stage-2 inspection report will not be progressed to the publication stage until the requirements under this procedure have been exhausted. Following review of the submission, the Director of Regulation will decide to:

a) Request further engagement with the provider through the feedback process. Please refer to section 4.3 for further information on "Referral to feedback process".

[9] Or delegate.

[10] Personal data shall mean personal data as defined in article 4(1) of the General Data Protection Regulation (GDPR) — personal data means any information relating to an identified or identifiable natural person (data subject); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical psychological genetic, mental economic cultural or social identity of that natural person.

b) Refer for recommendation on the submission.

An acknowledgement letter will be issued to the provider within **10 working days** of receipt by the Director of Regulation of a valid submission. This letter will detail the Director of Regulation's decision on whether the submission is referred back to the feedback process or for a recommendation on the submission.

4.3 Referral to feedback process

As referenced in section 4.2 of this procedure, the Director of Regulation may decide to refer a submission back to the feedback process. Inspectors will follow the feedback process, which will include:

- a further review of the provider's completed feedback form
- a review of any additional feedback received through the submission
- and or direct engagement with the provider.

Where the stage-2 inspection report is referred back to the feedback process, the inspector or inspectors will conclude the feedback process within 10 working days of the referral and re-issue a stage-2 inspection report to the provider. The provider will then have **five working days** to consider the stage-2 inspection report and if required to make a further submission using the submission form. In doing so, the provider must comply with this procedure in making a submission to the Director of Regulation.

4.4 Recommendation on submissions

Where the Director of Regulation had decided the submission is being progressed for recommendation, the Director of Regulation will:

a) assign the submission to a senior manager to consider and make a recommendation or

b) convene a submission panel and appoint a chairperson from HIQA's

Regulation Directorate and other members of the panel from HIQA's Regulation Directorate to consider and make a recommendation.

If a panel is convened, it will consist of not less than two members, one of whom will be a senior manager.

Neither the sole senior manager identified in (a) above nor the panel members in (b) above will have direct involvement regarding the inspection of the service and the submission under review.

The senior manager or panel will review the submission with the inspector and his or her regional manager in attendance. The senior manager or panel will only consider information and documentation relevant to the submission. This may include (but is not limited to):

- stage-1 and stage-2 inspection reports
- inspection notebooks
- provider's submission and accompanying relevant contemporaneous documentation submitted by the provider
- other information submitted to the Director of Regulation for the purpose assessing compliance with the standards which are relevant to the submission.

The senior manager or panel chairperson shall prepare a "Submission Recommendation Report" (the "Recommendation Report") outlining the recommendations and rationale. The recommendation report may include recommendations relating to the regulatory judgments made and also recommendations to amend, for clarity, the wording in the stage-2 inspection report.

The Recommendation Report and all relevant information regarding the submission will be made available to the Director of Regulation in order to aid the Director of Regulation in making a decision on the provider's submission. The Director of Regulation shall review the Recommendation Report and all relevant information supporting the submission and make a decision on the regulatory judgments under review.

The Director of Regulation will set out in writing to the provider the decision (letter of decision) on whether the regulatory judgment has been upheld or not upheld, and shall include with the letter the Recommendation Report of the senior manager or panel. The letter of decision will be issued to the provider within **35 working days** of receipt of the satisfactorily completed submission.

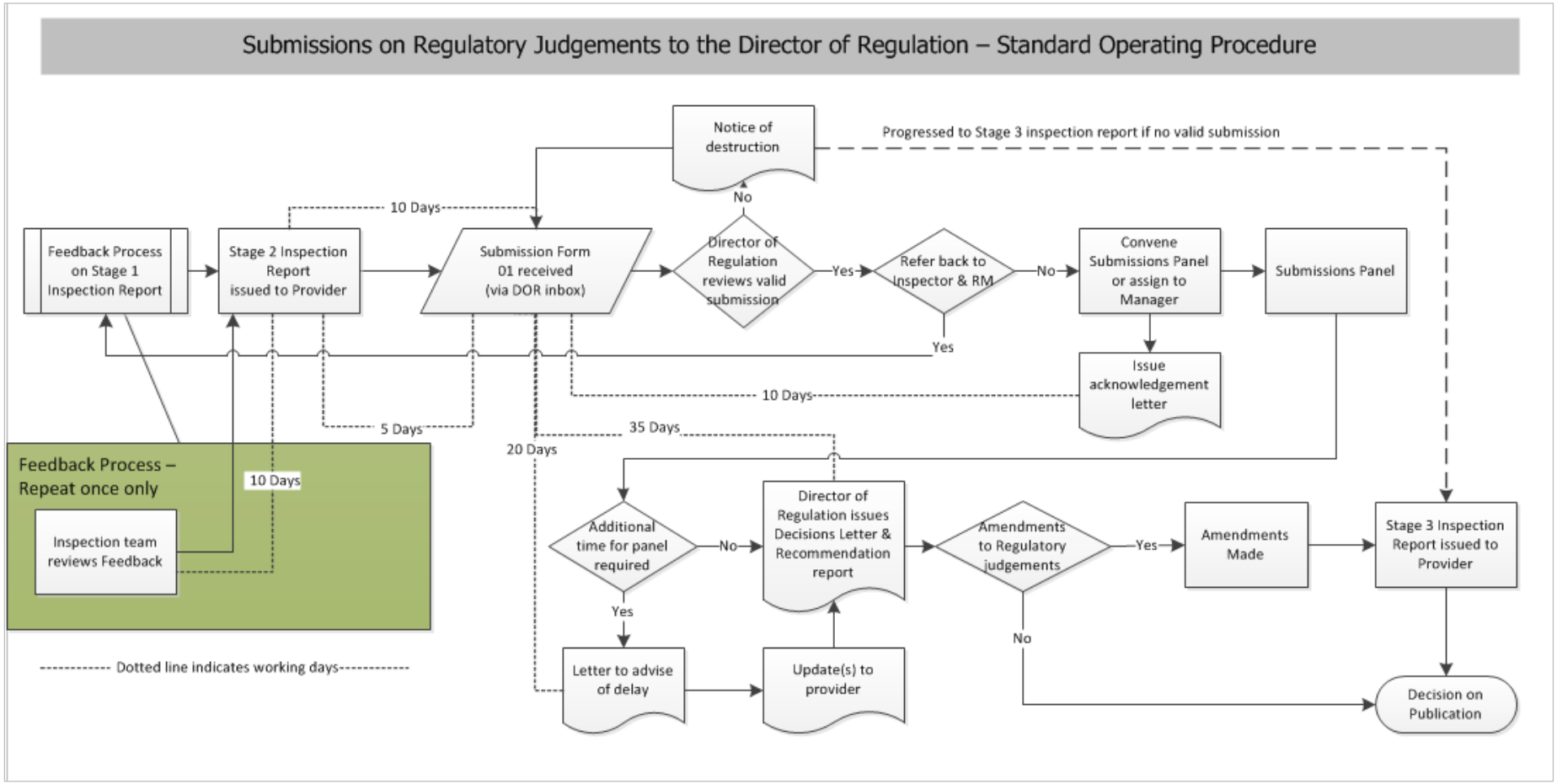
After the letter of decision has been issued by the Director of Regulation, the stage-3 inspection report is finalised to include any changes to be made and will then proceed for a decision on publication and be issued to the provider for information before it is published. At this stage, the provider cannot make a feedback return as the decision of the Director of Regulation is final.

In some circumstances, more time is required to finalise the Recommendation Report. In this instance, the provider will be advised of the delay within 20 working days of receipt of the valid submission from the provider.

5. Revision history

Revision	Description of change	Effective
001	Submission process to Director of Regulation - New Document	01 June 2019

Appendix 1 — Process map for submissions on regulatory judgments



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