SHELF-LIFE

TEXT MOVED TO MONOGRAPHS: RADIOPHARMACEUTICALS:
SUPPLEMENTARY INFORMATION

(JUNE 2013)

DRAFT FOR DISCUSSION

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## SCHEDULE FOR THE ADOPTION PROCESS OF DOCUMENT QAS/13.550

### Shelf-life

**Text moved to Monographs: Radiopharmaceuticals:**

**Supplementary information**

<table>
<thead>
<tr>
<th>Activity</th>
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<tr>
<td>First meeting at IAEA</td>
<td>3-7 December 2012</td>
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<tr>
<td>Second meeting at IAEA</td>
<td>6-10 May 2013</td>
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<td>Preparation of revision of text by IAEA</td>
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<td>Discussion at informal consultation on new medicines, quality control and laboratory standards</td>
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<tr>
<td>Revision of draft proposal</td>
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<tr>
<td>Further follow-up action as required</td>
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**Text moved to Monographs: Radiopharmaceuticals:**

**Supplementary information**

*Note from the Secretariat: The section on shelf-life has been newly created to replace the entry for “Shelf-life” in the section on “Terminology”, annexed to the General Monograph.*

The shelf-life (expiry period) of a radiopharmaceutical preparation depends primarily on the half-life of the radionuclide, the radiochemical stability and the content of longer-lived radionuclidic impurities in the preparation under consideration. Many radiopharmaceutical preparations contain radioisotopes with very short half-lives and such preparations therefore have very short shelf-lives. Such preparations require an expiry date and time to be indicated. For example, technetium-based preparations and positron emission tomography (PET) preparations are normally intended to be used within less than 12 hours (some within minutes) of preparation.

When establishing shelf-life, where appropriate, the specific radioactivity and radionuclidic purity should be taken into consideration. Radiopharmaceuticals that are subjected to transport should undergo stability testing using pharmacopoeial or end-user testing methodology to establish shelf-life under simulated transport conditions.

At the end of the expiry period, the radioactivity will have decreased to the extent where insufficient radioactivity remains to serve the intended purpose or where the specific radioactivity has decreased so much that either diagnostic procedure is perturbed or undesirable physiological responses might occur at the intended injection dose. The radionuclidic purity of preparation is a function of time, so that after expiry period radionuclide impurity content may be such that an unacceptable radiation dose would be delivered to the patient. In addition, chemical or radiation decomposition (radiolysis) may have reduced the radiochemical purity to an unacceptable level.

The shelf-life of a multidose radiopharmaceutical preparation, after aseptic withdrawal of the first dose, will also depend on microbiological considerations. For radiopharmaceutical preparations containing radioisotopes with long half-lives, microbiological considerations may take precedence over those based on the half-life of the radionuclide. For example, once the first dose has been aseptically withdrawn from a multidose container of an iodine-containing injection, the container should be stored at a temperature between 2° and 8 °C and the contents used within 7 days.