

Individual Case Safety Report
XML Document Type Definition Version 2.1

```
<!--
INDIVIDUAL CASE SAFETY REPORT
XML DOCUMENT TYPE DEFINITION VERSION 2.1
-->

<!-- ===== -->
<!-- Entities -->
<!-- ===== -->
<!-- Use the lang attribute to indicate the language of an elements
      content via an ISO 639 language Code.
-->
<!ENTITY % lang.att "lang CDATA #IMPLIED">
<!-- Standard Character Entities to escape SGML special characters.
      When "<", ">", and "&" occur in text, they should be replaced
      by "&lt;", "&gt;", and "&amp;" respectively.
-->
<!-- Less Than "<" -->
<!ENTITY lt "&#38;#60;">
<!-- Greater Than ">" -->
<!ENTITY gt "&#62;">
<!-- Ampersand "&" -->
<!ENTITY amp "&#38;#38;">
<!-- ===== -->
<!-- Elements and Attributes -->
<!-- ===== -->
<!ELEMENT ichicsr (ichicsrmessageheader, safetyreport+)>
<!ATTLIST ichicsr
      lang CDATA #REQUIRED
>
<!-- M.1 ICH ICSR Message Header Information -->
<!ELEMENT ichicsrmessageheader (messagetype, messageformatversion,
messageformatrelease, messagenumb, messagesenderidentifier,
messagereceiveridentifier, messagedateformat, messagedate)>
<!ATTLIST ichicsrmessageheader
      %lang.att;
>
<!--
Field ref:  M.1.1
Field title:      Message Type
Field name: messagetype
Field length:     16AN
Field values:     iccsr
-->
<!ELEMENT messagetype (#PCDATA)>
<!ATTLIST messagetype
      %lang.att;
>
<!--
Field ref:  M.1.2
Field title:      Message Format Version
Field name: messageformatversion
```

Field length: 3AN
Field values:
Comment : In Step 4 ICSR DTD version 2.1, this field will have value "2".
-->
<!ELEMENT messageformatversion (#PCDATA)>
<!ATTLIST messageformatversion
%lang.att;
>
<!--
Field ref: M.1.3
Field title: Message Format Release
Field name: messageformatrelease
Field length: 3AN
Comment : In Step 4 ICSR DTD version 2.1, this field will have value "1".
-->
<!ELEMENT messageformatrelease (#PCDATA)>
<!ATTLIST messageformatrelease
%lang.att;
>
<!--
Field ref: M.1.4
Field title: Message Number
Field name: messagenumb
Field length: 100AN
Comment : This field is important for the efficient tracking of Reports.
Since the SafetyReportID field is optional, the identification and
acknowledgement of safety reports must be done on the basis of the Message
Number an the position of each Safety Report in a Message.
Comment : The Message Number is specific to one transmission between one
Sender and one Receiver.
-->
<!ELEMENT messagenumb (#PCDATA)>
<!ATTLIST messagenumb
%lang.att;
>
<!--
Field ref: M.1.5
Field title: Message Sender Identifier
Field name: messagesenderidentifier
Field length: 60AN
Comment : This field is of primary importance for efficient tracking of
Safety Reports. It permits a Receiver to define a Thread of Reports related
to a Case and to analyse the sequence of follow-ups. It is also required for
the acknowledgement of Reports.
Comment : It should be a coded value agreed between correspondents through
an Interchange Agreement. Message not having pre-agreed values in this field
should be rejected.
-->
<!ELEMENT messagesenderidentifier (#PCDATA)>
<!ATTLIST messagesenderidentifier
%lang.att;
>
<!--
Field ref: M.1.6
Field title: Message Receiver Identifier
Field name: messagereceiveridentifier
Field length: 60AN

```
-->
<!ELEMENT messagereceiveridentifier (#PCDATA)>
<!ATTLIST messagereceiveridentifier
    %lang.att;
>
<!--
```